United States Department of Agriculture

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Animal and Plant Health Inspection Service

Revisions to USDA-APHIS 7 CFR part 340 Regulations Governing the Importation, Interstate Movement, and Environmental Release of Genetically Engineered Organisms

Draft Programmatic Environmental Impact Statement – January, 2017

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ACRONYMS AND ABBREVIATIONS

AMS	Agricultural Marketing Service
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
Bt	*Bacillus thuringiensis*
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
DNA	deoxyribonucleic acid
EA	environmental assessment
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GE	Genetically engineered
GE HR	Genetically engineered herbicide resistant
GE IR	Genetically engineered insect resistant
GE P/I-producing plants	GE plant the produces pharmaceutical or industrial compounds (P/I)
GHG	Greenhouse gas
HR	Herbicide resistant, herbicide resistance
HRW	Herbicide resistant weed
IPCC	Intergovernmental Panel on Climate Change
N_2O	Nitrous oxide
NOx	Nitrogen oxides
NAAQS	National Ambient Air Quality Standards
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program
NPS	Non-point source
OECD	Organization for Economic Cooperation and Development

ACRONYMS AND ABBREVIATIONS

PIP	Plant incorporated protectants
PMPI	Plant made pharmaceutical and industrial compounds
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ARMS	U.S. Department of Agriculture-Agricultural Resource Management Survey
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USC	United States Code
USFWS	U.S. Fish & Wildlife Service
WPS	Worker Protection Standard for Agricultural Pesticides

Executive Summary

The mission of the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is to protect the health and value of American agriculture and natural resources. The Plant Protection Act of 2000 (PPA; 7 U.S. Code §§ 7701-7772), as amended, provides APHIS authority to issue regulations that serve to prevent or mitigate plant pest and noxious weed risks. APHIS protects and promotes U.S. agricultural production and trade by establishing, implementing, and enforcing regulations it promulgates under the PPA. Regulation requires balanced oversight: When applied appropriately, it ensures achieving objectives such as protecting agriculture from plant pests and noxious weeds, while avoiding actions that may inhibit innovation, stigmatize new technologies, or create trade barriers.

ES 1 APHIS Regulatory Authority

APHIS regulates genetically engineered (GE) organisms that may pose plant pest risks under the authority of the PPA and APHIS implementing regulations in Title 7, part 340 of the U.S. Code of Federal Regulations (7 CFR part 340). GE organisms are subject to current 7 CFR part 340:

> if the donor organism, recipient organism, or vector or vector agent[1] belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

These regulations are designed to manage and control plant pest risks through APHIS oversight of the importation, interstate movement, and environmental release of certain GE organisms.

ES 2 Purpose and Need for Revising 7 CFR part 340

APHIS is proposing to revise 7 CFR part 340 to address advances in biotechnology that have occurred since the regulations were issued in 1987, issues and recommendations contained in the USDA Office of Inspector General (OIG) 2005 and 2015 audit reports (USDA-OIG 2005, USDA-OIG 2015), provisions of the 2008 Farm Bill (Pub.L. 110–234, H.R. 2419, 122 Stat. 923), align the regulations with Plant Protection Act (PPA) of 2000, as amended, and to make its regulation commensurate with the potential environmental risks described by the National Research Council (NRC 2002).

[1] These terms are defined in § 340.1 of the regulations.

ES 2.1 Recommendations from Program Reviews

In 2002, the National Research Council found that it should be possible to "relatively quickly screen modified plants for potential environmental risk and then conduct detailed tests on only the subset of plants for which preliminary screening indicates potential risk. The committee found "that there are good arguments for regulating all transgenic crops. To be effective, such a regulatory system must have an efficient and accurate method for rapidly evaluating all transgenic plants to separate those that require additional regulatory oversight from those that do not." "The environmental risk regulatory oversight should be designed to winnow the potentially riskier transgenic crops from the less risky ones before a substantial regulatory burden is imposed on the less risky ones."

In 2005, the USDA Office of the Inspector General (OIG) conducted an audit of APHIS' regulatory program for GE organisms (USDA-OIG 2005). The OIG recommended that APHIS exercise broader and more stringent oversight of field tests of GE organisms, and update its regulations to consolidate all requirements for conducting field tests, as well as incorporate the provisions of the Plant Protection Act of 2000. In a subsequent 2015 audit report, the OIG emphasized that APHIS needed to complete implementation of recommendations from the 2005 audit (USDA-OIG 2015). Among the recommendations provided APHIS in the 2015 audit report, the OIG stated that APHIS needed to revise its regulations (7 CFR part 340) to consolidate all requirements for conducting field tests of regulated material in order to minimize the inadvertent release of GE material; that APHIS clarify its regulations regarding the use of metal shipping containers and movement of GE seeds; and that APHIS update its regulations to incorporate the provisions of the Plant Protection Act of 2000, to specifically include incorporation of authority to control noxious weeds. APHIS agreed with these recommendations (USDA-OIG 2015), and has, as part of implementing the recommendations, issued proposed revisions for 7 CFR part 340.

In 2008, Section 10204 of the Farm Bill (The Food, Conservation, and Energy Act of 2008) required the Secretary of Agriculture to take action on each issue identified in an internal APHIS review document, ''Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework,'' and where appropriate, promulgate regulations.

ES 2.2 Noxious Weed Authority under the PPA

When the current 7 CFR part 340 regulations were issued in 1987, only the Federal Noxious Weed Act of 1974 (FNWA; 7 U.S.C. 2801) authorized APHIS to regulate noxious weeds. The FNWA definition a of "noxious weed" limited APHIS authority to only those plants that were of foreign origin and new to or not widely prevalent in the United States. The PPA of 2000 provided APHIS broader authority for noxious weed regulation. This prompted APHIS in 2010 to revise the noxious weed regulations in 7 CFR part 360, and also revise the manner in which plants were evaluated for noxious weed risk to determine whether to list them in 7 CFR part 360.

As part of revision of part 360, APHIS developed an approach that included two overarching considerations for designating a plant as a noxious weed: (1) identifying what direct injury or damage (physical harm) the plant causes; and (2) identifying what indirect damage the plant may have on agriculture, irrigation, navigation, natural resources, the environment, and

public health within the United States. APHIS then evaluated how likely it was for the plant to become established in areas within the United States in which it was not known to exist, in the absence of federal regulation. APHIS' final consideration was whether placing the plant under federal regulation would affect the likelihood or introduction or dissemination of the plant. In general, APHIS listed a plant as a federal noxious weed if: (1) APHIS determined the plant to be invasive and have significant negative impacts, if introduced or disseminated within the United States; and (2) APHIS determined that federal regulation of a plant meeting the first criterion could reduce the likelihood of such introduction or dissemination.

This approach meant that there were certain plants that APHIS determined to be weeds, but not to be federal noxious weeds. This distinction between a weed and a federal noxious weed warrants emphasis. "Weeds," in the broadest sense of the term, could include any plant growing where and/or when it is unwanted; even plants that are desirable in some settings could be considered weeds in others. The plants that APHIS evaluated for inclusion on the federal noxious weed list were, in general, a particular type of weed: An invasive, usually non-native plant that impacted natural and/or agronomic ecosystems, often with significant negative consequences. Of the problematic weeds evaluated, only a fraction were determined to be ones for which federal regulatory controls to prevent their introduction or dissemination were justified; these plant taxa were added to the list of federal noxious weeds in part 360. Part 360 currently lists 111 aquatic, terrestrial, or parasitic plant taxa as noxious weeds.

The regulations in part 360, while effective, continue to have a significant restriction that limits their applicability to GE organisms: They are predicated on a determination by APHIS that a taxon is a federal noxious weed. For plants that have not been genetically engineered, there are usually many reference points that are available and pertinent to this determination, including international experience with the weed, scientific literature regarding the plant's biology, published studies, and other data.

For GE plants, there is usually a great deal of data and experience with the unmodified plant. In most cases these non-GE plants are highly domesticated and cultivated widely within the United States, and there is an extensive body of scientific literature regarding their biology. However, when a new GE trait is introduced into the plant, there may be little data or previous experience available for APHIS to rely on in evaluating the properties of the resulting GE plant-trait combination. Instead, in order to determine whether the GE plant could function as a noxious weed, APHIS would have to rely on its own independent evaluation of the plant itself, based on information provided by the plant's developers.

Over the past 20 years of regulation APHIS found that most GE plants developed using domesticated plant species, especially plants without weedy relatives, are unlikely to present a weed risk. In general, most of the GE plants that APHIS has been regulating, such as domesticated crop varieties of corn and soybeans modified with common agronomic traits, do not qualify as "noxious weeds."

However, in recent years, there has been an increasing diversity of both agronomic and non-agronomic traits genetically engineered into plants. In addition, there has been an increased use of plants in genetic engineering that, in their unmodified state, are known to possess

weedy characteristics (e.g., hardy, perennial, fast growing, prolific), or are sexually compatible with wild and weedy relatives. For these types of modified plants, the potential for weediness in the engineered plant, or conveying of weedy characteristics through cross-pollination with relative species, may present concerns as to noxious weed risks, and potential adverse impacts on resources protected under the PPA's noxious weed authority.

Where a GE plant may present noxious weeds concerns, evaluating such plants solely on the basis of plant pest risk may not be sufficient to designate them as regulated articles. Under the PPA's definition of plant pest, a plant must be parasitic in order to be considered a plant pest. With limited exceptions, such as mistletoe, dodder, and striga, few plants are known to be parasitic. While the current 7 CFR part 340 implements APHIS' plant pest authority, it does not utilize the noxious weed authority provided by the PPA of 2000. Because noxious weed risk has become an important aspect of the regulation of GE plants, and the fact that it is more scientifically and legally justified to consider weed risk under the noxious weed authority rather than under the plant pest authority, APHIS considers it both appropriate and necessary to incorporate the noxious weed authority provided APHIS under the PPA, and to begin to evaluate GE plants for noxious weed risk.

ES 3 Proposed Revisions to Regulations

The proposed revisions to 7 CFR part 340 would update the regulations by revising terms and definitions, and, in conjunction with incorporation of noxious weed authority, broaden the scope of GE organisms that could be evaluated and potentially regulated under 7 CFR part 340. While the scope of GE organisms that APHIS would evaluate for plant pest and noxious weed risk would be broadened, the revisions would focus and limit ultimate regulatory oversight to GE organisms that posed a plant pest or noxious weed risk, as identified in a science-based risk assessment. Specifically, APHIS intends to revise 7 CFR part 340 to:

- Implement its noxious weed authority provided in the PPA, specifically for GE organisms.
- Refine the regulatory framework so that USDA regulatory oversight is focused on those GE organisms that pose risks as plant pest and noxious weeds, and inefficient regulatory burdens are eliminated.
- Revise the basis of regulatory review from one in which GE organisms are regulated based on the use of plant pests in their development, to one in which APHIS evaluates the GE organisms themselves for plant pest and noxious weed risks. This entails provision of new/revised terms and definitions for "genetic engineering", "genetically engineered organism", and "regulated organism" so that organisms that are produced by techniques that use recombinant or synthetic nucleic acids to create or modify a genome, and that pose plant pest or noxious weed risks, are subject to regulation under 7 CFR part 340.[2]
- Institute a more efficient, science-based regulatory review process to distinguish those GE organisms that merit regulation from those that do not, and excluding certain types

[2] Traditional breeding techniques (including marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion), and chemical or radiation-based mutagenesis, would not be considered genetic engineering.

of GE organisms from the need for regulatory review. Regulatory review will be conducted on the "front end" of GE organism research and development activities prior to authorization of permits for the importation, interstate movement, or environmental release of regulated GE organism.

- Eliminate the notification procedure, and authorize the interstate movement, importation, and environmental release only under permit.

The proposed revisions are expected to promote process efficiency by allowing APHIS to focus its resources on oversight of GE organisms that have potential plant pest or noxious weed risks, and eliminating oversight of GE organism that are unlikely to pose such risks.

ES 3.1 Scoping and Public Involvement

In a stakeholder message sent on February 27, 2015, and a Federal Register notice published on March 4, 2015, APHIS announced the withdrawal of its 2008 proposed rule that would have amended 7 CFR part 340, and plans for new stakeholder engagement regarding APHIS regulation of GE organisms. Stakeholder engagement and outreach began in April 2015 when APHIS announced the opportunity for stakeholders and the public to provide initial feedback with written comments on the future of biotechnology regulation during a 90-day public comment period. APHIS received 196 submissions representing over 220,000 public comments. A variety of stakeholders provided comments, including non-governmental organizations, trade associations, industry, and the academic community. The comments received on this docket (APHIS-2015-0036) are available at https://www.regulations.gov/docket?D=APHIS-2015-0036.

Scoping for this draft Programmatic Environmental Impact Statement (dPEIS) began on February 5, 2016, when APHIS published its notice of intent (NOI) to prepare a dPEIS in the Federal Register.[3] The NOI solicited public comments to help define the scope of the Alternatives[4] and potential environmental impacts and issues that APHIS should consider in this dPEIS. Written comments were accepted from the public for an extended comment period (at the request of commenters) that ended April 21, 2016. APHIS received 126 submissions from the public including two petitions with 11,693 and 20,271 signatures, respectively, and a collection of 9,644 form letters. Comment on the dPEIS NOI are publically available on the Regulations.gov website.[5]

ES 3.2 Alternatives Considered and Evaluated in this dPEIS

Based on scoping, APHIS developed three Alternatives for consideration in revision of 7 CFR part 340, which are evaluated in this dPEIS. These Alternatives are listed below and a summary of the Alternatives provided in the following section, ES 3.2.

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[3] 81 Federal Register, No. 24 (February 5, 2016), pp.6225-6229

[4] "Alternatives" is capitalized in this dPEIS to indicate the alternative regulatory frameworks considered in revision of 7 CFR part 340, and distinguish from the more common use of "alternative".

[5] Environmental Impact Statement; Introduction of the Products of Biotechnology [Docket ID: APHIS-2014-0054]: https://www.regulations.gov/docket?D=APHIS-2014-0054

Alternative 1 – No Action: No revisions to the existing 7 CFR part 340 regulations would be made. APHIS would continue oversight of GE organisms that may pose a plant pest risk under the current regulatory framework.

Alternative 2 – Preferred Alternative (proposed rule): Revise 7 CFR part 340 to incorporate the noxious weed authority provided to APHIS in the PPA; eliminate the notification process and authorize the interstate movement, importation, and environmental release of GE organisms only under permit; and institute an upfront risk assessment process to evaluate potential plant pest and/or noxious weed risks first, exercising permitting authority only if these assessments indicate that a GE organism poses a plant pest or noxious weed risk.

Alternative 3 – Comprehensive Regulation: Incorporate noxious weed authority and establish regulation to mitigate the potential economic impacts of GE crop plants on non-GE crop producers and markets.

ES 3.3 Alternatives Considered but Dismissed from Detailed Analysis

APHIS considered various other alternatives for revision of 7 CFR part 340. APHIS evaluated these alternatives relative to the Agency's PPA authorities, and their potential efficacy and feasibility in fulfilling the purpose and need for revisions of the regulations. Based on these evaluations, APHIS dismissed several of the alternatives considered in revision of 7 CFR part 340 as plausible paths forward. These alternatives were not evaluated in this dPEIS, but are discussed briefly below along with the specific reasons for dismissing them from further consideration.

Withdraw 7 CFR part 340 and Regulate Plant Pests under part 330, and Noxious Weeds under part 360

Based on the assumption that most GE crop plants are unlikely to pose a noxious weed or plant pest risk (in biological, non-economic terms) APHIS considered rescinding its current regulations at 7 CFR part 340 and regulating GE organisms under existing 7 CFR part 330 (Federal Plant Pest Regulations; General; Plant Pests; Soil, Stone, and Quarry Products; Garbage) and 360 (Noxious Weed Regulations) if they posed a plant pest or noxious weed risk, respectively. While this alternative was considered, as proposed in the NOI, it was dismissed from further analysis for several reasons. Public comments received in response to the dPEIS NOI expressed concern, which is shared by APHIS, that implementing this alternative regulatory framework could have a negative impacts on international trade and matters of coexistence in the United States. APHIS also determined that, on reevaluation, this alternative is not operationally feasible without substantial changes to the regulations in 7 CFR parts 330 and 360. For these reasons, APHIS dismissed this alternative from any further evaluation.

Revise 7 CFR part 340 for APHIS Regulation of GE Organisms as Plant Pests, but without incorporating Noxious Weed Authority

One regulatory alternative that APHIS considered but dismissed was to revise the current 7 CFR part 340 as to how it determines what may be a plant pest and regulated under PPA authority, without incorporating the noxious weed authority provided by the PPA. This alternative may not encompass a sufficient range of current and future GE organisms that

could pose risks to resources protected under the noxious weed authority of the PPA. Consequently, this alternative was dismissed from further consideration.

Revise the Regulatory Framework in 7 CFR part 340 that Describes APHIS's Ability to Determine a GE Organism as a Plant Pest, but Keep Notifications

Under this alternative APHIS would revise 7 CFR part 340 regulations as proposed under the Preferred Alternative, but would retain the current notification procedures. APHIS has determined that it would have more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency if all regulated importations, interstate movements, and environmental releases are authorized under the permitting procedure. Consequently, this consideration was dismissed from further evaluation.

Regulate Based on the Concept of "Novelty"

APHIS considered but dismissed an alternative where APHIS would regulate potential plant pests and noxious weeds based on the novelty of the introduced trait in the GE organism, regardless of the method used to introduce that trait. Novel traits can be developed through various techniques, such as traditional selective breeding, chemical or radiation based mutagenesis, cell fusion, or using more modern genetic engineering methods. Regardless of the method or technology used, APHIS, under this alternative, would regulate the potential plant pest and noxious weed risk of organisms based singularly on the novelty of the introduced trait itself. This approach would result in APHIS regulation of all organisms with novel traits that presented a risk to plant health, both GE organisms and non-GE organisms. Applying the concept of novelty as a trigger for regulatory oversight would be a paradigm shift, and would likely require a new Act of Congress or discovering authority elsewhere in existing USDA statutes. Consequently, this Alternative was dismissed as a plausible path forward in revision of 7 CFR part 340.

ES 3.4 Summary of the Alternatives Considered

ES 3.4.1 No Action Alternative: Continue Regulation under Current 7 CFR part 340

Under the No Action Alternative, no revisions to 7 CFR part 340 would be made. APHIS would continue its current regulatory program overseeing the interstate movement, importation, and environmental release of GE organisms. APHIS would retain the plant pest trigger as specified in the existing 7 CFR part 340, continue to authorize the importation, interstate movement, and environmental release of certain GE organisms using the current notification and permitting procedures (USDA-APHIS 2011, USDA-APHIS 2012), and use the petition process to evaluate the regulatory status of GE organisms that were previously determined to be regulated articles under 7 CFR part 340. APHIS would also continue to conditionally exempt certain GE organisms from permit requirements for interstate movement and would retain the prescriptive container, labeling, and identity standards in 7 CFR part 340.

A GE organism would be considered to be a regulated article if APHIS determined the donor organism, recipient organism, vector, or vector agent used in development of the GE organism is a plant pest, or for which there is reason to believe is a plant pest. This current trigger for regulation is based in part on the presence of a gene sequence from a plant pest, a gene sequence that is not linked with plant pest risk. Furthermore, some GE organisms lack

plant pest gene sequences. As a result, under this Alternative, GE organisms that pose a risk to plant health might avoid regulation. The No Action Alternative does not provide for sufficient incorporation of recommendations by USDA OIG audits and the 2008 Farm Bill. It also does not provide for sufficiently utilizing APHIS' noxious weed authority under the PPA for regulation of GE organisms that may pose a noxious weed risks.

ES 3.4.2 Alternative 2: Preferred Alternative – Implement the Proposed Rule

APHIS has made a preliminary determination that action should be taken as described for the Preferred Alternative that requires revision of the regulations at 7 CFR part 340. Regulatory revisions under consideration are based on those factors summarized above in section ES 2 – Purpose and Need. The proposed revisions have the potential to increase regulatory effectiveness, efficiency, and transparency, and decrease potential adverse environmental impacts. The actions described for the Preferred Alternative represent current Agency thinking and are not a final rule.

ES 3.4.2.1 Regulatory Scope

Under the Preferred Alternative, APHIS would establish protocol that provides for more expedient determinations of the regulatory status of GE organisms subject to regulation. Prior to permitting, a risk assessment will be conducted to evaluate plant pest and noxious weed risk. Only those GE organisms that are determined to pose a noxious weed or plant pest risk will be subject to permitting requirements. This will eliminate the unnecessary expenditure of Agency resources on the regulation of GE organisms that are unlikely to pose a plant pest or noxious weed risk; allow the Agency to focus regulation on GE organisms that present risks as plant pests or noxious weeds; provide for a more efficient and effective regulatory framework; and alleviate the burden of unnecessary regulation on the agricultural biotechnology sector.

Under the Preferred Alternative, APHIS would broaden the scope of organisms that may be considered under 7 CFR part 340 by revising the definitions for "genetic engineering," "GE organism," and "regulated organism." The revised definitions would allow for regulation of GE organisms that are not currently regulated under 7 CFR part 340, and specify the types of GE organisms APHIS would consider to be regulated organisms under the revised 7 CFR part 340.

The proposed revisions would remove the limiting concept and criteria that a GE organism would be regulated if the donor, vector, or vector agent is a plant pest. The current criteria reflects the concern in the 1980s that if an organism was modified using genetic material from a plant pest, or a plant pest was used as a vector or vector agent to modify an organism's genome, the resulting GE organism could also be a plant pest.

APHIS' experience has led to a reevaluation of this approach. Although a plant pest may contribute or vector genes to a GE organism, this has not been shown to cause that GE organism, particularly if it is a plant, to become a plant pest. Indeed, experience has shown that the use of genes from donor organisms which are plant pests, as well as the use of vectors which are from plant pests, is unlikely to result in plant pest risks of any sort in recipient organisms.

Rather, the most common use of plant pest components in genetic engineering involve genetic material, such as the 35S promoter for cauliflower mosaic virus and the nopaline synthase (nos) terminator from *Agrobacterium tumefaciens*, which is in itself unable to be expressed and does not confer plant pest traits. Rather, it facilitates the expression of other genes in the GE organism or vectors genetic material that give the GE organism its intended property. For example, the 35S promoter facilitates expression of a gene or part of a gene, but does not code for cauliflower mosaic virus or other plant pest traits. Likewise, the disarmed version of *Agrobacterium tumefaciens* is a common vector of genetic material into the recipient organism, but does not confer any plant pest trait to the recipient organism.

Consequently, APHIS would no longer regulate a GE organism solely on the basis that the donor, vector, or vector agent was a plant pest. The mere involvement of a plant pest as a donor, vector, or recipient in the genetic engineering process will no longer be the determining factor in APHIS's regulatory oversight of GE organisms.

Regulated GE Organisms

A GE organism would be regulated based on the revised terms and definitions for "genetic engineering," "GE organism," and "regulated organism," and whether it presents a plant pest or noxious weed risk. Under the Preferred Alternative, a regulated organism is any GE organism that meets one or more of the following criteria:

- prior to genetic engineering, belonged to any taxon listed in accordance with § 340.2 and met the definition of a plant pest § 340.1 (As § 340.2 currently does, proposed § 340.2 would specify that certain taxa are plant pests or are known to contain to plant pests. Section 340.1 would contain definitions of terms used in the proposed regulations.); or
- the GE organism has received DNA from any taxon listed in accordance with § 340.2, the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, and the GE organism has not been evaluated by APHIS for plant pest risk in accordance with § 340.4; or
- the GE organism is a plant that has a plant and trait combination that has not been evaluated by APHIS for plant pest and noxious weed risk in accordance with § 340.4; or
- the GE organism is any of the foregoing that has been evaluated by APHIS in accordance with § 340.4 and determined to pose a risk as a plant pest or noxious weed, or is a GE organism that has otherwise been determined by the Administrator to pose a risk as a plant pest or noxious weed.

APHIS is aware that a novel GE organism could be developed that may not easily meet the criteria of the first three categories of regulated organisms. The last criteria provides that APHIS may regulate such an organism.

ES 3.4.2.2 Incorporation of Noxious Weed Authority

Incorporating the noxious weed authority provided to APHIS under the PPA into 7 CFR part 340 would clearly define and broaden the spectrum of potential risks that APHIS could consider under regulations, and provide APHIS with an additional regulatory means to address those resources protected under the noxious weed authority of the PPA. Any GE organism that meets the definition of noxious weed (defined in section 2.2.2.4 below) would be subject to APHIS review, regulation, and permitting requirements for interstate movement, import, or environmental release.

ES 3.4.2.3 Elimination of the Notification Procedure

The current option for authorization via notification provided for in 7 CFR § 340.3 would be eliminated and the importation, interstate movement, and environmental release of regulated organisms would be conducted solely under APHIS permit. APHIS has determined that it would have a more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency if all regulated movements are authorized under the permitting procedure. Elimination of the notification procedure and singular use of the permitting procedure is respondent to the USDA OIG and Farm Bill recommendations.

ES 3.4.2.4 Institute a More Efficient Risk Assessment Process for Regulatory Status Determinations

APHIS would revise its regulatory status review and determination procedures. Under the Preferred Alternative, plant pest gene sequences alone will not automatically trigger regulation under 7 CFR part 340. Under the Preferred Alternative, regulatory status determinations would be initiated in two ways: (1) APHIS would conduct a regulatory status determination on its own initiative, and (2) in response to requests for regulatory status determinations by developers or other individuals. In both instances, regulatory status determinations will be based on science-based risk assessments. These analyses would include a plant pest risk assessment (PPRA), a weed risk assessment (WRA), or both. Because the WRA system is new, APHIS is making the WRA system publicly available along with the proposed rule. To view the WRA system, go to http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule.

APHIS Risk Assessments and Regulatory Review

APHIS would proactively conduct plant pest risk assessments (PPRA) and weed risk assessments (WRA) on its own accord, absent of regulatory status request described below, which would be used to determine whether a GE organism poses a risk as a plant pest or noxious weed, and should be regulated under 7 CFR part 340. APHIS would analyze plant pest and noxious weed risks first, and subsequently implement risk-appropriate regulatory controls over those GE organisms that are determined by APHIS to pose plant pest or noxious weed risks.

Once the risk analyses are completed by APHIS, the importation, interstate movement, or environmental release of GE organisms that were determined to pose plant pest or noxious weed risks, as documented and confirmed in the APHIS risk analysis, would be subject to APHIS permitting requirements. If APHIS determined that a GE organism is unlikely to pose a plant pest or noxious weed risk, that GE organism could be moved or introduced into

the environment without APHIS oversight. However, it may still be subject to EPA requirements, as well as other applicable federal, state, and county requirements. For GE plants developed for human and animal food purposes, the developer would have the option to consult with the FDA for compliance with FSMA and FFDCA, as well undergo early food safety evaluation with the FDA (US-FDA 2006).

Regulatory Status Evaluations: Requests for Evaluation or Reevaluation

The current regulations in § 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. Under the Preferred Alternative the petition process would not be applicable, however, APHIS would provide a similar method of inquiry for individuals wishing to have the regulatory status of a GE organisms evaluated. The proposed revisions to § 340.4 would describe the process by which persons could request an initial evaluation or subsequent reevaluation of the regulatory status of a GE organism. The outcome of a regulatory status evaluation is a determination by the Agency that a GE organism is a non-regulated organism or a regulated organism subject to permitting.

Any person would be able to submit a request to APHIS to have a GE organism's regulatory status evaluated, or to request the reevaluation of the regulatory status of a previously evaluated regulated organism. APHIS would conduct a risk analysis that includes an evidence-based, standardized approach to analyzing plant pest and/or noxious weed risks associated with the GE organism. The regulations would provide the necessary information that would be required to be submitted with a regulatory status request in order for APHIS to conduct its evaluation.

Public Notices of Request for Evaluation of Regulatory Status

Public notices on regulatory inquiries, and all APHIS determinations of regulatory status, would be published in the Federal Register for public review and comment. APHIS would make both the request and the risk analyses available for public review. Proposed paragraph (c) of § 340.4 would describe the process for making evaluation of regulatory status available to the public. The first notice would propose a regulatory status for the GE organism, and request public comment. If no comments are received on the notice, or if the comments do not affect the conclusions of the risk analysis or the proposed regulatory status of the organism, APHIS will provide notification through the APHIS stakeholder registry at the end of the comment period announcing that the proposed regulatory status has been finalized. APHIS will subsequently publish a notice in the Federal Register compiling these determinations. If comments lead APHIS to change its proposed regulatory status for the organism, APHIS will publish a subsequent notice in the Federal Register characterizing these comments and announcing the new regulatory status.

Regulatory Status Register

All regulatory status determinations made by APHIS will be listed and made publically available on a website. APHIS is making a draft list of such GE organisms available along with the proposed rule. APHIS encourages stakeholders to review this list and submit specific public comment regarding the listed plant/trait combinations.

For purposes of the proposed rule, the lists will be maintained at the following Web site: http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule. If the proposed rule is finalized, APHIS would use a different URL for maintenance of the regulatory status register, which will be publicly available.

ES 3.4.2.5 Exclusions and Exemptions from Regulation

GE organisms developed through traditional breeding and chemical or radiation-based mutagenesis would not be subject to 7 CFR part 340. APHIS has never considered such techniques to constitute genetic engineering, and they would continue to be excluded. For purposes of the revised regulations under the Preferred Alternative, an organism would not be considered a "GE organism" if:

1. The genetic modification to the organism is solely a deletion or single base pair substitution that could otherwise be obtained through the use of chemical- or radiation-based mutagenesis.

2. The genetic modification is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion).

3. The organism is a "null segregant," that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

ES 3.4.2.6 Regulation of GE Biological Control Agents

Biocontrol involves the reduction of plant pest and weed populations through the use of natural enemies such as parasitoids, predators, pathogens, antagonists, or competitors to suppress plant pest and weed populations. Under the Preferred Alternative, APHIS would regulate a GE organism that is intended for use as a biological control (biocontrol) agent if APHIS determines that it is a plant pest or noxious weed, with a limited exception; GE vertebrate biocontrol agents. Although such organisms could fall within the scope of the PPA's definition of plant pest, particularly if they are herbivores, it is long-standing APHIS policy not to regulate vertebrates as plant pests.

ES 3.4.2.7 Regulation of GE Plants That Produce Pharmaceutical or Industrial Compounds

Certain varieties of plants, to include crop plants, are genetically engineered to produce pharmaceutical or industrial compounds, termed plant-made pharmaceutical and industrials (PMPIs). Under current 7 CFR part 340, APHIS regulates plants genetically engineered to produce pharmaceutical or industrial compounds (GE P/I-producing plants) because they were developed using genetic material from plant pest, or a plant pest was part of the development process. Under the Preferred Alternative, it is expected that most of the GE P/I-producing plants that APHIS evaluates will be found unlikely to pose a plant pest or noxious

weed risk. Consequently, federal oversight of PMPIs and GE P/I-producing plants will require adjustments in oversight among APHIS, the FDA, and EPA. APHIS has identified several options that have the potential for adequate federal oversight of outdoor plantings of GE P/I-producing plants, which are discussed in greater detail below in section ES 4.4 Federal, Tribal, and State Governance.

ES 3.4.2.8 Plant Incorporated Protectants – Small Scale Field Testing

Plant-incorporated protectants (PIPs) fall under the regulatory oversight of the EPA and APHIS. Currently, the EPA requires experimental use permits (EUPs) for small scale field testing of PIP containing GE plants when field tests are over 10 acres in size, and APHIS exercises regulatory oversight of field testing of GE PIP producing plants on or under 10 acres. The Preferred Alternative would shift federal oversight of small-scale (10 acres or less) outdoor plantings of GE PIP producing plants (or rather, the PIP itself) to the EPA. APHIS is fully committed to coordinating with EPA in order to give the EPA sufficient time to stand up a program for federal oversight of small scale field testing of GE PIP producing plants, if the Preferred Alternative is implemented (the proposed rule is finalized). APHIS and EPA oversight of GE PIP producing plants is discussed below in section ES 4.4 – Federal, Tribal, and State Governance.

ES 3.4.2.9 Herbicide Resistant GE Plants and Herbicides - Synchronous Decisions with the EPA

The EPA registers and has oversight of the herbicides used on herbicide resistant (HR) crop plants, but does not regulate GE HR plants themselves. Rather, GE HR plants are regulated by APHIS under 7 CFR part 340 To date, GE HR plants have been regulated by APHIS because they were developed using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current 7 CFR part 340. However, under the Preferred Alternative, APHIS expects that many of the GE HR plant-trait combinations it evaluates will not be found to present plant pest or noxious weed risks. Due to the more efficient regulatory review process for GE organisms that APHIS is proposing to implement, it is important that regulatory status determinations made by APHIS are in synchrony with the EPA's herbicide registration and review procedures. APHIS will work with the EPA to explore possible solutions to better coordinate the commercial availability of seed for GE HR crops concomitant with the registration of herbicides intended to be used on those crops. Synchrony in regulatory decisions between APHIS and the EPA is further discussed below in section ES 4.4 – Federal, Tribal, and State Governance.

ES 3.4.3 Alternative 3: Comprehensive Regulation Inclusive of Economic Impacts of GE Plant Material on Non-GE Crop Producers and Markets

ES 3.4.3.1 Regulatory Scope

Under Alternative 3, APHIS would adopt the revisions considered under Alternative 2 and expand the scope of harms it would consider under noxious weed authority. Under the PPA definition for noxious weed, the term "injury or damage" would be interpreted to include negative effects caused by the mere presence of a GE organism where it is not wanted. This interpretation of noxious weed authority would extend to economic harms that may be

caused by GE organisms. There would not need to be evidence of biological harm for APHIS to exercise its authority under the PPA.

Hence, noxious weed harm would be expanded to include economic harms that derived from the cross-pollination of GE crops with non-GE crops, or commingling of GE crop material with non-GE crops or crop products. GE organisms that are unlikely to pose a plant pest or noxious weed risk under current regulations would be evaluated for potential economic harms. GE organisms with the potential to cause such harm would require a permit for environmental release, to include commercial crop production. By virtue of inclusion of potential economic harms under the noxious weed authority provided APHIS in the PPA, APHIS would likely regulate the field testing and commercial production of the majority of GE crops, including GE P/I-producing plants.

Under Alternative 3, the permit conditions for GE organisms would be specifically designed to limit cross-pollination between GE plants and non-GE crops by specifying isolation distances; require management of volunteer plants to prevent GE crop plants from flowering in abandoned, fallow, and rotated fields; and ensure that only GE crops that have been granted international approval in the major export markets are grown in the United States.

ES 3.4.3.2 Registration and Pinning System

All non-GE crop producers (conventional and organic) that wish to receive protections from injury or harm from the mere presence noxious weeds provided under the regulations would need to be registered with APHIS to confirm that they are legitimate business entities. A registration system for non-GE crop producers would be developed, and non-GE crop producers would need to register their production systems with APHIS to establish authenticity and qualify for protections under 7 CFR part 340. In addition, a voluntary national web-based pinning map would be developed to identify the location and acreage of GE and non-GE crops cultivated in the United States. Registered non-GE crop producers would also need to provide the GPS coordinates of their crop fields using this system in order to receive the protections provided under 7 CFR part 340.

Further, the only regulated GE crop plants that would be permitted for commercial-scale cultivation in the United States would be those crop plants that have received international approval in the major export markets. This requirement would be instituted to reduce the potential for low level presence (LLP) occurring in countries importing U.S. agricultural commodities.

ES 3.4.3.3 Tracking and Reporting

GE plant developers would be required to maintain and provide to APHIS a list of regulated crop plants they offered for sale each year and verify whether these crops have been approved for import into major international export markets. Developers and producers of regulated GE crop plants would be required to track and record the planting locations and acreage of all regulated crop plants and submit that information to APHIS as requested. All registered producers of non-GE crops would likewise need to track, record, and report the location and acreage of their crops on a voluntary national pinning map in order to receive protections under 7 CFR part 340.

ES 3.4.3.4 Isolation Distances

GE developers and producers would need to verify that all regulated GE crops maintained the isolation distances from non-GE crops specified in the permit. Permits would specify the isolation distances necessary to separate the GE and non-GE crop to achieve less than 0.1% cross pollination for seed production and 1% for grain production. The isolation distances required would be based on the best available science. Producers of regulated GE crops would share the responsibility for meeting the isolation distance with non-GE crop producers; producers of both non-GE and regulated GE crops would need to contribute equally to the isolation distances required for maintenance of registration and permit requirements, respectively. Biotechnology developers would have the responsibility for obtaining permits and ensuring isolation distances and volunteer plant management requirements were met. Similarly, non-GE crop producers would be required to maintain their registration with APHIS and adhere to registration requirements.

ES 3.4.3.5 Management of Volunteer GE Crop Plant

Permits would require volunteer plant management plans be developed and implemented to prevent regulated GE crop plants from flowering in abandoned, fallow, and rotated fields. All land used for regulated GE crop production must be monitored pursuant to permit requirements to ensure that crops are harvested and volunteers are managed in abandoned, fallow, and rotated fields.

ES 3.4.3.6 Compliance

Developers and growers of regulated GE crops can be held accountable for harm to non-GE producers if isolation distances and other permit conditions are not followed. Non-GE crop producers who felt that isolation distances were not maintained could request an inspection by APHIS. If the APHIS inspection revealed that the isolation distance was in violation of permit requirements, the GE developer would be subject to penalties as described in the PPA (§ 7734). If required isolation distances were found to be maintained and all other permit conditions were followed, the GE developer would not be subject to penalties.

ES 3.4.3.7 Exclusions and Exemptions from Regulation

APHIS would exempt the same categories of GE organisms as outlined under the Preferred Alternative, unless that GE organism was identified as a potential MPNW.

ES 4 Summary of Potential Impacts on the Human Environment

ES 4.1 Environmental Impacts

APHIS evaluated the potential impacts that could derive from APHIS decisions and actions under the three regulatory frameworks described; namely decisions and actions in the oversight of the importation, interstate movement, and field testing of a regulated GE organism, and APHIS determinations of regulatory status for GE organisms. Under all the Alternatives, the geographic range of potential impacts encompasses all 50 states and U.S. territories, with the areas affected by 7 CFR part 340 primarily those used for cropland, rangeland, and forestland. Those aspects of the human environment addressed in the dPEIS include the following:

Topics Considered in Evaluating Potential Impacts	
Acreage and Areas Used for Agriculture and Forestry	**Biological Resources**
Physical Environment	• Soil Biota
• Soils	• Invertebrates
• Air Quality	• Vertebrates
• Water Quality and Resources	• Plant Pests and Disease
Human Health	• Agricultural Weeds and Noxious Weeds
Animal Food and Welfare	• Gene Flow and Weediness
Socioeconomic Impacts	• Biodiversity

APHIS identified differences with regard to the potential impacts that may derive from the three regulatory frameworks considered. Based on the dPEIS and Regulatory Impact Analysis conducted by APHIS (USDA-APHIS 2016c), the most salient potential impacts that would derive from revision of the regulations are socioeconomic in nature, and these are summarized in the following section.

Due the broader scope of GE organisms that would be evaluated under the Preferred Alternative and Alternative 3, GE organism-trait combinations that otherwise would not be regulated under the current 7 CFR part 340, would be subject to regulation and permitting requirements under these Alternatives. To the extent regulatory oversight of such GE organisms reduces the potential risks to physical and biological resources, to include noxious weed risks, there could be seen environmental protections not realized under the No Action Alternative. While both the Preferred Alternative and Alternative 3 are expected to further protections for the physical environment, biological resources, human health, and animal health and welfare, Alternative 3 would likely have, to some degree, a chilling effect on research, development, and innovation in the agricultural biotechnology sector. In addition, the feasibility of full implementation of Alternative 3 is questionable. Hence, to the extent that plant biotechnologies may benefit society and the environment, such benefits are less likely to be realized under Alternative 3, relative to the Preferred Alternative.

ES 4.2 Socioeconomic Impacts

ES 4.2.1 Alternative 2: Preferred Alternative – Implementation of Proposed Rule

The proposed revisions to 7 CFR part 340 under the Preferred Alternative are expected to benefit developers, producers, consumers, public and private research entities, and the Agency.

APHIS Cost Changes

APHIS costs of regulating GE organisms that pose plant pest or noxious weed risks are expected to change under the proposed rule. Implementation costs of the proposed rule for APHIS would include those incurred for outreach activities, developing guidance documents, training, and adjusting the current permit system. Current annual personnel costs of conducting GE activities (costs of activities that would be affected by the proposed rule) are estimated to total about $5.6 million. With the proposed rule, annual costs are expected to range from $2.5 million to $7.8 million, depending on the volume of permits, weed risk assessments, inspections, and NEPA activities. Fewer permits would be issued, and

notifications and petitions would be eliminated, while more risk assessments for regulatory status determinations would be performed.

In addition, costs to APHIS of implementing the proposed rule would include outreach activities, developing guidance documents, training, and adjusting the current permit system. APHIS estimates that the public outreach, guidance and training would cost about $88,000 (one time cost). Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current "Am I Regulated" process outside the electronic permitting system without new costs. If APHIS' e-permitting system were to be used, it would have to be revised to handle such requests and responses.

Agricultural Biotechnology Sector

Under the Preferred Alternative, regulatory burden is expected to decrease thereby benefiting the agricultural biotechnology sector. Direct regulatory costs to biotechnology developers would be reduced for those GE organisms that are not considered to pose a plant pest or noxious weed risk. Savings to the regulated community would result in part from a reduced need to collect certain field data, refined reporting requirements, and lower management costs when compared to current costs for permits and petitions. Costs borne by regulated entities under the proposed rule would be those associated with rule familiarization, recordkeeping, and providing information during the application process. APHIS is also proposing to exclude from regulation under the Preferred Alternative GE organisms that are equivalent to what otherwise would be achieved through conventional breeding. For the regulated community, these cost savings are expected to more than offset new costs.

For the Preferred Alternative, APHIS estimates that biotech developers could save from $485,000 to $861,000 per GE trait when EPA and/or FDA also have regulatory oversight, and from ~ $1.5 million to $5.4 million per GE trait when USDA is the only regulatory agency. Because the Preferred Alternative is expected to facilitate research, development, and innovation in the agricultural biotechnology sector, APHIS expects that the number of new GE organisms developed annually will increase over time. For the purposes of economic analysis, APHIS assumes, on an annual basis, newly developed GE organisms will range from 6 (the approximate annual average), 10 (an intermediate number), and 12 (twice the average). For GE organisms that would solely require USDA oversight, the annual savings could be from $8.8 to $32.4 million if 6 new organisms were developed, from $14.7 million to $53.9 million if 10 were developed, and from $17.6 to $64.7 million if 12 were developed. For GE organisms that are submitted for multi-agency evaluation, the annual savings could be from $2.9 million to $5.2 million if 6 new organisms are developed, from $4.9 million to $8.6 million if 10 are developed and from $5.8 million to $10.3 million if 12 were developed.

Indirect benefits are also expected to result from a more expedient review and regulatory status determination process. These include reduced regulatory uncertainty that may facilitate small companies' ability to raise venture capital, and reduced regulatory requirements that may increase greater participation by the public sector in agricultural biotechnology research and development. The latter effects could spur innovation in GE crop plant development, particularly in small acreage crops where genetic engineering has not been utilized due to the expense of regulation. Public sector research and development in

agricultural biotechnology, which is generally conducted on much smaller scales than that conducted by large agri-businesses, would be expected to benefit from the proposed procedural changes.

Producers of GE Crops

GE crops can improve profitability at the farm level (Brookes and Barfoot 2013a, Klümper and Qaim 2014, Brookes and Barfoot 2015), and growers of GE crops are expected to benefit under the Preferred Alternative. For example, U.S. farmers have realized increased net gains due to their use of GE crops, totaling approximately $58.4 billion in extra income between 1996 and 2013 (Brookes and Barfoot 2015). Potential economic benefits to producers of GE crops are expected to continue if not improve.

Under the Preferred Alternative, regulatory costs are expected to be lower than the status quo, thereby potentially spurring developer innovation, especially among smaller companies and universities. If the regulatory relief spurs innovation, farmers may benefit by having access to a wider variety of GE plant-trait combinations to meet their specific needs in the management of plant pests, disease, and agricultural weeds, and other factors that impact their operations. Among the types of innovations expected are crops with resistance to pests and disease; tolerance of stress conditions such as drought, high temperature, and salt; and more efficient use of soil nutrients. These types of traits can potentially lower farmer input costs (tillage, water, fertilizer, pesticides) and help sustain yields under adverse growing conditions. Hence, in comparison to the No Action Alternative, the proposed revisions to regulations under the Preferred Alternative may more readily help sustain or even improve farm-level profitability and resilience.

Consumers

Potential beneficial impacts to consumers of commodities derived from GE crops would be expected to continue, as under the No Action Alternative. Agricultural commodities derived from GE crops are recognized as economically beneficial to domestic markets and are expected to remain so (Fernandez-Cornejo, Wechsler et al. 2014a; Klümper and Qaim 2014; Brookes and Barfoot 2015).

Producers of Non-GE Crops

The longstanding market for organically grown products continues to expand and a market for conventionally grown foods produced without GE plant products has also emerged (e.g., "non-GMO" labeled foods). In 2014, there were 14,093 USDA certified and exempt organic farms in the United States (USDA-NASS 2014a).[6] Organic food sales in the United States approached an estimated $35 billion, and sales of organic personal care products, linens, and other non-food products were an estimated $3.2 billion in 2014 (Greene, Wechsler, Adalja et al. 2016).

[6] The National Organic Standard states VIII Introduction 2012 Census of Agriculture USDA, National Agricultural Statistics Service that all farms and handling operations that display the "USDA Organic" seal must be certified organic by the state or by a private agency, accredited by the USDA, to ensure the National Organics standards are followed. Farms that follow the National Organic standards and have less than $5,000 in annual sales can be exempt from certification. These exempt farms may use the term "organic" but may not use the "USDA Organic" seal.

Price premiums for organic products average around 30%, but can be much higher (Crowder and Reganold 2015). For example, the USDA's Agricultural Marketing Service reports organic corn and soybean prices that are generally two to three times higher than conventional prices (Greene, Wechsler et al. 2016). Grower prices for fresh organic apples and organic apples for juice were more than twice as high as for conventionally grown apples in 2007, and premiums for organic milk averaged 69% in 2010 (Greene and McBride 2015).

One of the challenges in organic and non-GE crop production systems is preventing the accidental comingling with GE crop material in order to protect price premiums. Potential adverse impacts to non-GE crop producers are those related to cross-pollination and commingling of GE crop material with non-GE crops or crop products, leading to instances of unintended presence. This is particularly important for identity preserved and organic crop commodities.

For example, during the years 2011 – 2014, the incidence of affected organic farms was around 0.7%. In 2014, 31 farms, out of a total of 14,093 certified organic farms (~0.2%) self-reported losses of $506,552. In 2015, 32 farms, out of 21,818 total certified organic farms (~0.1%), reported a total of $520,671 on losses due to the unintended presence of GE crop material, with an average loss of $16,271 (USDA-NASS 2016). Based on data from 2011 to 2015, the incidence of losses to organic production from the unintended presence of GE material in organic crops or crop products would be expected to follow this trend, with affected organic farms comprising less than 1% of total organic farms.

However, if the Preferred Alternative leads to the development and adoption by growers of new varieties of GE crop plants, there may be an increase in the potential for incidences of unintended presence of GE crop material in non-GE crops or crop products. This would primarily be due to the fact that there could be more crop types in production, or rather, crops that are targeted for specific markets that need segregation. Hence, an increase in development and adoption of new varieties of GE crops would necessitate maintaining segregation of GE crop products from those produced via conventional, organic, "non-GMO" and identity preserved cropping systems and supply chains. While neither the pace of commercialization nor volume of GE products commercialized is expected to significantly change from current levels; innovation in the agricultural biotechnology sector is expected to increase under the Preferred Alternative, and there could be seen a wider variety of GE crop plants in commercial production.

The economic impact to growers of organic and non-GMO commodities from such unintended presence would depend on the price premium affected. For instance, as discussed above, organic commodities can receive a significant price premium in the food and personal care products markets (e.g., from 30% to %500) relative to the price of commodities derived from conventionally grown crops. Because "organic" and "non-GMO" commodities can always be sold as "conventional" commodities, it is the price premium above the conventional price that represents a measure of the value affected by the unintended presence of GE plant material.

Currently, the organic field crops of barley, buckwheat, flaxseed, hops, oats, peanuts, proso millet, rice, rye, sorghum, sunflower seeds, and wheat, have no GE comparators in the

market These are crops where the seed is the valued part of the plant, and therefore the crops most likely to be impacted by commingling or cross pollination with GE crops, in the event such GE crops are commercialized.

Unauthorized Releases

Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the human and animal food supply have occurred, and, over the long-term, it is possible, if not likely, that such incidents will occur again. While it is possible that such incidents will continue, it is also expected that such incidents will be rare in occurrence. Financial losses resulting from unauthorized releases are difficult to quantify due to a variety of factors governing the market price of agricultural commodities. However, a couple of examples are provided. One example would be that of the well-publicized StarLink corn incident. While not explicitly an unauthorized release for APHIS, it serves as an example of potential costs. StarLink corn was deregulated by APHIS, yet did not have an established tolerance for human food consumption set by the EPA.[7] In 1998, the EPA registered StarLink corn for commercial use, provided that all grain derived from StarLink corn was directed to domestic animal food or to industrial uses (e.g., biofuels). StarLink corn, specifically the bacillus thuringiensis (Bt) protein Cry9C, was not authorized for human food uses, and there were no established tolerance limits for human food. In September 2000, residues from StarLink corn were detected in taco shells, indicating that it had entered the human food supply. While there were and are several varieties of Bt corn on the market, StarLink (Cry9C) was illegal in human food; it was only approved for animal food.

Of the few estimates available, this incident resulted in $298 to $964 million in lost revenue for producers in market year 2000/2001 (Lin, Price and Allen 2003). A separate study estimated that the presence of StarLink in the food supply caused a 6.8% drop in the price of corn, lasting for 1 year. In total, nearly 300 human food products were taken off the market (Lin, Price et al. 2003), not necessarily because StarLink corn had been detected in all of the products, but as a precaution taken by the manufacturers of the products. The U.S. share of corn (for starch use) imports into Japan declined from 93% to 62% during November 2000 through March 2002. South Korea's imports of U.S. corn for food manufacturing during the same year-and-a-half period were down 53% from the comparable period before the incident, a decline of about 1.2 million tons (Lin, Price et al. 2003).

Similarly, GE Liberty Link rice 601 (LLRICE 601), which was regulated by APHIS, was detected in samples taken from commercial long grain rice. While Both USDA and FDA reviewed the available scientific data and concluded that there was no human health, food safety, or environmental concerns, the economic consequences of the unauthorized release were substantial. The market costs of commingling of APHIS regulated LLRICE 601 with non-GE rice, worldwide, including the costs associated with the loss of export markets, seed testing, elevator cleaning, and food recalls in countries where the variety of rice had not been approved, ranged from $741 million to $1.3 billion (US-GAO 2008).

[7] Section 408 of the FFDCA authorizes the Environmental Protection Agency (EPA) to establish a tolerance for the maximum amount of a pesticide residue that may be legally present in or on a raw agricultural commodity. The Food and Drug Administration (FDA) is responsible for the enforcement of pesticide tolerances and food additive regulations established by EPA. This enforcement authority is derived from section 402(a)(2)(B) and of the FFDCA.

Hence, while it is possible that, over the long-term, unauthorized releases will continue to occur, and such incidents are expected to be rare in occurrence, when they do occur, the impacts on commodities markets can be substantial. Under the Preferred Alternative, unauthorized releases are expected to decline as a result of revised permitting, reporting, and inspection requirements, and because the total number of GE crop plants regulated by APHIS would likely be much less than that regulated under the No Action Alternative and Alternative 3.

ES 4.2.2 Alternative 3: Comprehensive Regulation Inclusive of Economic Impacts of GE Plant Material on Non-GE Crop Producers and Markets

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown. Alternative 3 would affect developers and growers of GE crops, growers of non-GE crops, and APHIS. Plant biotechnology developers and growers of regulated crop plants would be required to track and record the location and acreage of MPNW (mere presence noxious weeds) being grown and implement a volunteer plant management program. In order to identify the location and proximity of non-GE crops to GE crops, all non-GE crop producers would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning map on a regular basis.

APHIS Costs

APHIS would need to develop a national pinning system to identify the location of non-GE crops, and a system to certify non-GE crop producers. APHIS would also need to provide a large number of additional inspectors and devote increased resources to the administration of compliance and response to complaints of noncompliance, such as with required crop isolation distances. These costs are expected to be significant considering APHIS inspections currently administer around 100,000 acres, and Alternative 3 would increase the scope of potentially permitted area to about 170 million acres, the area of cropland currently cultivated with GE crops.

Agricultural Biotechnology Sector

Developers of GE crop plants would have the responsibility for submitting permit requests and ensuring growers of their products adhered to the separation distances and volunteer plant management requirements specified in the APHIS permit. Developers of crop plants derived from biotechnologies defined under regulations would have increased tracking, monitoring, and reporting responsibilities for regulated crops produced in the United States. Developers of GE plants that were cultivated for commercial purposes and designated by APHIS as MPNWs, would share responsibility for management of a portion of required buffer areas/zones. These requirements could impose substantial costs on the developer.

The increased tracking, monitoring, and reporting responsibilities, and responsibility for management of buffer areas/zones, would increase potential liabilities for developers of GE crop plants. An increase in potential exposure to liability, whether real or perceived, could dampen or impede innovation and development of new GE crop varieties, reduce grower

adoption of GE crop plants, and in some instances may lead to grower abandonment of GE crops for production of a traditionally bred crop plant under a conventional or organic cropping system. Hence, where the cost of regulation proves burdensome, developers may opt to allocate certain resources to more profitable ventures, and there could be seen a decline in investment and innovation in the agricultural biocenology sector. To the extent such a regulatory framework impedes innovation and development in the agricultural biotechnology sector, there may be seen reductions in the economic benefits to GE crop producers, and consumers by way of agricultural commodity market pricing. Under Alternative 3, the costs to biotechnology developers would likely increase, perhaps substantially.

One of the major obstacles to the commercialization of GE organisms is obtaining synchronization of approvals among international trading partners. Undesired commingling can jeopardize export markets for U.S. producers, creating an unfavorable economic climate and uncertainties among importers and exporters of these commodities. Under Alternative 3 APHIS' broad interpretation of the noxious weed authority would enable APHIS to delay the commercial introduction of GE crop plant until approvals in major export markets also occurred. This measure aimed at reducing asynchronous approvals would benefit grain exporters and certain farmers who export their crops. However, such delays in commercialization of a GE crop plant could substantially impact the net returns on investment for the developer. Studies show that the cost of foregone benefits (opportunity costs) stemming from a delay in product release can overshadow both research and regulatory costs. The opportunity costs of the regulatory process include direct expenses and the associated expense of delays in commercialization, regulatory review and authorization by the USDA and EPA, or FDA consultation or early food safety evaluation, as appropriate. In addition to the compliance costs associated with regulatory approval, biotechnology firms also incur debt servicing charges while potential revenues from a commercialized GE commodity are delayed.

Producers of GE Crops

Producers of GE crops would be responsible for maintaining required separation distances/buffer areas by removing farmland from production or growing non-GE crops on a portion of that land that was required as buffer area. To the extent that this Alternative would increase buffer area requirements, and management of those areas, the cost of providing those areas would be a net loss to the agricultural market in production of human and animal food, and fiber. To the extent that this Alternative results in reductions in the instances of unintended presence of GE plant material in non-GE crops or crop products, there would be potential economic benefits to growers to both GE and non-GE crops, as well as consumers. To the extent it prevents the production of GE crops that have not been approved overseas, there would be economic benefits to grain exporters, as it would decrease the likelihood of trade disruption due to the presence of GE trait material that is unapproved in international markets.

The additional regulatory burden could discourage certain farmers from cultivating regulated GE crops, choosing rather to produce traditionally bred crop plants under conventional or organic cropping systems. Such a shift in choice would likely be determined by potential net returns to the farmer. Currently, organic and non-GMO verified commodities, as well as IP

commodities, receive a price premium in the market, above that of conventionally grown non-IP and GE crop commodities.

Producers of Non-GE Crops

Alternative 3 would provide some protection to non-GE crop producers against losses incurred by unintended presence by requiring establishment of separation distances (or buffer zones) between commercially grown GE and non-GE crops, and management of GE volunteer plants. The permit conditions for cultivation of regulated crops would be specifically designed to limit cross-pollination between GE and non-GE crops by specifying separation distances; volunteer plant management requirements to prevent GE crops from flowering in abandoned, fallow, and rotated fields; and to ensure that only crops that have received approval in the countries of major export markets are grown in the United States. In order to receive these benefits non-GE crop producers would need to register with APHIS to establish authenticity, and regularly record and report their crop locations on a national pinning map. Certification would impose some modest costs on those who wished to benefit from the program and substantial costs on the government to develop these programs.

Some costs for non-GE crop producers may be reduced because growers of GE crops would absorb some of the cost of reducing the risk of unintended presence (e.g., maintenance of separation distances, volunteer plant management). Non-GE crop producers who think neighboring GE crop producers have not maintained required separation distances or managed volunteer plants pursuant to regulations could request an inspection by APHIS. Non-GE growers would be responsible for any commingling that occurs during harvest and transport of the crop commodity as commingling at this stage is within their control.

Unauthorized Releases

The fundamental purpose of the regulatory framework under Alternative 3 is prevention of cross-pollination and commingling of GE and non-GE crops. While most crops would be regulated by APHIS, they would be permitted for planting and permitting requirements would be designed to facilitate coexistence of GE, non-GE, and organic cropping systems. Under Alternative 3, there is some uncertainty as to potential for adverse impacts from unintended presence. On one hand, the incidence of unintended presence may decline under Alternative 3, relative to the Preferred Alternative, if, due to regulatory burden, producers opt to produce conventional cultivars, as opposed to GE varieties, and the number of GE crops in production declines. However, if GE crops were to continue to be commercially produced, despite the increased regulatory burden, as a result of the sheer number of GE crops in commerce, which would be regulated under APHIS permit, the incidence of unauthorized could potentially increase relative to the Preferred Alternative.

ES 4.3 Summary of Potential Impacts

As of December 2016, APHIS has issued more than 18,000 authorizations for the environmental release of GE organisms at multiple sites encompassing all 50 states and U.S. territories. These releases were primarily for research and development of improved crop varieties. Additionally, APHIS has issued more than 12,000 authorizations for the importation of GE organisms, and nearly 12,000 authorizations for the interstate movement of GE organisms. APHIS has, to date, denied slightly more than 1,500 requests for permits

or notifications, many of which were denied because APHIS ultimately decided the requests lacked sufficient information on which to base an Agency decision.

APHIS authorized environmental releases have encompassed more than 100 different types of GE organisms, and include row crops, trees, turf grasses, and ornamental crops. The vast majority of GE organisms regulated by APHIS have been GE crop plants. Less than 1% of the total number of authorized field releases involved non-plant species. When conducted according to permit and notification requirements, field trials of GE organisms have presented minimal environmental risk. APHIS is not aware that any of the non-plant GE organisms regulated by APHIS having had any identifiable impacts on the environment.

APHIS has evaluated 159 petitions for non-regulated status, of which, APHIS reached determinations of non-regulated status for 125 (as of December 2016). For those GE crop plants that APHIS determined are not subject to 7 CFR part 340: The available science provides little evidence that the cultivation of the presently commercialized GE crops have resulted in adverse environmental impacts that are unique or differ from conventional cropping systems (e.g., (Sanvido, Romeis and Bigler 2007, NAS 2016, Brookes and Barfoot 2013, Klümper and Qaim 2014) and others).

The development of insect pest resistance to GE plant incorporated protectants (PIPs) will remain a primary concern in commercial agriculture, which the EPA is addressing by requiring implementation of insect resistance management strategies (US-EPA 2016a). The development of herbicide resistant weed (HRW) populations will also remain a primary concern. This is not unique to GE crops, it is a concern in any cropping system where herbicides are used, GE and non-GE alike. Development of feral populations of GE crop plant-wild type hybrids, and introgression of trait genes into wild populations will also remain a concern for a limited number of crops such as canola; those crops with well-established wild relative species in the United States.

Currently, only two traits, insect resistance (IR) and herbicide resistance (HR), have been widely used in commercial agriculture, and these traits utilized largely among the crops of corn (e.g., HR, IR), soybean (e.g., HR, IR), cotton (e.g., HR, IR), and canola (e.g., HR). These types of GE plant-trait combinations currently in commercial production have been found to have no more or fewer adverse effects on the environment than non-GE crops produced conventionally (NRC 2010a, NAS 2016b). A few other GE traits, such as resistance to specific viruses (e.g., papaya, plum) and reduction of browning in the flesh of apples and potatoes, have also been utilized, although these types of GE crops produced, currently, on a relatively small number of acres worldwide (NAS 2016b).

The use of insecticides, which can present risks to non-target organisms and human health, has typically been lower in GE IR cropping systems, relative to non-GE, non-organic crops (NRC 2010a). For example, a recent study by Yi and Sangwon found that the impact per hectare of corn and cotton crops on the ecological health of freshwater systems decreased by about 50% in the last decade (Yi and Sangwon 2015). This change was primarily attributed to the use of GE IR crops, which reduced the application of insecticides, and use of less environmentally benign herbicides such as atrazine. In some cases, as has been found with insect and disease resistant GE crops, suppression of pest and pathogen populations are so

extensive as to provide benefits to nearby non-GE crop producers (NAS 2016b). It should be borne in mind that while reductions in insecticide use are notable, and considered a distinct environmental benefit, these reductions are based on kilograms/tons of insecticide used, and the weight or volume of pesticide used conveys little meaningful information without understanding pesticide toxicity, or the potential harmfulness of a pesticide, which varies widely among the pesticides used. This said, any reduction in synthetic chemicals use is considered of human health and environmental benefit. There is no definitive evidence that GE HR based cropping systems have any effect on the long-term increase or decrease in herbicide use. The use of GE HR crops initially correlated with decreases in the total amount of herbicide applied per acre of crop per year, but these decreases have generally not been sustained (NAS 2016b).

Advances in biotechnologies are expected to refine the precision with which crop varieties will developed, and a greater diversity of commercial crop varieties (NAS 2016b). While it is difficult to predict the scope of improved crop varieties that will emerge in the coming decades, beneficial traits likely to be utilized include improved tolerance to abiotic stresses such as drought and thermal extremes; increased efficiency in plant physiological processes such as photosynthesis and nitrogen use; and improved herbicide resistant varieties (NAS 2016b). Expansion of traits that provide resistance to fungal, bacterial, and viral diseases is likely. Such GE crop plants could help reduce the adverse environmental effects that can derive from commercial cropping systems, and contribute to protecting natural resources. For example, new types of GE plant-trait combinations include those that may help to maintain conservation tillage (and hence protect soil, air and water resources) through effective weed control; reduce insecticide and fungicide use through development of crop plants resistant to pests and pathogens; reduce fertilizer inputs through development of crop plants with higher nutrient utilization efficiency; and reduce water use via GE plants with decreased water requirements. Other products such as GE food plants with improved nutrient profiles, and decreased levels of anti-nutrients, naturally occurring toxins, and allergens may improve the nutritional value and safety of human and animal foods.

To the extent such GE plant-trait combinations are developed and adopted for commercial purposes, benefits to public health and the environment may follow. While these types of GE crop plants are expected to be developed and commercially produced under the No Action Alternative, due to the regulatory relief provided, both in terms of procedure and costs, there is likely to be more research, development, and innovation in the agricultural biotechnology sector under the Preferred Alternative. Due the extensive regulatory oversight that would be exercised under Alternative 3, there could be a chilling effect on innovation in the agricultural biotechnology sector, and development and commercialization of new GE plant varieties impeded.

Commercial crop production of any type, whether a conventional, organic, or GE cropping system always has some degree of impact on the environment. Air pollutants, introduction of pesticides and fertilizers (organic or synthetic) to surface water and groundwater, soil erosion as a result of tillage, and loss of biodiversity and habitats are all potential impacts that can derive from commercial crop production. These are issues that all commercial agricultural systems face, not just those growing GE crops, in providing sufficient human and animal food, fiber, and biofuels to meet market demands. The degree of environmental

impact can be minor or noticeably adverse, depending on a variety of factors that include the type and quantity of agronomic inputs used in crop production, agronomic practices, geographic locale, local biota, weather, inherent soil characteristics, and the crop type being produced.

In agriculture, resource utilization efficiencies can be improved in different ways and requires continuous research and innovation (FAO 2014b). Modern agriculture strives to balance these potential environmental impacts with societal needs for human and animal food, fiber, and biofuels. Accordingly, the main challenges for all agricultural systems are to improve nutrient, weed, and pest and disease management while sustaining maximal crop yields on minimal areas of land. These challenges are location-specific and encompass valuation of environmental, economic, and societal needs and concerns. Such efficiencies are directly affected by the choice of plant cultivars that exist for various types of crops, and the agronomic practices used in the management of crop production (e.g., tillage; timing and quantity of agronomic inputs such as insecticides, herbicides, fertilizers; irrigation).

In commercial crop production, both in the United States and abroad, sustaining maximal crop yields will remain a primary concern in efficiently meeting market demands for human and animal food, fiber, and biofuel, particularly in the context of increasing population, limited lands, persistence of pests, diseases, and weeds, and an increasingly constrained resource base (FAO 2014b). To the extent agricultural biotechnologies facilitate achieving maximal crop yields with minimal inputs, and reduce environmental impacts, they provide valuable options for commercial crop producers (FAO 2014b). This is particularly important when considering the well-recognized impacts of agriculture on environmental quality; increasing demands on water resources; increasing global demand for human and animal food, fiber, and biofuel; and relatively uncertain effects of global warming and regional climate change on crop production (e.g., drought, pest infestations) (Backlund, Janetos and Schimel 2008, Brevik 2013, Hatfield, Takle, Grotjahn et al. 2014, IPCC 2014).

Fundamentally, sustainable agricultural productivity encompasses not only the transformation of resources into agricultural products that benefit human welfare, but also the extent to which environmental benefits or costs are coproduced with the agricultural system (FAO 2014b). The stewardship of such environmental benefits or costs, collectively using conventional, GE, and organic cropping systems is and will remain an ongoing effort shared by industry, growers, and state and federal agencies. The potential environmental impacts of a GE cropping system will vary according to the specific crop species being cultivated, the pests, diseases, and weed problems present in a given area for that specific crop, the particular phenotype conferred by the introduced trait gene and gene product(s), the naturally occurring biota in the area, and abiotic environmental factors.

Bearing these factors in mind, the Preferred Alternative would likely provide benefits to U.S. agriculture and the environment not as readily realized under the No Action Alternative and Alternative 3. Under the Preferred Alternative the proposed revisions to 7 CFR part 340 would broaden the scope of GE organisms that would be evaluated by APHIS for potential risks, while focusing and limiting ultimate regulatory oversight to GE organisms that presented risks as plant pests or noxious weeds. This would include those GE organisms developed without the use of a plant pest, such as those developed through genome editing.

APHIS would be able to reduce unnecessary regulation and focus greater attention and resources on the permitting of interstate movement, importation, and controlled environmental release of GE organisms that posed risks as plant pests and noxious weeds. The increase in regulatory scope and stringency, and the improved efficiencies in the regulatory review of GE organisms under the Preferred Alternative is expected to provide additional protections for the human environment, both incrementally and cumulatively, relative to the No Action Alternative and Alternative 3. For example, the likelihood of introduction of a GE plant with weedy characteristics, a trait that could be conferred to wild relative populations through hybridization, is expected to be reduced under the Preferred Alternative, relative to the No Action Alternative.

The scope of GE organisms that would be evaluated under Alternative 3 would be inclusive of that of the Preferred Alternative, and the environmental protections conferred under Alternative 3 expected to be commensurate to those of the Preferred Alternative. However, the scope of regulated GE organisms would be expanded to include those that presented potential economic harms, the purpose of which is to facilitate the co-existence of GE, non-GE, and organic cropping systems. In effect, APHIS would serve a wide-scale permitting authority regulating the vast majority of GE crops in commercial production, with both GE and non-GE producers subject to APHIS requirements for co-existence. The regulatory burden on developers and crop producers under Alternative 3 would likely have, to some degree, a chilling effect on research, development, and innovation in the agricultural biotechnology sector. Any impeding of the benefits of biotechnology to U.S. crop production could present risks to U.S. agriculture as a whole, and future markets for U.S. agricultural commodities. Consequently, the Preferred Alternative, which is expected to facilitate innovation in the agricultural biotechnology sector, would likely provide benefits to U.S. agriculture and the environment not realized under the No Action Alternative and Alternative 3, and better serve to facilitate the sustainable production of human and animal food, fiber, and biofuels to meet domestic and international market demands.

In implementing any new regulations, APHIS will continue to work with the FDA, EPA, and other federal agencies to ensure that its revised regulations do not duplicate or conflict with those of other agencies in a way that would result in adverse cumulative impacts on regulated entities or the environment. Such coordination is discussed further below. For future APHIS actions conducted under any of the Alternatives considered, NEPA analyses will continue to be conducted on a case-by-case basis, as applicable, to examine the potential environmental impacts of APHIS decisions and actions in the regulation of GE organisms.

ES 4.4 Federal, Tribal, and State Governance

ES 4.4.1 Federal Oversight

The Coordinated Framework provides as a guiding principle that, "[i]n order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable." APHIS considers the proposed revisions to 7 CFR part 340 under the Preferred Alternative to be entirely consistent with this principle: APHIS will no longer consider GE organisms to be regulated articles solely

because a plant pest was used as a donor, vector, or vector agent in its development, it will consider whether the GE organisms itself may present a plant pest and/or noxious weed risk.

The proposed revisions to 7 CFR part 340 under the Preferred Alternative would update the regulations by revising terms and definitions, and, in conjunction with incorporation of noxious weed authority, broaden the scope of GE organisms that could be evaluated and potentially regulated under 7 CFR part 340. While the scope of GE organisms that APHIS would evaluate for plant pest and noxious weed risk would be broadened, the revisions would focus and limit ultimate regulatory oversight to GE organisms that posed a plant pest or noxious weed risk, as identified in a science-based risk assessment. The proposed revisions are expected to promote process efficiency by allowing APHIS to focus its resources on oversight of GE organisms that have potential plant pest or noxious weed risks, and eliminating oversight of GE organism that are unlikely to pose such risks. The regulatory framework being considered under the Preferred Alternative is consistent with the principles of the Coordinated Framework, with the noted effects on the Coordinated Framework, discussed below.

Under the Preferred Alternative (Proposed Rule), APHIS would no longer require permitting for field testing of GE organisms prior to determination of their plant pest or weed risks. Rather, APHIS would conduct plant pest and noxious weed risks first, and only require permits for field testing of GE organism that were determined to pose a plant pest or noxious weed risk. For those GE plants that are determined unlikely to pose a plant pest or noxious weed risk, biotech developers will be able to field test without APHIS authorization. In effect, it is expected that APHIS would be regulating a fewer number of GE plants and other organisms, eliminating unnecessary regulation, but regulating a broader range of GE organisms that presented risks as plant pests or noxious weeds.

One concern that has arisen is whether the reduction of APHIS oversight of field trials of certain GE plants that are not subject to 7 CFR part 340 will lead to increased levels of GE plant material in the human and animal food supply, prior to premarket food consultation with the FDA. While this is considered a possibility, APHIS does not expect the process of GE plant development, field testing, and commercialization to be substantially altered as a result of implementation of the Preferred Alternative, for a couple of reasons.

First, it is in the biotechnology developer's best interest to sustain the same level of supervision over the development process, and comply with legal and industry procedure required for successful commercialization of their product, as at present. In general, developers have various legal, quality control, and marketing motivations to maintain rigorous voluntary stewardship measures. APHIS believes that developers would continue to utilize such measures for field testing even in cases where USDA would not require a permit. As an example, the undesired cross-pollination or commingling of GE plants under development with other plants:

- introduces unwanted characteristics and variability in the GE plant that confounds molecular characterization and other studies for which field tests are conducted;
- increases legal exposure from unauthorized use of intellectual property (if another developer's traits are inadvertently incorporated into their lines);

- increases legal exposure if unauthorized GE plant material is detected in human or animal food crops; and
- introduces the possibility of the loss of intellectual property and/or confidential business information, such as, if a trait (proprietary information) were to escape a developer's control.

Even after deregulation, seed companies are motivated to adhere to strict stewardship requirements to maintain the integrity of their crops and reduce legal exposure. APHIS therefore believes that rigorous stewardship measures would continue to be utilized for field testing of GE crop plants, even in cases where APHIS would not require a permit.

Second, while under the Preferred Alternative research, development, and innovation in the agricultural biotechnology sector is expected to increase, neither the pace of commercialization nor volume of GE crop plants commercialized is expected to significantly change, as the FDA and EPA will still have oversight of GE crop plants developed for commercial purposes that are subject to FDA and EPA authorities. Developers of GE crops plants would remain subject to the FFDCA, FIFRA, and all other laws and regulations providing protection of human health and the environment, and required to comply with these laws and implementing regulations, as under the No Action Alternative.

Bearing these considerations in mind: As the Coordinated Framework notes, a "mosaic" of statutes have, to date, provided Agencies with authority to exercise oversight of GE organisms, and Agencies functioning within the Coordinated Framework oversee different aspects of the risk that a GE organism may pose. Accordingly, for those GE organisms APHIS no longer views as plant pest or noxious weed risks under the Preferred Alternative, other Agencies may continue to exercise oversight, relative their authorities to do so. However, APHIS acknowledges that the proposed revisions to 7 CFR part 340 could have direct or indirect impacts on the manner in which FDA and EPA exercise their roles within the Coordinated Framework; these potential impacts are discussed below.

Plant Made Pharmaceutical and Industrial Compounds

In general, GE plants intended for human and animal food purposes are not required to be evaluated for safety by the FDA before going to market. However, the developer is responsible for ensuring the safety of their products for human and animal consumption, and complying with all laws and regulations governing human and animal food safety. Developers of GE crop plants are encouraged to consult with the FDA prior to marketing human and animal foods, and developers consider these voluntary food safety consultations with FDA to be necessary, if not critical, for successful commercialization of the their product in the U.S. market, as well international trade of food commodities derived from GE plants. To date, there has been an excellent record of compliance with FDA guidance. For this reason, APHIS believes that developers will continue to consult with the FDA and use rigorous stewardship measures in the field testing of human and animal food crops even when APHIS has determined that a GE organism does not pose a plant pest or noxious weed risk.

While APHIS believes this will be the case for GE food plants, a concern under the proposed revisions to 7 CFR part 340 is oversight of GE plants that are not intended for human or animal food; these are varieties of plants, to include crop plants, genetically engineered to produce pharmaceutical or industrial compounds (plant-made pharmaceuticals and industrials). For the purposes of this dPEIS, these are referenced as PMPIs, and GE P/I-producing plants. A recent, well-publicized example of such a plant is *Nicotiana benthamiana*, which was genetically engineered to produce antibodies to the Ebola virus, and used in the development of an Ebola vaccine. When plants are genetically engineered in such a manner, the plants and the pharmaceutical or industrial products they produce may fall within the purview of multiple regulatory agencies: APHIS, the EPA, and/or FDA.

APHIS has authority to evaluate GE P/I-producing plants for plant pest and/or noxious weed risk under the PPA. The FDA has authority to regulate plant made pharmaceuticals under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 9). The EPA has authority to regulate plant made compounds with pesticidal properties (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 et seq.), and PMPIs that are determined to be chemical compounds under the Toxic Substances Control Act (TSCA, 15 U.S.C. 2601 et seq.). Hence, while APHIS may regulate the plant itself, products obtained from GE P/I-producing plants may be regulated by FDA (authority over pharmaceuticals) or EPA (authority over certain industrial compounds), depending on their intended use.

Under current 7 CFR part 340, APHIS regulates GE P/I-producing plants because they were developed using genetic material from plant pest, or a plant pest was part of the development process. Accordingly, APHIS currently exercises oversight of all field trials of regulated GE P/I-producing plants; this oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring. Based on APHIS' oversight, the FDA and EPA determine the appropriate degree of oversight and monitoring pursuant to their own statutory authorities. PMPIs may then be regulated by FDA (authority over drugs) or EPA (authority over certain industrial compounds), depending on their intended use.

Under the proposed revisions to 7 CFR part 340, a GE plant would not be regulated solely because a plant pest was used as a vector, vector agent, or donor of genetic materials in its development. Rather, a GE plant would be a regulated organism if it had a plant-trait combination that APHIS has not yet evaluated for plant pest and/or noxious weed risk, if it had received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, or if it was evaluated by APHIS and found to present a plant pest or noxious weed risk. In brief, the GE P/I-producing plant itself would have to pose a plant pest or noxious weed risk to be regulated under the proposed revisions to 7 CFR part 340.

As a result, because most plants do not inherently present plant pest or noxious weed risks, particularly domesticated plants, and traits introduced for the production of pharmaceutical or industrial compounds are unlikely to confer plant pest or noxious weed risk to a domesticated plant, it is expected that most of the GE P/I-producing plants that APHIS evaluates will be found unlikely to pose a plant pest or noxious weed risk. Hence, such plants could be grown

outdoors without the need for permits and without APHIS oversight. Such a plant could also be planted before or without an evaluation by the FDA or EPA.

APHIS recognizes that federal oversight of outdoor plantings of GE P/I-producing plants could be necessary to prevent the unlawful entry into the food supply of material from such plants. Establishing growing and handling conditions to confine such plants, and inspecting to ensure such conditions are followed, may enable corrective actions before material from the plants is inadvertently released and causes public health or economic impacts. One of the reasons APHIS' oversight of such crops has been an important part of the Coordinated Framework for oversight of GE plants is that companies are not necessarily required to notify FDA or EPA when the company plants a GE P/I-producing plant. For example, for GE P/I-producing plants whose products fall under FDA authority, FDA has no regulations governing the planting of such crops. For crops genetically engineered to produce pharmaceuticals, companies only have to come to FDA when they have reached the point that they are ready to begin clinical trials with the pharmaceutical derived from the plant. This could be years after they first started growing the pharmaceutical-producing plant in the field.

Hence, a gap in the federal oversight of GE P/I-producing plants could result in the unintentional or inadvertent introduction into the human or animal food supply of unevaluated PMPI products, even when the intended purpose of the plants is not for human or animal food use. For example, a company could self-determine that the compound produced by the plant is generally recognized as safe (GRAS) for use, and therefore conclude it had no legal obligation to keep surplus GE P/I-producing plants out of the human or animal food supply, to keep such GE P/I-producing plants from spreading pollen to plants grown for human and animal food purposes, or even to notify any federal agency that they were planting such crops. In addition to potential food safety risks posed by such plants should they enter the food supply, a gap in federal oversight could generate concerns from the general public regarding the safety and wholesomeness of the human or animal food supply, which could adversely impact agricultural interests.

APHIS has identified several options that have the potential for adequate federal oversight of outdoor plantings of GE P/I-producing plants.

- Under one option, a statute would be enacted, or existing statutory authority amended, to grant one of more federal agencies explicit authority to provide oversight of outdoor plantings of all GE PMPI-producing plants and to evaluate GE PMPI-producing plants for all possible risks, beyond plant pest and noxious weed risks.
- For industrial-producing plants subject to EPA's jurisdiction, a second option is for EPA to develop a program to regulate industrial-producing plants and issue regulations if warranted.
- Under a third option, APHIS would enter into a memorandum of understanding (MOU) and services agreement with the appropriate federal agencies to provide personnel and other resources to assist those agencies in their oversight of outdoor plantings of PMPI-producing GE plants, recognizing that federal agencies may not

have authority to require notification and/or oversight of the outdoor planting of some of these plants.

- Under a fourth option, those federal agencies would supply their own personnel and resources to exercise oversight of outdoor plantings of PMPI-producing GE plants, recognizing that federal agencies may not have authority to require notification and/or oversight of some of these plants.

APHIS recognizes that there are challenges associated with each of these options. For example, the first option would require legislation to be enacted, which is not within the purview of the Executive Branch of the Federal government. Additionally, all options could require Federal Agencies to incur the costs associated with setting up new regulatory programs. The second option would require time for EPA to stand up a genetically engineered industrial-producing plant oversight program for plants subject to EPA jurisdiction. The third option, in turn, would require policies, procedures, and guidance regarding APHIS' interaction with other Federal Agencies to be developed prior to implementation. To that end, it is important to note that APHIS does not prefer any of these options over the other, nor does the Agency consider the options listed above necessarily to be exhaustive. Rather, we put them forward to indicate that the Agency is aware of the implications of this rule with regard to PMPIs, and to request specific public comment regarding the best manner to address this issue.

Plant Incorporated Protectants – Small Scale Field Testing

Plant-incorporated protectants (PIPs) fall under the regulatory oversight of the EPA. Currently, the EPA requires experimental use permits (EUPs) for small scale field testing of PIP containing GE plants when field tests are over 10 acres in size, and APHIS exercises regulatory oversight of field testing of GE PIP producing plants on or under 10 acres. In brief, to date, the EPA has largely relied on USDA oversight and inspections of small scale filed trials since jurisdictions currently overlap. Under the current regulations in 7 CFR part 340, APHIS requires permits or notifications for the environmental release of all GE plants that meet the definition of a regulated article and produce PIPs, and exercises oversight of all outdoor plantings of these regulated PIP-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring.

To date, APHIS has regulated PIP-producing plants when they were genetically engineered using a plant pest as the donor, vector, or vector agent, and fall under the scope of regulated article as defined in the current regulations at 7 CFR part 340. However, under the Preferred Alternative (proposed rule), a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Rather, the GE plant would be a regulated organism if it had a plant/trait combination that the Agency determines presents a plant pest or noxious weed risk, or has not yet evaluated for plant pest and/or noxious weed risk. As discussed above for GE P/I-producing plants, because most plants do not inherently present plant pest or noxious weed risks, particularly domesticated plants, and traits introduced for the production of PIPs are unlikely to confer plant pest or noxious weed risk to a domesticated plant, it is expected that most of the GE PIP producing plants that APHIS evaluates will be found unlikely to pose a plant pest or noxious weed risk. Hence, such plants could be grown outdoors without the need for permits

and without APHIS oversight. Thus, such plants could be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight. Under the Preferred Alternative (proposed rule), APHIS would only require permits for PIPs planted on 10 acres or less if they were determined to present a plant pest or noxious weed risk, or have not yet been evaluated by APHIS for such risk.

APHIS understands that the Preferred Alternative would shift federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs to the EPA. The EPA may decide to require experimental use permits for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. The EPA would need to develop a program to oversee small-scale testing of PIPs and issue regulations if warranted. APHIS is fully committed to coordinating with EPA in order to give the EPA sufficient time to stand up a program for federal oversight of small scale field testing of GE PIP producing plants, if the Preferred Alternative is implemented (the proposed rule is finalized). APHIS understands that an MOU and services agreement may be necessary to provide personnel and other resources to assist the EPA during the interim period while the EPA implements its own program of oversight for the oversight of outdoor planting of PIPs 10 acres or less.

APHIS recognizes that there are challenges associated with such a transition that would also require EPA to incur the costs associated with setting up a revised regulatory program. Further, such a transition would require policies, procedures, and guidance regarding APHIS' interaction with EPA. APHIS does not consider the approach listed above necessarily to be exhaustive. Rather, APHIS puts it forward to indicate that the Agency is aware of the implications of the Preferred Alternative with regard to small-scale testing of PIPs and to request specific public comment regarding the best manner to address this issue.

Herbicide Resistant GE Plants and Herbicides - Synchronous Decisions with the EPA

The EPA registers and has oversight of the herbicides used on GE HR crop plants, but does not regulate GE HR plants themselves. Rather, GE HR plants are regulated by APHIS under 7 CFR part 340 To date, GE HR plants have been regulated by APHIS because they were developed using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. However, as discussed previously in this section, under the Preferred Alternative, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Under the Preferred Alternative, APHIS expects that many of the GE HR plant-trait combinations it evaluates will not be found to present plant pest or noxious weed risks. Thus, such plants could be grown outdoors without the need for permits and without APHIS oversight.

Commenters to the proposed update to the Coordinated Framework on the Regulation of Biotechnology published on September 22, 2016 (81 FR 65414-65415), expressed the need for coordination between USDA and EPA regarding the timing of deregulation/determination of non-regulated status of herbicide-resistant crops and the registration of herbicides. APHIS recognizes that the asynchronous timing of the deregulation of herbicide-resistant plants and the associated herbicide registration may lead to situations where a developer could sell the GE HR plant/seed without waiting for the associated herbicide registration. In such a

situation, farmers may be tempted to use an herbicide that is not registered for use on the GE HR crop, which would comprise an illegal use of an herbicide.

In light of the challenges associated with the asynchronous regulatory actions on the part of APHIS and EPA, APHIS will work with EPA to explore solutions to better coordinate the commercial availability of seed for herbicide resistant crops concomitant with the registration of herbicides intended to be used on those crops. Furthermore, APHIS intends to limit the scope of its decisions to be on an individual/specific herbicide resistant crop basis (e.g., glyphosate resistant cotton) so that the EPA and APHIS are making decisions on the same specific herbicide resistant crop/herbicide combinations.

This coordination presents challenges because once APHIS determines a GE organism does not represent a risk as a plant pest or noxious weed, APHIS cannot continue to regulate the GE organism or delay announcing the regulatory status determination. When APHIS receives a request for regulatory status determination of an herbicide resistant crop, it is likely to be three or more years before a developer is ready to undergo registration review at EPA. If APHIS determines that the herbicide resistant plant is not a risk as a plant pest or noxious weed, APHIS does not have the authority in the PPA to require permits with regulatory controls for the movement and outdoor planting of that herbicide tolerant plant during those subsequent years. Nor is it within APHIS authority for APHIS to withhold making a regulatory status evaluation decision for several years and requiring permits for field testing during that time. The issue has not been the illegal use of pesticide during the field testing of herbicide resistant crops by developers but instead is the illegal use of pesticide by farmers on seed that has been deregulated by APHIS and is commercially available before the commercial availability of the herbicide designed for those crops.

One option to address this coordination would be to enact a new statute or amend an existing statute to make it illegal to sell seeds for herbicide resistant crops before the registrations were completed for use on those crops. Another option might involve a voluntary agreement by seed developers to withhold selling seed of herbicide-resistant crops until EPA registrations are completed for the herbicide products designed for those crops. In cases where APHIS makes a decision deregulating an herbicide-resistant crop or determines under § 340.4 that an herbicide resistant crop is unlikely to pose a risk as a plant pest and/or noxious weed and will no longer be a regulated organism and no herbicide product has been registered by EPA for use on that herbicide resistant crop, APHIS would indicate on the APHIS Regulatory Status List website and websites associated with deregulation decisions that no herbicide product is registered bv EPA for use on this herbicide resistant crop and it is illegal to use any herbicide product on these crops unless registered by EPA for such use. Additionally, APHIS would include language in deregulation decision letters sent to the developer and Federal Register notices associated with § 340.4 final determinations indicating it is illegal to use herbicides on these crops until the herbicide product is registered by EPA for use on the herbicide resistant crop. This decision letter and all other information regarding APHIS's decisions would also be made available to the public on the APHIS website.

APHIS does not consider the approaches listed above necessarily to be exhaustive and recognizes that one of the options listed would require legislation to be enacted, which is not

within the purview of the Executive Branch of the Federal government. However, APHIS puts them forward to indicate that the Agency is aware that asynchronous timing of the deregulation of herbicide-resistant plants and the associated herbicide registrations can lead to significant problems, and to request specific public comment regarding the best manner to address this issue.

ES 4.4.2 Tribal Governments

APHIS consultations with federally recognized tribal entities are based on their special status as independent governments. APHIS contacted representatives of federally-recognized tribes to facilitate discussions of potential impacts of the proposed revisions to 7 CFR part 340 on tribal resources, and it is APHIS' intention to continue to communicate with tribal representatives during the rulemaking and NEPA processes. Individually and collectively, tribal comments and input inform APHIS' decision-making. Under all of the Alternatives, APHIS would continue to consult with tribal representatives, and share applications for permits with tribal representatives, when there are regulated GE organisms proposed for release on or in proximity to tribal lands.

ES 4.4.3 State Governments

The revision of 7 CFR part 340 would not affect APHIS partnerships with states in the oversight of GE organisms. Under all the alternatives considered, APHIS would continue working with states to ensure states are aware of importations, movements, and environmental releases taking place within their jurisdiction, how these activities are performed and confined, and provide states the opportunity to request additional restrictions be placed on permitted activities to mitigate plant pest and noxious weed risks. APHIS expects that states would be required to adjust to minor programmatic and procedural changes under the regulatory frameworks described for the Preferred Alternative and Alternative 3.

ES 4.5 Endangered Species Act Compliance

It is important to note that the adoption of either the Preferred Alternative and Alternative 3 alone would not result in direct or indirect impacts to threatened and endangered (T&E) species. However, individual decisions made while implementing either alternative could impact T&E species. APHIS will consider these actions appropriately using the current ESA effects analysis process to analyze potential effects on T&E species. If APHIS determines that an action may affect T&E species or critical habitat, APHIS will consult with the U.S. Fish and Wildlife Services (USFWS) as required by the ESA.

The proposed revisions to the regulations do not differ materially from the existing rule regarding effects on T&E species and critical habitats. They also do not change the processes APHIS would use to analyze these effects. APHIS will continue to use the processes it has developed over the years in consultation with the USFWS. Changes to the regulations under the Alternatives considered will enhance APHIS' ability to take measures on individual actions to reduce the potential for effects on listed species and critical habitat and improve compliance with Section 7 of the ESA.

APHIS has determined that the proposed revisions to regulations under the Preferred Alternative and Alternative 3 will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, neither consultation under Section 7(a)(2) of the Act nor the concurrences of the USFWS is required.

ES 4.6 Environmental Statutes, Executive Orders, and International Standards and Treaties

During the planning and implementation of Agency actions, to include regulatory activities conducted pursuant to 7 CFR part 340, APHIS must comply with applicable federal statutes, regulations, executive orders (EO), federal memoranda, and international standards and treaties.

The dPEIS describes the relationship of federal laws, regulations, and EOs to APHIS regulation under 7 CFR part 340, and APHIS' compliance with these requirements. The dPEIS also describes trade agreements, and other international agreements and arrangements to which the United States is party. Under all the Alternatives considered, APHIS would continue to promote harmonization of biosafety and biotechnology policies through development of technical consensus documents and guidelines within the Organization of Economic Cooperation and Development (OECD), specifically the Working Group on the Harmonization of Regulatory Oversight in Biotechnology.

1 Purpose and Need

1.1 Overview

The mission[8] of the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is to protect the health and value of American agriculture and natural resources. The Plant Protection Act of 2000 (PPA; 7 U.S.C. § 7701, et seq.) provides APHIS authority to issue regulations that serve to prevent or mitigate plant pest and noxious weed risks. APHIS protects and promotes U.S. agricultural production and trade by establishing, implementing, and enforcing its regulations promulgated under the PPA.

APHIS regulations at Title 7 of the Code of Federal Regulations (CFR) part 340 (Title 7: CFR part 340), implementing the PPA, address plant pest risks that may be associated with genetically engineered (GE) organisms. These regulations govern the importation, interstate movement, and environmental release of GE organisms. The regulations are intended to control plant pest risks using current scientific information, so as to provide oversight appropriate for and consistent with the degree of risk associated with GE organisms.

APHIS first promulgated these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 (FPPA; 7 U.S.C. §§ 150aa–150jj, repealed) and the Plant Quarantine Act of 1912 (PQA; 7 U.S.C. §§ 151–167, repealed), two acts that were subsumed into the PPA of 2000, along with other provisions. APHIS is proposing to revise 7 CFR part 340 to address advances in biotechnology that have occurred since the regulations were issued in 1987, issues and recommendations contained in the USDA Office of Inspector General (OIG) 2005 and 2015 audit reports (USDA-OIG 2005, USDA-OIG 2015), provisions of the 2008 Farm Bill (Pub.L. 110–234, H.R. 2419, 122 Stat. 923), align the regulations with the PPA, as amended, and to make its regulation commensurate with the potential environmental risks described by the National Research Council (NRC 2002).

1.2 APHIS Statutory Authority under the PPA and Implementing Regulations

The PPA was enacted in 2000 to consolidate and expand several older laws for regulating plant pests and diseases, including the FPPA, the PQA, and the Federal Noxious Weed Act (FNWA) (formerly 7 U.S.C. § 2801, et seq.). The PPA expands and clarifies USDA's authority to protect American agriculture against domestic and foreign plants pests. The expanded authority enables APHIS to regulate certain biological control agents and increases its regulatory oversight over noxious weeds. The PPA also repealed the FPPA and PQA, but included a clause (7 U.S.C. § 7758(c)) that retained regulations promulgated under them until APHIS issued new regulations under the PPA. The authorities consolidated in the PPA provide, in part, the basis for the Agency's proposed revisions to 7 CFR part 340.

The PPA authorizes the Secretary of Agriculture to prevent the dissemination of plant pests and noxious weeds into or within the United States. Among its "Findings" for the PPA (§402), Congress recognized that:

[8] For more information about the USDA-APHIS mission see: http://www.aphis.usda.gov/about_aphis/

". . . it is the responsibility of the Secretary to facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests or noxious weeds" (7 U.S.C. § 7701(3)); and

" . . . the unregulated movement of plant pests, noxious weeds, plants, certain biological control organisms, plant products, and articles capable of harboring plant pests or noxious weeds could present an unacceptable risk of introducing or spreading plant pests or noxious weeds;…" (7 U.S.C. §7701(7)).

Under the PPA, APHIS is responsible for preventing the importation and dissemination of plant pests and noxious weeds. The PPA specifically authorizes APHIS to regulate, "any plant, plant product, biological control organism, noxious weed, article, or means of conveyance" that could spread a plant pest or noxious weed (§ 7712). The definition of "plant pest" in the PPA includes organisms that could directly or indirectly injure, damage, or cause disease in any plant or plant product (§ 7702(14)).

The definition of "noxious weed" in the PPA includes (§ 7702(10)): "…any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment."

APHIS regulates both GE and non-GE organisms for potential plant pests and noxious weed risk. APHIS regulates non-GE plant pests under 7 CFR § 330.200 and non-GE noxious weeds under 7 CFR part 360. Regulations at 7 CFR part 340 apply to introductions of GE organisms that are plant pests or potential plant pests, but does not explicitly codify the noxious weed provisions of the PPA. Consequently, APHIS does not currently regulate GE organisms as potential noxious weeds. As with non-GE plant pests regulated under 7 CFR part 330, authorization must be obtained from APHIS prior to the importation, interstate movement, or environmental release of any GE organism that is a potential plant pest.

1.3 Recommended Revisions to APHIS' Biotechnology Regulatory Program

In 2005, the USDA Office of the Inspector General (OIG) conducted an audit of APHIS' biotechnology regulatory program and provided APHIS recommendations for exercising broader and more stringent oversight of GE organism (USDA-OIG 2005). In a subsequent 2015 audit, the OIG emphasized that APHIS needed to complete implementation of 3 primary recommendations from the 2005 audit that had not been fully addressed (USDA-OIG 2015). These were that APHIS revise its regulations (7 CFR part 340) to consolidate all requirements for conducting field tests of regulated material in order to minimize the inadvertent release of GE material; that APHIS clarify its regulations regarding the use of metal shipping containers and movement of GE seeds; and that APHIS update its regulations to incorporate the provisions of the Plant Protection Act of 2000, to specifically include incorporation of authority to control noxious weeds.

During this time frame further recommendations were provided by Congress in the Food, Conservation, and Energy Act of 2008 (Farm Bill). Section 10204 of the 2008 Farm Bill requires the Secretary of Agriculture to take action on each issue identified in an APHIS document entitled ''Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework,''[9] and where appropriate, promulgate regulations.

1.4 AHIS Noxious Weed Authority

APHIS has become increasingly aware of the need to revise the regulations to evaluate GE plants for noxious weed risks. When, in 1987, APHIS first issued 7 CFR part 340 under the authority of the FPPA and PQA, APHIS' authority to regulate noxious weeds was the Federal Noxious Weed Act of 1974 (7 U.S.C. 2801, FNWA). The FNWA definition of "noxious weed" limited APHIS' authority, at that time, to plants that were of foreign origin and new to or not widely prevalent in the United States.

In 2000, the PPA was issued, which subsumed the FPPA and PQA, replaced the FNWA, and provided a new definition of noxious weed. The PPA also provided APHIS explicit authority to issue regulations listing noxious weeds that are prohibited or restricted from entering the United States or that are subject to restrictions on interstate movement within the United States, and provided persons with the right to petition APHIS to add or remove noxious weeds from this list. In 2010, APHIS revised the noxious weed regulations, found in 7 CFR part 360, to reflect the noxious weed provisions of the PPA. It also led APHIS to revise the manner in which APHIS evaluates plants for noxious weed risk to determine whether to list them in part 360. In general, APHIS lists a plant as a federal noxious weed if APHIS determines the plant to be invasive and to have significant negative impacts, if introduced or disseminated within the United States, and if APHIS determines that federal regulation could reduce the likelihood of such introduction or dissemination.[10]

This approach means that there are certain plants that APHIS has determined to be weeds, but not to be federal noxious weeds. This distinction between a weed and a federal noxious weed warrants emphasis. "Weeds," in the broadest sense of the term, could include any plant growing where and/or when it is unwanted; even plants that are desirable in some settings could be considered weeds in others. The plants that APHIS evaluates for inclusion on the federal noxious weed list are, in general, a particular type of weed: An invasive, usually non-native plant that impacts natural and/or agronomic ecosystems, often with significant negative consequences. Of the problematic weeds APHIS has evaluated, only a fraction (around 1.4%)[11] have been determined to be ones for which federal regulatory controls to prevent their introduction or dissemination are justified; these plant taxa are added to the list

[9] To view this document, go to www.aphis.usda.gov/biotechnology/downloads/supportingdocs/LessonsLearned10-2007.pdf

[10] USDA - Federal Noxious Weeds: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/SA_Noxious_Weeds

[11] Since 2011, around 1700 weeds have been evaluated. Only 24 have been deemed to meet the criteria for inclusion on the list of Federal noxious weeds.

of federal noxious weeds in part 360. Part 360 currently lists 112 aquatic, terrestrial, or parasitic plant taxa as federal noxious weeds.[12]

The regulations in part 360, while effective, have restrictions that limits their applicability to GE organisms: They are predicated on a determination by APHIS that a taxon is a federal noxious weed. This determination is easier for plants that have not been genetically engineered, because there are usually many reference points that are available and pertinent to this determination, including international experience with the weed, scientific literature regarding the plant's biology, published studies, and other data. For GE plants, there is likewise, usually a great deal of data and experience with the unmodified plant, as the vast majority of GE plants are developed using domesticated plants that are widely cultivated in the United States, for which there is an extensive body of scientific literature regarding the plants biology. Indeed, due of their economic importance, domesticated crop plants are often some of the most well-studied and well characterized (Ellstrand, Heredia, Leak-Garcia et al. 2010). However, when a desired trait is genetically engineered into a plant, there may, in certain instances, be little data available or previous experience for APHIS to rely on in evaluating the properties of the resulting GE plant-trait combination. Instead, in order to determine whether the GE plant could function as a noxious weed, APHIS would have to rely on its own independent evaluation of the GE plant-trait combination, based on information provided by the plant's developers.

Historically, there has not been a significant need for APHIS to evaluate GE plants for noxious weed risk. Most of the GE plants that APHIS has regulated in the past, such as varieties of corn and soybeans modified with common agronomic traits, do not qualify as "noxious weeds". This is because most GE plants to date have been domesticated crop plants, which are not weedy in character prior to introduction of a desired trait. Domestication, a breeding process for selection of desired traits and adaptation of plants to cultivation, has generally led to elimination of weedy characteristics in most crop plants, although there are exceptions (Ellstrand, Heredia et al. 2010). For example, domestication has generally led to the elimination of weedy traits such as seed shattering, seed dormancy, and invasiveness. Fully domesticated plants cannot survive on their own in the wild; corn would be an example (Gepts 2004). Moreover, the phenotypic traits that have historically been introduced into crops through genetic engineering do not confer weediness characteristics to the plant. Because the vast majority plants that have been genetically engineered were not weeds prior to modification, and the common insect and herbicide resistant traits introduced have not conferred weedy characteristics to the GE plants, evaluating the plant solely for plant pest risk has not been problematic. For GE plants that APHIS has determined are not subject to 7 CFR part 340, APHIS has not subsequently encountered any situations where the GE plants began to act as noxious weeds.

However, in recent years, there has been an increasing diversity of both agronomic and non-agronomic traits engineered in plants, GE plants comprised of multiple traits, and an increased use of plants in genetic engineering that, in their unmodified state, are known to possess weedy traits. There may be some applications where weedy characteristics may even be desired, such as for plants used in the production of biofuel. For example, switchgrass

[12] Federal Noxious Weed List: https://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist.pdf

(*Panicum virgatum*), which has long been used in the production of ethanol, has growth patterns in an unmodified state that are characteristic of a weed, and, recently, has been genetically engineered to improve its utility in ethanol production. Considering these factors, and that genetic engineering may, in certain instances, enhance the weediness traits that are already present in a plant in its unmodified state, evaluation of GE plants for noxious weed risk has emerged as a necessary aspect of effective regulation.

Moreover, APHIS' current regulatory structure, which entails evaluating GE plants solely for plant pest risk, is not sufficient to properly identify all risks that these plants present to other plants and plant products. Indeed, under the current structure, such plants may entirely escape regulation. While, in the past, GE plants have almost always used a plant pest to vector genetic material, in recent years GE techniques have arisen that do not use plant pests as donor organisms or vectors. If plants are genetically engineered without the use of a plant pest as a vector or donor, this would require APHIS to consider the plant itself to be a plant pest in order to designate it as a regulated article. However, under the PPA's definition of plant pest, a plant must be parasitic in order to be considered a plant pest. With limited exceptions, such as mistletoe, dodder, and striga, very few plants are known to be parasitic. Hence, for the reasons described, APHIS considers it both appropriate and necessary to begin to evaluate GE plants for noxious weed risk.

1.5 History of Revisions to 7 CFR part 340

Since 1987, APHIS has amended 7 CFR part 340 regulations six times to include new procedures or exemptions that promote regulatory efficiency.[13] For example, the 1993 revision implemented a simplified notification process for authorizing introductions of some GE crops. This process was limited to six crops that APHIS identified as having low plant pest risk based upon available science and APHIS' experience regulating GE versions of those six plant species. For GE plants to qualify for the notification process; the plants had to meet specific eligibility criteria. Most common crops engineered with familiar agronomic or product quality traits qualify for the notification process. Parties using the notification procedure were also required to meet performance standards designed to prevent the unintended introduction and spread of plant pests.

The 1993 revision also established an optional petition process: an applicant could request that a GE plant not be regulated because of absence of potential to pose a plant pest risk. In considering a petition, APHIS carefully reviews the data submitted by the applicant, which is usually compiled during several years of field testing. APHIS also considers relevant information from results of studies reported in the scientific literature. The Agency's risk analyses are based on knowledge it has acquired and documented during 30 years of regulatory oversight of GE organisms. Under APHIS authority, pursuant to 7 CFR part 340,

[13] 70 Federal Register, No. 85 (Wednesday, May 4, 2005), pp. 23009 - 23011 (permit requirements for plant producing industrial compounds); 62 Federal Register, No. 85 (Friday, May 2, 1997), pp. 23945 – 23956 (extensions and notification expansion); 58 Federal Register, No. 60 pages (Wednesday, March 31, 1993) 17044 - 17059 (Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Non-regulated Status); 55 Federal Register, No. 250 (Friday, December 28, 1990), pp. 53275 – 53276 (interstate movement of Arabidopsis); 53 Federal Register, No. 76 (Wednesday, April 20, 1988), pp. 12910 - 12913 (interstate movement of microorganisms).

a GE organism is not regulated if the Agency determines that it is unlikely to pose a plant pest risk in the United States.

In 1997, the regulations were revised again. At that time, the notification process was extended to include all plants meeting the eligibility criteria. Two additional criteria were added to those of the 1993 rule – plants must not be federally listed noxious weeds, and plants must not be considered by APHIS or a State Government to be weeds in the area of the proposed field test. APHIS experience has shown that it can be particularly challenging for some developers to meet the performance standards when field testing certain types of GE plants such as trees, other perennials, and wheat. APHIS typically requires that permits for these provide additional oversight and enforcement requirements to assure that they remain confined.

APHIS is again proposing to revise its regulations. The proposed revisions to 7 CFR part 340 are expected to promote process efficiency by focusing APHIS' resources on oversight of GE organisms that pose plant pest or noxious weed risks, as determined by science-based risk assessments, and eliminating unnecessary regulatory burdens on APHIS and the agricultural biotechnology sector. The salient reasons for a revision are to:

- Reflect advances in genetic engineering that have occurred over the last 29 years, and APHIS experience in assessing the plant pest risk of GE organisms.
- Respond to the recommendations of the 2005 and 2015 OIG audits, and the 2008 Food, Conservation, and Energy Act of 2008 (Farm Bill).
- Align the regulations with the PPA of 2000, as amended.
- Make its regulation commensurate with the potential environmental risks described by the National Research Council (NRC 2002).

1.6 Summary of Proposed Revisions to 7 CFR part 340

In light of the factors reviewed above, APHIS intends to make the following revisions to the current regulations at 7 CFR part 340:

- Incorporate the noxious weed authority from the PPA and evaluate GE plants for their noxious weed risk. In recent years there has been an increasing diversity of both agronomic and non-agronomic traits engineered in plants, as well as an increased use of plants in genetic engineering that, in their unmodified state, are known to possess weedy traits; consequently there is a correspondingly higher risk that a GE plant may pose a noxious weed risk.
- Provide revised terms and definitions for "genetic engineering", "genetically engineered organism", and "regulated organism" so that organisms that are produced by techniques that use recombinant or synthetic nucleic acids to create or modify a genome, and that pose plant pest or noxious weed risks, are subject to regulation under 7 CFR part 340.[14]

[14] Traditional breeding techniques (including marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion), and chemical or radiation-based mutagenesis, would not be considered genetic engineering.

- Refine the regulatory framework so that USDA oversight is focused on those GE organisms that present plant pest and noxious weed risks, as determined by science based risks assessments, and unnecessary regulatory burdens are eliminated.
- Change the current APHIS regulatory review framework from one in which GE organisms are regulated based on the use of plant pests in their development, to one in which APHIS evaluates the GE organisms themselves for plant pest and noxious weed risks.
- Institute a more efficient regulatory review process for GE organisms where plant pest and noxious weed risks are evaluated first, prior to authorization of any interstate movement, importation, or environmental release.
- Eliminate the notification procedure and authorize the interstate movement, importation, or environmental release only under permit.

The proposed revisions to the regulations will allow for more efficient use of Agency resources because permits will be required for and limited to those GE organisms that are likely to pose a risk as a plant pest or noxious weed. This will allow for a level of oversight consistent with the degree of risk associated with some GE organisms, and a more appropriately focused implementation of APHIS' PPA authorities.

1.7 Background on the Regulation of Genetically Engineered Organisms

GE organisms have been regulated in the United States for almost 30 years. During this time, genetic engineering has evolved to become a routine, approved method for plant development. More recently, advances in biotechnology have resulted in the development of new methods for the introduction of desirable traits into plants and other organisms that can be integrated into existing agricultural production systems. As of 2015, commercial GE crop production occurred in 28 countries on six continents, in both developing and industrialized countries. Collectively, GE crops were grown on more than 440 million acres worldwide. Nineteen countries had GE crop acreage exceeding 100,000 acres (James 2015). Corn, cotton, and soybeans currently account for more than 90% of global GE crop production. Socioeconomic benefits are cited as the most important factors influencing the global adoption of GE crops (Brookes and Barfoot 2013a, Klümper and Qaim 2014, Brookes and Barfoot 2015). In Figure 1-1, two important trends in the global adoption of GE crops are apparent. Between 1996 and 2014 there was a continuous increase in acreage used for GE crops, and between 2010 and 2011 the acreage of GE crops in developing countries began to exceed that of industrial countries.

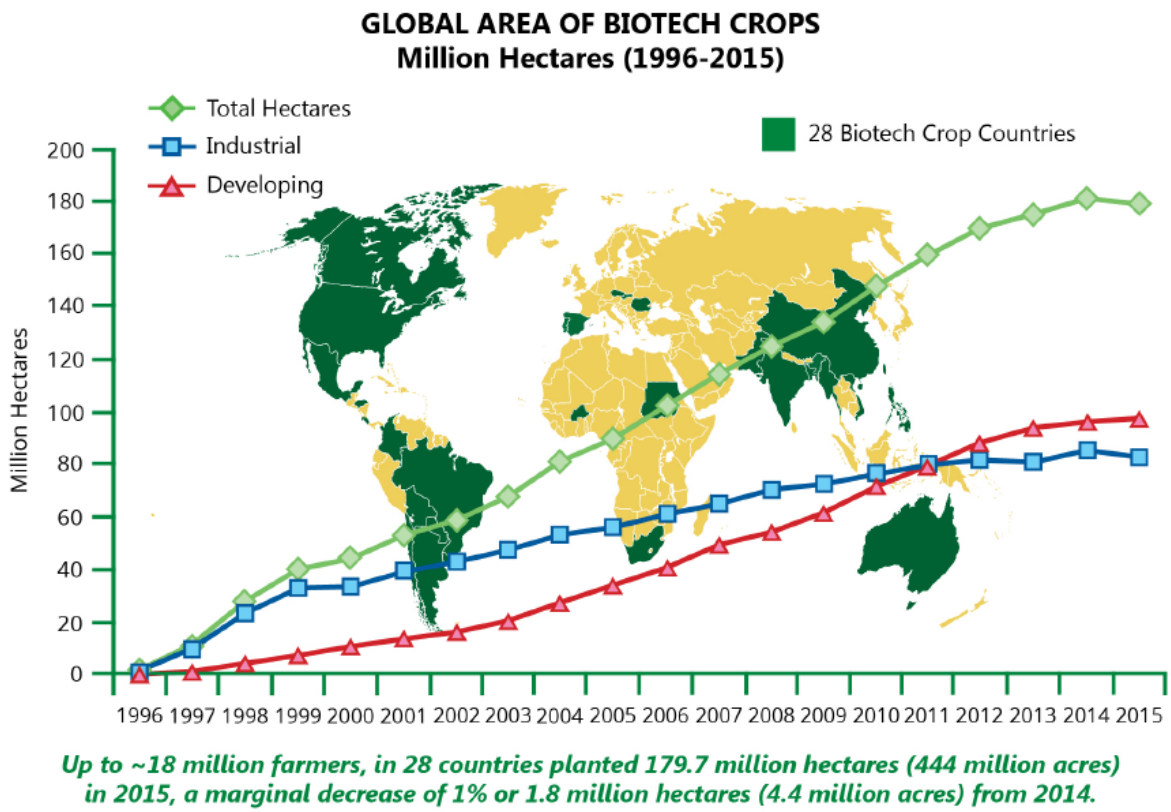

Figure 1-1. Global Adoption of GE Crops: From 1996 to 2015
Source: (James 2015)

The worldwide increase in GE crop adoption has been accompanied by continued interest in development of new varieties of GE crops. Research and development are underway in the United States and several other countries (e.g., Brazil, Argentina, India, Canada, China) to expand the crop plant options available to growers to meet market demands for human and animal food, and fiber. To date, most GE plants that have been developed and adopted for commercial use were plants with single transgenes[15] that conferred resistance[16] to an herbicide or insect pests, although stacked trait varieties of GE plants are increasingly used, and it is expected such varieties will see further development and use. Future GE organisms are anticipated to be plants expressing new traits and combinations of traits. These may include GE plants that have resistance to a range of pests and diseases, resistance to a broader

[15] A transgene is a gene that is taken from the genome of one organism and introduced into the genome of another organism using a number of genetic engineering techniques. The introduction of a transgene has the potential to change the phenotype of an organism.

[16] "Resistance" to herbicides is defined by the Herbicide Resistance Plant Committee of the Weed Science Society of America (WSSA) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type. In a plant, resistance may be naturally occurring or induced by such techniques as genetic engineering or selection of variants produced by tissue culture or mutagenesis. "Tolerance" is distinguished from resistance and defined as the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. The terms "resistance" and "tolerance" may be used interchangeably in the literature, and clarified here as to use in this dPEIS.

variety of herbicides, tolerance to physical stress (e.g., drought, cooler climates), and more nutritional value as food for human and animal consumption. Some future GE plants may have multiple traits incorporated to regulate metabolic pathways or alter the expression of endogenous genes. Other examples include: microorganisms engineered to produce biofuel from biomass; plants developed for the production of pharmaceutical and industrial compounds; and insects modified to enhance their use as biological control agents.

These newly developed GE organism-trait combinations are expected to provide benefits in the way pests and diseases are managed, sustaining crop product quality and yield, and reduce agronomic inputs such as insecticides and fertilizers. Historically, certain GE crop plants have been found to provide net economic benefits at the farm level, which could also be seen with future GE crop plants developed, for instance, for pest and disease resistance. These newly developed GE organisms, some of which may be developed via more advanced genome editing and similar techniques, techniques that are novel to domestic and international regulatory agencies, may also require a more refined attention as to their potential environmental and human health risks. In the United States, GE organisms are reviewed under what is called the Coordinated Framework, described below.

1.7.1 Federal Oversight Under the Coordinated Framework

Since 1986, the U.S. government has regulated GE organisms consistent with the regulatory framework described in the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework). [17] The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products, and explains how federal agencies use existing federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles:

> (1) The process of modifying an organism independent of the safety of the organism: although the new biotechnology processes can be used to produce risky organisms, traditional techniques can also be used. It is the characteristics of the organism, the environment, and the application that determine risk (or lack thereof) of the introduction—not the technique used to produce the organism.
>
> (2) Agencies will seek to operate their programs in an integrated and coordinated manner that will encompass the entire range of those plants, animals, and microorganisms modified through genetic engineering.
>
> (3) Where regulatory oversight or review for a particular GE organism is to be performed by more than one agency, coordinated review must occur.
>
> (4) To the extent possible, responsibility for a GE organisms use should reside with a single agency.

[17] Coordinated Framework for Regulation of Biotechnology: https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

(5) Because this comprehensive regulatory framework uses a mixture of existing federal law, some of the statutory nomenclature for certain actions may seem inconsistent; regardless of the nomenclature, the public should be aware that the reviews conducted by each of the regulatory agencies are intended to be of comparable rigor.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA-APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). Currently, these federal agencies are in the process of working with the Executive Office of the President to modernize a number of Coordinated Framework issues and activities; this effort is distinct from and compatible with APHIS' effort to revise its biotechnology regulations at 7 CFR part 340.

1.7.1.1 USDA-APHIS

USDA-APHIS regulations at 7 CFR part 340 were promulgated before enactment of the PPA of 2000 (7 U.S.C. 7701–7772) under the authorities of the FPPA and the PQA. These statutes, which were intended to protect the health and value of American agriculture by preventing or mitigating plant health risks, were superseded by the PPA in 2000. Therefore, APHIS currently regulates the importation, interstate movement, and environmental release of certain GE organisms under the authorities of the PPA. A GE organism is considered to be a regulated article if it is genetically engineered and the donor organism, recipient organism, vector, or vector agent used in engineering the organism is a plant pest or if the Administrator has reason to believe the GE organism is a plant pest.

A person may petition the Agency for a determination that a GE organism is non-regulated under 7 CFR part 340. Under 7 CFR § 340.6(c)(4), a petitioner is required to provide information related to the plant pest risk of the article that is the subject of the petition. The Agency may then use the information to determine whether the regulated article is unlikely to present a plant pest risk greater than that of the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk and issues a determination of non-regulated status.

1.7.1.2 EPA

The EPA regulates the sale, distribution, and uses of pesticides, including genetically engineered pesticides, under the authorities of the Federal Food Drug and Cosmetic Act (FFDCA) (21 U.S.C. §301 et seq.) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, et seq.), as amended by the Food Quality Protection Act (FQPA) of 1996 (H.R.1627). FIFRA and the FFDCA require the EPA to carefully evaluate any pesticide intended for use on human or animal food crops before making a registration decision.

FIFRA requires all pesticides sold or distributed in the United States (including imported pesticides) to be registered by EPA. Pesticides that pass EPA's evaluation under FIFRA are granted a license or "registration" that permits their sale and use according to the

requirements set by EPA to protect human health and the environment. Prior to registration for use the EPA must determine, via science based risk assessments, that the pesticide will not have unreasonable adverse effects on humans, the environment, or non-target species if it is applied in accordance with the proposed use. After a pesticide is registered, the only legal uses of a pesticide are those described on the EPA-approved label. One of the purposes of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment.

The EPA regulates pesticides that are expressed by GE organisms, termed plant incorporated protectants (PIP), under FIFRA. GE crops grown for seed production or direct sales must have a FIFRA Section 3 registration with the EPA if they contain a PIP. Before issuing a PIP registration, the EPA assesses the potential risks of PIPs produced by GE organisms. The EPA requires extensive studies to evaluate risks to human health, non-target organisms, and the environment. For new PIPs that have not been registered with the EPA, individuals must obtain an experimental use permit (EUP) from the EPA before planting any crop containing a PIP if the total area planted exceeds ten acres. While PIPs fall under the regulatory oversight of the EPA, APHIS currently exercises regulatory oversight of all PIP plantings on under 10 acres of land since jurisdictions currently overlap; this includes plant genetically engineered to produce pharmaceutical or industrial products (PMPIs).

The EPA also regulates certain biological control organisms, which have been genetically engineered for pest and disease control, under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53, et seq.).

The FFDCA requires EPA to set tolerances, or exemptions from tolerances, for the allowable residues of pesticides that are applied to human and animal food. The FQPA significantly strengthened the safety criteria in the FFDCA. In setting a tolerance, the EPA must find, based on evaluation of health and safety information, that there is a "reasonable certainty of no harm" from exposure to the pesticide residues. EPA may also exempt pesticides from the tolerance requirement in cases where such exemptions are found to meet the same standard of reasonable certainty of no harm. Tolerance limits include strong provisions for protecting infants and children, as well as other sensitive subpopulations. Several factors are considered in establishing tolerance limits, these include:

- the aggregate, non-occupational exposure from the pesticide (exposure through diet and drinking water and from using pesticides in and around the home);
- the cumulative effects from exposure to pesticides that have a common mechanism of toxicity, that is, two or more pesticide chemicals or other substances that cause a common toxic effect(s) by the same, or essentially the same, sequence of major biochemical events (i.e., interpreted as mode of action);
- whether there is increased susceptibility to infants and children, or other sensitive subpopulations, from exposure to the pesticide; and
- whether the pesticide produces an effect in humans similar to an effect produced by a naturally-occurring estrogen or produces other endocrine-disruption effects.

1.7.1.3 FDA

The FDA is responsible for ensuring the safety of all plant-derived foods,[18] including those products developed using genetic engineering. The FDA regulates food safety under the authority of the FFDCA (21 U.S.C. 301, et seq.). Human and animal food derived from GE plants must meet the same food safety requirements as foods derived from traditionally bred plants. To help ensure that firms are meeting their obligation to market only safe and lawful foods, the FDA encourages developers of GE plants to consult with the agency before marketing their products.

The FDA created the voluntary plant biotechnology consultation process in the 1990's to cooperatively work with GE plant developers to help them ensure foods made from their new GE plant varieties are safe. In this program, the crop developer explains to the FDA the steps they have taken to ensure the safety of food derived from the new GE crop plant before it enters the market. The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived using genetic engineering, in the Federal Register on May 29, 1992.[19] Under this policy, the FDA implements a voluntary consultation process to ensure that human and animal food safety issues or other regulatory issues are resolved before commercial distribution of food derived from GE plants. This voluntary consultation process provides a way for developers to receive feedback from the FDA related to complying with their obligations under federal food safety laws prior to marketing. The FDA encourages participation in a voluntary consultation process to help producers of food derived from GE crops comply with FDA regulations. Producers who use this process provide data and information to the FDA summarizing the basis for a conclusion that food derived from GE plants is as safe as comparable foods derived from non-GE plants.

In June 2006, the FDA issued *Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use* (US-FDA 2006). The guidance describes procedures for the early food safety evaluation of new non-pesticidal proteins produced by new plant varieties, including for example proteins produced in bioengineered plants, and fosters early communication by encouraging developers to submit to the FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any inadvertent introduction into the food supply of material from that plant variety.

The FDA recommends that sponsors and developers of new plant varieties intended for food use consult with the FDA about their evaluation of the food safety of any new proteins produced in these plants prior to the stage of development where the new proteins might inadvertently enter the food supply. Thus, the safety evaluation recommended by this guidance is termed an "early" food safety evaluation of new proteins. If a protein has been evaluated in an early food safety evaluation and no safety concerns are identified, FDA

[18] Under the Federal Food, Drug, and Cosmetic Act, food is defined as "food or drink for man or other animals."

[19] FDA: Statement of Policy - Foods Derived from New Plant Varieties; http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm

would not expect an additional early food safety evaluation to be submitted if the same protein is introduced into another plant species.

Submission of an early food safety evaluation for a new protein is not meant to substitute for a biotechnology consultation with FDA about a food derived from a new bioengineered plant variety. If a developer decides to commercialize a new bioengineered plant variety, the FDA expects that the developer will participate in the consultation process. However, a developer may use the information developed for the early food safety evaluation of a new protein in the biotechnology consultation process.

1.8 NEPA Analysis of Proposed Revisions to 7 CFR part 340

APHIS has prepared this draft programmatic environmental impact statement (dPEIS) pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. §4321 et seq.), APHIS NEPA implementing procedures (7 CFR part 372), and Council on Environmental Quality (CEQ) NEPA implementing regulations (40 CFR parts 1500-1508) to help inform Agency decision making. As identified by CEQ,[20] major federal actions for which programmatic NEPA analyses may be required tend to fall within the following categories:

1. Adoption of official policy or regulations that will result in, or substantially alter, Agency programs and regulatory processes.

2. Adoption of formal plans described in documents prepared or approved by federal agencies that guide or prescribe future Agency actions and use of federal resources.

3. Adoption of formal programs that support the implementation of a specific policy or plan.

4. Approval and implementation of specific projects, such as construction or management actions that can occur locally, regionally, or nationally. Project level actions include those that are approved by permit, or other regulatory decision-making processes, as well as federally assisted or funded activities.

CEQ recommends agencies give particular consideration to preparing a PEIS when initiating or revising national or regional rulemaking, such as the proposed revisions to 7 CFR part 340 regulations. Consequently, APHIS has prepared this dPEIS to evaluate the potential effects of the proposed rule and Alternatives (discussed in Chapter 2) on the “human environment”. Per CEQ regulations (40 CFR 1508.14) "human environment" means the relationships among people, to include economic and social considerations, and the natural and physical environment.

Because 7 CFR part 340 largely concerns U.S agricultural interests, which include international trade, the scope of analysis in this dPEIS encompasses a broad geographic and temporal scale. This is necessary to clarify and sufficiently communicate the range of

[20] CEQ - Final Guidance for Effective Use of Programmatic NEPA Reviews: https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/programmatic-reviews:

possible effects on the human environment that may follow revisions to 7 CFR part 340 regulations, and meaningfully inform the Agency, public, and decision-making process. Future project level, site specific impacts that could derive from decisions made under authority of 7 CFR part 340 will be examined in subsequent NEPA analyses on a case-by-case basis, and may be tiered from this dPEIS, as appropriate.

1.8.1 Public Involvement

Public scoping for an EIS is required under NEPA regulations (40 CFR §1501.7 - Scoping). Subject matter considered in this dPEIS was in part identified in a scoping process during which government agencies, the public, and other stakeholders were invited to submit comments. Scoping began on February 5, 2016, when APHIS published its notice of intent (NOI) to prepare a dPEIS in the Federal Register.[21] The NOI solicited public comment to help define the issues to be considered in the PEIS and scope of Alternatives; Alternatives to consider in revision of 7 CFR part 340 regulations. A summary of the Alternatives evaluated in this dPEIS is provided below, and further details discussed in Chapter 2:

Alternative 1 – No Action: No revisions to the existing 7 CFR part 340 regulations would be made. APHIS would continue oversight of GE organisms that may pose a plant pest risk under the current regulatory framework.

Alternative 2 – Preferred Alternative (Proposed Rule): Revise 7 CFR part 340 to incorporate the noxious weed authority provided to APHIS in the PPA; eliminate the notification process and authorize the interstate movement, importation, and environmental release of GE organisms only under permit; and institute an upfront risk assessment process to evaluate potential plant pest and/or noxious weed risks first, exercising permitting authority only if these assessments indicate that a GE organism poses a plant pest or noxious weed risk.

Alternative 3 – Comprehensive Regulation: Incorporate noxious weed authority and establish regulation to mitigate the potential economic impacts of GE crop plants on non-GE crop producers and markets.

The initial comment period lasted until March 7, 2016. The comment period was extended until April 21, 2016, at the request of some commenters for extension of the comment period.[22] At the close of this comment period APHIS had received 126 submissions from the public including two petitions with 11,693 and 20,271 signatures, respectively, and a collection of 9,644 form letters. Comments received were from individuals from academic organizations (14), professional organizations (5), trade groups (33), industry (11), non-governmental organizations (20), and unspecified individuals (42). Many commenters requested that APHIS analyze certain topics in the dPEIS, summarized below:

- terms and definitions used in the regulation of GE organisms
- use of noxious weed authority

[21] 81 Federal Register, No. 24 (February 5, 2016), pp.6225-6229: Available at https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02211.pdf

[22] NOI Docket ID: APHIS-2014-0054: Environmental Impact Statements; Availability, etc.: Introduction of the Products of Biotechnology; https://www.regulations.gov/#!documentDetail;D=APHIS-2014-0054-0029

- plant pest and noxious weed risk assessment process
- regulatory triggers
- exceptions and exemptions
- elimination of notifications and petitions for non-regulated status
- communication and transparency
- NEPA implementation

Relevant issues raised through the scoping process were incorporated into the formulation of the regulatory alternatives and environmental concerns evaluated in this dPEIS. A summary of stakeholder meetings and public outreach is provided in Appendix 1, and summary of the public comments on the NOI in Appendix 2. Public comments on the NOI are available online at www.regulations.gov (Docket ID: APHIS-2014-0054).

2 Proposed Program Alternatives

APHIS is considering three Alternative regulatory approaches in revision of 7 CFR part 340. The Alternatives considered were developed to address the purpose and need, described in Chapter 1, and Council on Environmental Quality (CEQ) regulations at 40 CFR part 1502.14 - Alternatives Including the Proposed Action. CEQ requires agencies to evaluate a range of reasonable alternatives when considering a proposed action, such as revision of agency regulations. Agencies are to rigorously explore and objectively evaluate all reasonable alternatives to a proposed action, and for alternatives that were considered but eliminated from detailed evaluation, briefly discuss the reasons for their elimination.

Described below are the Alternatives, or regulatory frameworks, that APHIS is evaluating. The potential impacts of these Alternative on the human environment is discussed in Chapters 3 through 7. APHIS will use this dPEIS, and public comments on the analyses discussed, to inform its decision on which of the Alternatives best fulfills the purpose and need for revision of 7 CFR part 340.

2.1 Program Alternative 1: No Action

APHIS is considering a No Action Alternative pursuant to CEQ regulations at 40 CFR part 1502.14. For this dPEIS, "no action" means there would be no revision to current 7 CFR part 340 regulations and "no change" in the direction or level of intensity of APHIS' current regulatory actions. Hence, the No Action Alternative is to forego revisions to 7 CFR part 340 and continue APHIS' current regulatory program. In this sense, the No Action Alternative serves as a baseline to which the other alternative regulatory frameworks can be compared in respect to the potential impacts of regulatory actions on the human environment.

2.1.1 Overview

Currently, 7 CFR part 340 requires APHIS authorization for the importation, interstate movement, or environmental release of GE organisms that are regulated articles. Before taking any action, an applicant must receive acknowledgement of a notification by APHIS in accordance with 7 CFR §340.3, or obtain a permit in accordance with 7 CFR §340.4. Applicants requesting authorization under the notification or permit process must submit a plan for each importation, interstate movement, or environmental release of a regulated GE organism to APHIS (USDA-APHIS 2011, USDA-APHIS 2012). APHIS evaluates the adequacy of confinement practices the applicant plans to use to ensure that a regulated article will not escape and persist in the environment, when it is imported, moved or released for field testing. Under the No Action Alternative, APHIS would continue to authorize the importation, interstate movement, and environmental release of certain GE organisms using the current notification and permitting procedures (USDA-APHIS 2011, USDA-APHIS 2012), and use the petition process to evaluate the regulatory status of GE organisms that were previously determined to be regulated articles under 7 CFR part 340. APHIS would also continue to conditionally exempt certain GE organisms from permit requirements for

interstate movement and would retain the prescriptive container, labeling, and identity standards in 7 CFR part 340.

2.1.2 Regulatory Scope

Under the current regulations, a GE organism is regulated by APHIS if it meets the definition of a regulated article (7 CFR part 340.1). A regulated article is:

> Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

Hence, a GE organism is considered to be a regulated article if the donor organism, recipient organism, vector, or vector agent is a plant pest, or if APHIS has reason to believe the GE organism is a plant pest. Current regulations define a plant pest as "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."

Current regulations provide for a petition process (§ 340.6), which allows individuals to request that APHIS consider non-regulated status of GE organisms that were previously determined by the Agency to be regulated articles. A petitioner is required to present detailed information and scientific data regarding the regulated article indicating why the article should no longer be regulated. Notification, permitting, and petition processes are described in further detail below.

As of December 2016, APHIS has determined non-regulated status in response to 125 petitions and extension requests, out of 159 petitions received. All of these determinations have been for GE plants, and the vast majority for crop plants. APHIS determinations of non-regulated status apply to the GE plant(s) as well as their progeny, meaning the deregulated GE plant can be used in plant breeding programs and in agriculture without further oversight from APHIS. APHIS maintains a publically available list of petitions and determinations of non-regulated status on its website.[23]

While the majority of GE organisms APHIS has regulated, and currently regulates, are plants, APHIS may also regulate invertebrate and microbial species that are, or are believed

[23] USDA-APHIS-BRS: Petitions for Determination of Non-regulated Status; https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml

to be, plant pests (e.g., insects and nematodes; protozoa; bacteria; fungi; and viruses). GE microbial species may be engineered for use as microbial pesticides, and regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Specifically excluded from the scope of current regulations are GE microorganisms where the recipient microorganism is not a plant pest, and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions. Also excluded is nonviable material derived from GE organisms.

APHIS currently provides an "Am I Regulated" consultative procedure where individuals can inquire with APHIS as to whether a GE organism is regulated under 7 CFR part 340.[24] Biotechnology developers may consult with APHIS on whether the organisms they are developing may be regulated articles under 7 CFR part 340, prior to any regulated activity, i.e., importation, interstate movement of release into the environment. If a developer is unsure whether a GE organism meets the definition of a regulated article, as described in 7 CFR part 340, they may, and commonly do, seek a review from APHIS by sending a signed letter of inquiry to APHIS (Regulated Article Letter of Inquiry Submission Process) with sufficient details to describe the modifications to the organism, how it was transformed and the intended activity. APHIS informs the inquirer of the regulatory status of the GE organism, and posts the inquiry letter and the Agency response on the APHIS website.

APHIS also provides assistance to organizations involved in GE research and development, including small businesses and academic researchers, to facilitate compliance with regulations governing the import, interstate movement, and field release of GE organisms. Compliance assistance is provided to the regulated community through Agency actions to assist developers and other entities develop or maintain their quality management systems. The Agency has implemented a Biotechnology Quality Management System (BQMS) Program to provide this form of assistance.

2.1.3 Authorization of Imports, Interstate Movements, and Environmental Releases

Under current regulations, the importation, interstate movement, and environmental release of regulated GE organisms may be authorized under permit, but only certain plants may be eligible for authorization through notification, which is a streamlined permitting process.[25] Currently, the majority of authorizations are done under notification (~ 90%). Examples of GE organisms introduced under the notification procedure are certain GE crop plants developed to be resistant to insects or herbicides.

[24] USDA-APHIS-BRS: Am I Regulated (AIR) Under 7 CFR part 340? Referred to as the AIR process; https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

[25] USDA-APHIS-BRS: Permits, Notifications, and Petitions; https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions

Actions taken by APHIS on permits and notifications are reviewed for compliance with NEPA, as required, and typically authorized under a categorical exclusion,[26] consistent with APHIS' NEPA implementation regulations (7 CFR part 372). This process complies with Council on Environmental Quality (CEQ) and USDA regulations for implementing NEPA.[27]

Notification

The notification process was added to APHIS' practices in 1993 and modified in 1997. The rationale for notification was to simplify the application process and increase the efficiency with which APHIS evaluates certain GE plants. It is not applicable to non-plant organisms. Most regulated GE plants meet eligibility criteria required to qualify for evaluation under the notification process (USDA-APHIS 2011). Under the notification procedure, applicants must provide information about the GE plant and its introduction into the environment sufficient for APHIS to evaluate eligibility for the notification process. The eligibility criteria for notification are described in 7 CFR part 340.3(b). Over the past decade, APHIS has authorized between 700 and 1,500 notifications per year for importations, movements, and environmental releases. Listed below are the eligibility criteria for notification, which are described in 7 CFR part 340.3(b):

- The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Plant Protection Act (7 U.S.C. 7712), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.
- The introduced genetic material is "stably integrated" in the plant genome, as defined in §340.1.
- The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease.
- The introduced genetic material does not:
  - Cause the production of an infectious entity, or
  - Encode substances that are known or likely to be toxic to non-target organisms known or likely to feed or live on the plant species, or
  - Encode products intended for pharmaceutical or industrial use.
- To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be:
  - Noncoding regulatory sequences of known function, or
  - Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

[26] See 7 CFR 372.5(c) for more information about the APHIS categorical exclusion process.

[27] CEQ regulations for implementing NEPA at 40 CFR 1500); USDA regulations implementing NEPA at 7 CFR part 1b; and APHIS regulations at 7 CFR part 372.

- The plant has not been modified to contain the following genetic material from animal or human pathogens:
  - Any nucleic acid sequence derived from an animal or human virus, or
  - Coding sequences whose products are known or likely causal agents of disease in animals or humans.

The notification procedure uses performance-based standards that are described in 7 CFR part 340.3(c). The use of the performance-based standards that do not vary from one notification to the next facilitates rapid administrative turnaround on notifications. In addition to meeting these eligibility criteria to qualify for the notification process, applicants must also ensure that six performance standards are met for any introduction of a GE plant. The six performance standards described in 7 CFR part 340.3(c) are:

- If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.
- When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release.
- The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.
- There must be no viable vector agent associated with the regulated article.
- The field trial must be conducted such that:
  - The regulated article will not persist in the environment, and
  - No offspring can be produced that could persist in the environment.
- Upon termination of the field test:
  - No viable material shall remain which is likely to volunteer in subsequent seasons, or
  - Volunteers shall be managed to prevent persistence in the environment.

APHIS reviews notifications to verify that the GE plants meet the eligibility criteria, and evaluates whether the proposed importation, interstate movement, or environmental release can be done in a manner that meets the required performance standards described in the regulation. In many ways, the criteria for review and approval of notifications are similar to those for permit applications, although the notification procedure relies on applicants agreeing to meet the performance-based standards described in the regulations, rather than submitting an application for APHIS review describing the specific measures they will employ for the activity (as is the case for permits).

Under the notification procedure, applicants provide APHIS with information about the GE plant, and the activities to be conducted during the importation, interstate movement, or environmental release sufficient for APHIS to evaluate eligibility for the notification procedure and any potential impacts on plant health and the environment that could result

from authorization of the requested activity. This information includes, among other things, information on the plant species, introduced gene(s), location(s), and anticipated timeframe and duration of the activity.

When APHIS receives a notification application, it is reviewed by APHIS for completeness to verify that the GE organisms proposed for introduction meet the eligibility criteria for a notification and that performance standards can be met. If APHIS completes the review process and finds that all regulatory requirements have been met, the notification is authorized in a process termed "acknowledgement," and the applicant may proceed with the proposed introduction under the terms of the notification as prescribed in 7 CFR §340.3. APHIS acknowledgements of notifications are effective for 1-year terms that begin on the date of introduction/release (7 CFR § 340.3(e)(4)).

As specified in § 340.3(e), APHIS must complete its notification review process within 30 days of receipt for environmental releases and importations, and within 10 days for the interstate movements of a regulated article.

In APHIS' experience, most notifications are for GE organisms which are unlikely to pose a plant pest or noxious weed risk. Under the proposed rule, notifications would be eliminated. It is expected that most of these GE organisms would no longer require APHIS authorization for interstate movement, importation, or environmental release and the remainder would require authorization under the permitting system. A key goal of the proposed regulation is to reduce regulatory burden where it is not warranted thereby freeing up resources to focus more oversight where plant pest and noxious weed risks may occur.

Permitting

If a regulated article does not meet the eligibility criteria for notification, a more stringent APHIS permit is required (7 CFR § 340.4). For organisms that present a risk of establishment or persistence in the environment (e.g., are related to wild or weedy plants, insects, or microorganisms), a permit is required so that APHIS can specify appropriate conditions for confinement and monitoring (USDA-APHIS 2012). The current regulations specify the amount of time that APHIS is allotted for review of complete permit applications: 60 days for importation and interstate movement, and 120 days for environmental release. Approximately 10% of APHIS' authorizations are done under the permitting procedure.

In addition to the information required for notification, permit applicants must describe how developers of GE organisms will perform field testing, including specific measures to keep the GE organism confined to the authorized field site and measures to ensure that it does not persist after completion of the field test. The permitting provisions found in § 340.4 describe the information required for permit applications, the standard permit conditions, and administrative information (e.g., timeframes, appeal procedure, etc.).

For an environmental release, permit applicants must provide APHIS with details about the introduced genetic material, gene products, biology of the organism, its origin, its intended use, and procedures for field production and isolation. For movement or importation permits, applicants must also disclose the destination, mode of transportation, and safeguards that will be used to prevent escape. For importation, an application is required for each individual

shipment. APHIS uses the information provided by the applicants and from other sources to establish permit conditions to ensure confinement when a GE organism is imported into, moved within, or released into the environment of the United States. Failure to comply with permit conditions may invalidate a permit and incur enforcement actions and penalties.

Standard permit conditions are listed in the regulation, and APHIS can supplement these with additional conditions or requirements, as necessary. Specific conditions designed to minimize risks associated with a regulated GE organism and its introduction are included as a part of a permit. Permit conditions are more restrictive than performance standards for releases made under notifications, so APHIS has greater compliance oversight of releases made under permits. Permits are valid for one or multiple years from the date of issue, depending on the type of organism and the nature of the request.

Current regulations at § 340.4(h) also provide APHIS with the ability to issue courtesy permits in order to facilitate the movement of GE organisms that are not subject to the regulations in 7 CFR part 340, but whose movement might otherwise be hindered because of their similarity to organisms or articles that are regulated by other APHIS programs. For example, fruit flies (*Drosophila* spp.), which are commonly used in research.[28]

2.1.3.1 Importation and Interstate Movement

The current regulations (§§ 340.7 and 340.8) include various provisions and prescribed standards for containers, marking, and identity that apply to shipments of regulated articles. For example, there are instructions regarding how to label containers of imported regulated articles with the nature of the contents, origin and destination, and other information, as well as detailed instructions on which materials (plastic, metal, etc.) and dimensions may be used for containers of regulated articles. The current program has no special provisions for review of the importation of low-risk GE commodities intended for human and animal food, or food processing; these types of GE commodities can only be authorized for importation either under permit (§ 340.4) or via determinations of non-regulated status (§ 340.6).

2.1.3.2 Environmental Release

Field tests are standard practice in research and development of plant varieties, including GE plants. Field releases authorized under the current APHIS permit or notification procedures have been conducted by industry, academia, and government, and have taken place throughout the United States and its territories. To date, APHIS has issued more than 18,400 permits and notifications for field testing of GE organisms (the vast majority plants). Notification performance standards, and permit conditions as prescribed, are designed to limit regulated GE organisms to the field test site, and preclude persistence of the GE organism beyond termination of the field test. The person who is authorized for environmental release of a GE organism must comply with notification and permit requirements, and any supplemental conditions APHIS may impose on the authorization.

[28] USDA-APHIS: Fruit Flies; https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/pests-and-diseases/fruit-flies

2.1.4 Compliance, Enforcement, and Remediation

APHIS has the responsibility to establish and enforce regulations that protect American agriculture, the food supply, and the environment while allowing for the safe field testing, importation, and movement of GE organisms that may pose a plant pest risk. APHIS determines the conditions under which GE organisms can be introduced under the permit procedure, and reviews design protocols for some GE plants to be introduced under notification. One goal of APHIS regulatory operations programs[29] is to ensure compliance with all relevant provisions of the regulations, including authorizations under the permitting and notification procedures. Failure to adhere to APHIS regulations and all permit conditions can result in serious penalties, including fines. Violators may also be held responsible for remediation costs. A summary of the major incidents of noncompliance with APHIS biotechnology regulations since 1995 to the present is located on the BRS Compliance and Inspections website.[30]

Current regulations describe the compliance and enforcement actions APHIS may take under the authority of the Plant Protection Act (PPA). APHIS inspectors and compliance specialists perform targeted and random inspections to identify and evaluate potential noncompliance incidents. All importations, movements, and environmental releases of regulated articles are subject to inspection by federal and/or State inspectors. APHIS evaluates field sites, facilities, equipment, records of developers, and potential incidents reported by permittees and others. Those authorized to import, move, or release into the environment a regulated article must promptly notify APHIS of any unusual events that occur (§ 340.4(f)(10)(i-ii)). Authorizations under the permitting and notification procedures require that noncompliance incidents be self-reported within designated timeframes. APHIS must be orally notified immediately upon discovery, and notified in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.

2.1.5 Determinations of Regulatory Status

Petition for Determination of Non-regulated Status

Under the current regulations, APHIS may issue a determination of non-regulated status to a GE organism in accordance with the petition procedure described in § 340.6. A GE organism within the scope of 7 CFR part 340 can be removed from regulatory oversight such that it is no longer subject to the regulations at this part if it can be demonstrated that it is unlikely to pose a plant pest risk. Regulations at 7 CFR § 340.6, "Petition for Determination of Non-regulated Status," provide that an individual can petition APHIS to evaluate submitted data demonstrating that a regulated article is unlikely to pose a plant pest risk, and should not be regulated. If APHIS concludes that it is unlikely to pose a plant pest risk, it makes a determination of non-regulated status allowing introduction of the article without regulatory oversight under 7 CFR part 340.

A petition must include data demonstrating that the GE organism is unlikely to pose a plant pest risk for APHIS to make a determination of non-regulated status. Required data include a

[29] See https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_program_overview/ct_about_prog_func

[30] See https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_compliance_and_inspections/ct_compliance_history

description of the biology of the organism before it was genetically engineered, a comparison of the GE organism and its non-GE counterpart, and reports from field trials previously approved under permit for a GE organism. Depending on the organism and the GE trait involved, the petitioner may also need to consult with the FDA, and/or require review with the EPA. To date, all APHIS' decisions related to the Agency's petition process for a determination of non-regulated status have been for GE organisms that are plants.

A determination of non-regulated status means that APHIS has determined that a GE organism is no longer subject to 7 CFR part 340 regulations. When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be imported, moved interstate, or released into the environment anywhere in the United States or its territories, subject to compliance with EPA, and other federal and state agency requirements, as applicable. The FDA recommends that sponsors and developers of new plant varieties intended for human or animal food use, including GE plants, consult with the FDA about the safety and composition of the GE plant prior to its introduction into the food supply. For determinations of non-regulated status, APHIS conducts a plant pest risk assessment (PPRA) and NEPA analyses as appropriate, either an environmental assessment (EA) or an EIS.

Prior to a determination of non-regulated status for a GE organism, APHIS prepares a NEPA analysis to assess the possible effects its decision on the quality of the human environment.[31] This assessment includes an evaluation of possible effects on plants, animals, and humans consistent with NEPA requirements. Possible effects on threatened and endangered (T&E) species are evaluated according to the requirements of the Endangered Species Act (ESA). APHIS makes a determination of non-regulated status when it concludes that a GE organism is unlikely to pose a plant pest risk. Current regulations provide that APHIS may approve a petition, in whole or in part, which has been interpreted to mean that the Agency may determine different regulatory statuses for multiple GE organisms in one petition, or that a single organism might differ with respect to regulatory status based on the specific activities or uses involving the organism. APHIS has approved only one petition in part, which was for a GE sugar beet variety. This was done in response to a court decision to vacate a previous APHIS determination of non-regulated status.

Petition for Extension of Determination of Non-regulated Status

The current regulations also provide for extensions of determinations of non-regulated status. Petitioners seeking non-regulated status for a GE organism that is similar to one or more organisms for which a decision of non-regulated status has been previously made by APHIS, may request an extension of non-regulated status under 7 CFR §340.6(e). Decisions related to extension requests are made based on an evaluation of the similarity of a regulated article to one or more antecedent organisms for which a determination of non-regulated status has been made by APHIS. If the organism is sufficiently similar to the antecedent with respect to plant pest risk, then non-regulated status is extended from the antecedent(s) to the organism that is the subject of the petition request. The extension of non-regulated status has been issued 21 times since the process was initiated. For extensions, APHIS conducts a plant pest

[31] Human environment includes the natural and physical environment and the relationship of people with that environment (40 CFR§ 1508.14).

risk similarity assessment (PPRSA), which is appended to the determination documentation and NEPA analyses.

As of December 2016, APHIS has made determinations of non-regulated status for 125 GE organisms, in response to 159 petitions and extension requests. All determinations have been for GE plants. Approximately 40% have been plants engineered for herbicide resistance, and 25% for insect resistance (ISB 2015, USDA-APHIS 2016a). Each regulatory determination for a GE plant applies not only to the original transformed organism and genotypes described in the petition, but also to progeny produced from them in crosses with other plant varieties not regulated under 7 CFR part 340. If APHIS makes a determination of non-regulated status under 7 CFR part 340, and subsequently discovers new information indicating that a GE organism may pose a plant pest risk, APHIS can revise its decision and reinstate regulatory authority over the GE organism, though the Agency has never exercised this option.

2.2 Program Alternative 2: Preferred Alternative – Implement Proposed Rule

Revise the regulations concerning the introduction of GE organisms to incorporate the noxious weed authority provided to APHIS by the PPA; revise the scope of organisms considered under the regulations, and potentially regulated; and institute a more efficient risk analysis process where potential plant pest and noxious weed risks are evaluated first, and movement (import, interstate movement, environmental release) of a GE organism is regulated when it is determined a potential risk to plant health exists.

2.2.1 Overview of the Proposed Regulatory Framework

The Preferred Alternative is to revise 7 CFR part 340 to provide for a more efficient risk-based process in the regulation of GE organisms that may pose a risk as a plant pest or noxious weed and adversely affect the health and value of American agriculture. As discussed in Section 1 – Overview, the proposed revisions seek to update the regulations in response to advances in genetic engineering; respond to recommendations made to APHIS by the USDA's Office of Inspector General (OIG) in their 2005 and 2015 audits, and the 2008 Farm Bill (Food, Conservation, and Energy Act of 2008); and incorporate noxious weed authority provided APHIS under the PPA.

The proposed revisions under the Preferred Alternative would eliminate the notification procedure requiring all movements of regulated GE organisms be conducted under APHIS permit, a change responsive to the OIG and Farm Bill recommendations. The proposed revisions would update the regulations by revising terms and definitions, and, in conjunction with implementation of noxious weed authority, would broaden the scope of GE organisms that could be evaluated and potentially regulated under 7 CFR part 340. While the scope of GE organisms that APHIS would evaluate for plant pest and noxious weed risk would be broadened, the revisions would focus and limit ultimate regulatory oversight to GE organisms that posed a risk as a plant pest or noxious weed. This will be further accomplished by excluding certain types of GE organisms from the need for regulatory review (discussed following), and instituting a more efficient science-based risk analysis process to distinguish those GE organisms that merit regulation from those that do not. GE organisms that are unlikely to pose a risk as a plant pest or noxious weed would not be regulated. The regulatory review will be conducted on the "front end" of research and

development activities before any permits are issued for the import, interstate movement, or environmental release of regulated GE organisms. In effect, APHIS will be regulating a broader variety of GE organisms, but requiring fewer permits, or rather, restricting permitting requirements to GE organisms that pose plant pest and noxious weed risks.

The following is a general overview for organisms that fall within the scope of the proposed definition for GE organism and regulated organism under proposed revisions to 7 CFR part 340.0.

Until anyone who wishes to import a GE organism, move it interstate, or release it into the environment, no action would be required of that person. If the person believes that they possesses sufficient information to demonstrate that the organism presents no plant pest or noxious weed risk, they could submit this information to APHIS and request that APHIS conduct an evaluation of such risk. The process for submitting such a request, as well as the possibilities for how APHIS would act on that request, would be described in proposed § 340.4.

If APHIS evaluates the GE organism in accordance with § 340.4 and determines that it is unlikely to pose a risk as a plant pest and/or noxious weed, it would no longer be a regulated organism and may be imported, moved interstate, or released into the environment without further restriction under the proposed regulations. APHIS would maintain a list of the GE organisms it has reviewed, and issued regulatory status determinations for, on a publically available website.

If APHIS determines the GE organism presents a plant pest or noxious weed risk, it will be classified a regulated organism. Anyone attempting to import, move interstate, or release into the environmental such a regulated organism will require a permit from APHIS for doing so. APHIS' proposed permitting process would be set forth in § 340.3.

If APHIS issues a permit for the importation, interstate movement, or release into the environment of the regulated organism, the individual would have to comply with permitting conditions regarding such importation, interstate movement, or release into the environment. The individual would also have to comply with container and shipment requirements that pertain to the movement of regulated organisms. These requirements would also be set forth in § 340.3.

The individual would have to retain certain records regarding any permitted activities, which would be set forth in proposed § 340.5. Failure to retain such records, or comply with other regulatory requirements or permitting conditions, could result in enforcement actions. These would also be set forth in § 340.5.

Finally, based on the terms and definitions that APHIS is proposing to add or remove from 7 CFR part 340, as well as the revised scope of the regulations, the Agency would revise the title of part 340 to "Movement of organisms altered or produced through genetic engineering that are noxious weeds or plant pests or that there is reason to believe are noxious weeds or plant pests."

2.2.2 APHIS Proposed Changes to 7 CFR part 340

2.2.2.1 Regulatory Scope

Under the current regulations and the PPA, most plants are not plant pests, with the exception of a few parasitic plant species such as mistletoe, striga, and dodder. Current 7 CFR part 340 regulations apply to GE organisms that are parasitic plants, microorganisms, insects, fungi, and viruses, and those created using organisms which are or contain plant pests, as listed in current § 340.2. However, GE organisms may be and are developed without plant pest genes or gene sequences. This is especially true for GE plants which represent most of the submissions to APHIS for evaluation. Such GE plant-trait combinations may present noxious weed risks that cannot be assessed by APHIS under the scope of current regulations, as these GE plant-trait combinations may not meet the definitions of plant pest under the PPA and current 7 CFR part 340. In addition, although a plant pest (e.g., *Agrobacterium tumefaciens*, Cauliflower Mosaic Virus) may contribute genes or gene sequences to a GE organism, these sequences have not been shown to render the GE organism, particularly a GE plant, a plant pest.

Under the Preferred Alternative, APHIS would broaden the scope of organisms that may be considered under 7 CFR part 340 by revising the definitions for "genetic engineering," "GE organism," and "regulated organism." The proposed revisions would specify the types of GE organisms (described below) APHIS would consider to be regulated organisms under the revised regulations. These definitions capture categories of GE organisms that are not captured by the current 7 CFR part 340. The revisions of terms and definitions (detailed below), in conjunction with incorporation of noxious weed authority, would broaden the range of GE organisms APHIS may evaluate and potentially regulate under part 340.

The proposed revisions would update the regulations to remove the limiting concept and criteria that a GE organism would be regulated if the donor, vector, or vector agent is a plant pest. The current criteria reflects the concern in the 1980s that if an organism was modified using genetic material from a plant pest, or a plant pest was used as a vector or vector agent to modify an organism's genome, the resulting GE organism could also be a plant pest. Genetic engineering of crop plants has commonly involved use of genetic material from organisms considered plant pests, such as the 35S promoter for Cauliflower Mosaic Virus (donor) and the disarmed version of the nopaline synthase (nos) terminator from *Agrobacterium tumefaciens* (vector). As a consequence, many GE organisms that are not plant pests have been, and are, regulated under 7 CFR part 340. Although plant pest sequences have frequently been used in the engineering of GE organisms, these sequences have not been shown to cause GE organisms to become plant pests. APHIS' has no evidence that the use of gene sequences from donor organisms which are plant pests, as well as the use of vectors containing sequences from plant pests, results in a GE organism that is itself a plant pest. Furthermore, the use of disarmed *Agrobacterium* for introducing the new DNA into the recipient organism has not resulted in any plant pest risks. Consequently, APHIS would no longer regulate a GE organism solely on the basis that the donor, vector, or vector agent was a plant pest.

Hence, the mere involvement of a plant pest as a donor, vector, or recipient in the genetic engineering process will no longer be the determining factor in APHIS's regulatory oversight

of GE organisms. Rather, a GE organism would be regulated based on the revised terms and definitions for "genetic engineering", "GE organism", and "regulated organism", and whether it presents a plant pest or noxious weed risk . This is a fundamental shift in APHIS' approach to regulation; under the Preferred Alternative, APHIS would regulate the products of genetic engineering, rather than the methods by which those products are developed. A regulated organism is any GE organism that:

- prior to genetic engineering, belonged to any taxon listed in accordance with § 340.2 and met the definition of a plant pest in § 340.1 (As § 340.2 currently does, proposed § 340.2 would specify that certain taxa are plant pests or are known to contain to plant pests. Section 340.1 would contain definitions of terms used in the proposed regulations.); or
- has received DNA from any taxon listed in accordance with § 340.2, the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, and the GE organism has not been evaluated by APHIS for plant pest risk in accordance with § 340.4; or
- is a plant that has a plant and trait combination that has not been evaluated by APHIS for plant pest and noxious weed risk in accordance with § 340.4; or
- is any of the foregoing that has been evaluated by APHIS in accordance with § 340.4 and determined to pose a risk as a plant pest or noxious weed, or is a GE organism that has otherwise been determined by the Administrator to pose a risk as a plant pest or noxious weed.

APHIS is aware that a novel GE organism could be developed that may not easily meet the criteria of the first three categories of regulated organisms. The last criteria provides that APHIS may regulate such an organism.

APHIS would also revise its regulatory status review and determination procedures. APHIS would conduct plant pest risk assessments (PPRA) and weed risk assessments (WRA) on its own accord, prior to issuance of permits, and in response to regulatory status requests from developers seeking evaluation of a GE organism's plant pest or noxious weed risk. The regulatory status of GE organisms for which PPRAs and WRAs have been conducted and regulatory determinations made would be listed on a regulatory status register, which would be available to the public on APHIS' website. The register would list GE organism-trait combinations that pose a plant pest and/or noxious weed risk, and those that do not.

The notification process would be eliminated and the importation, interstate movement, and environmental release of regulated organisms would be conducted solely under APHIS permit. As a result of implementation of the revised risk analysis and regulatory inquiry process described above, the petition process for determinations of non-regulated status, as it is currently understood, would be eliminated.

In effect, APHIS would be regulating a broader scope of GE organisms that posed potential plant pest and/or noxious weed risks, yet requiring permits only for those GE organisms that posed plant pest or noxious weed risks. For example, APHIS would not be requiring permits

for newly developed GE crop plants, or rather, the plant-trait combinations, that are the same as or similar to GE plant-trait combinations that are already commonly used in commercial production (i.e., Bt corn and cotton, and glufosinate resistant corn and canola). Hence, the purpose of regulations under the Preferred Alternative is to broaden the scope of GE organisms that APHIS could evaluate under the regulations, while focusing and limiting ultimate regulatory oversight to GE organisms that, based on scientific analyses, were determined to pose a risk as a plant pest or noxious weed.

When APHIS determines that a GE organism is unlikely to pose a plant pest and/or noxious weed risk, it could be moved or introduced into the environment without APHIS oversight, subject to EPA regulations and requirements, the FDA's voluntary consultation for human and animal foods derived from GE crop plants, as well as all other federal, state, and county requirements, as applicable.

2.2.2.2 Incorporation of Noxious Weed Authority

Incorporating the noxious weed authority provided to APHIS under the PPA into 7 CFR part 340 would clearly define and broaden the spectrum of potential risks that APHIS could consider under regulations, and provide APHIS with an additional regulatory means to address those resources protected under the noxious weed authority of the PPA. Any GE organism that meets the definition of noxious weed (defined in section 2.2.2.4 below) would be subject to APHIS review, regulation, and permitting requirements for interstate movement, import, or environmental release.

APHIS would evaluate a GE plant as a potential noxious weed under the proposed regulations in the following manner. APHIS would begin by evaluating whether the plant, in its unmodified state, has weedy characteristics, that is, a plant biologically capable of causing notable physical injury or damage. This would serve as the baseline against which to evaluate the genotype of the GE plant. In evaluating the GE plant, APHIS would assess the likelihood that the modifications made to the genome of the plant alter its ability to cause notable physical harm or injury.

For GE plants that APHIS determines to be weedy prior to genetic modification, APHIS would endeavor to determine whether the plant's weediness has been enhanced to an extent that it has been engineered into a noxious weed. For GE plants that APHIS determines not to possess weedy traits prior to modification, APHIS would endeavor to determine whether weediness had been introduced into the organism through genetic engineering. Finally, in the event that a federal noxious weed is genetically engineered (something that has not occurred to date), APHIS would endeavor to determine whether the GE plant is still a noxious weed and warrants continued regulation.

If APHIS determines that the GE plant is a noxious weed, it would endeavor to gauge the direct or indirect injury or damage it could cause to crops, livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment. APHIS would make the results of this evaluation publicly available and share both the evaluation and the information on which it is based with the EPA and FDA, as warranted.

2.2.2.3 Amendment of Terms and Definitions

APHIS would amend terms and definitions relevant to the regulation of GE organisms under 7 CFR part 340. APHIS proposes to revise some of the definitions, to add new definitions, retain certain definitions currently found in § 340.1 of the regulations, and to remove definitions that would no longer be relevant.

2.2.2.3.1 APHIS is proposing to change the following terms and definitions from those in the current regulations

(a) **Genetic engineering:** Techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome. Genetic engineering does not include traditional breeding techniques (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion) or chemical or radiation-based mutagenesis.

(b) **Inspector:** Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

(c) **Interstate:** From one state into or through any other state or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

(d) **Move (moving, movement):** To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.

(e) **Permit**: A written authorization, including by electronic methods, by the Administrator to move regulated organisms and associated articles under conditions prescribed by the Administrator.

(f) **Plant:** Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed.

(g) **Plant pest:** Any living stage of a protozoan, invertebrate nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

(h) **Recipient organism:** The organism whose nucleic acid sequence will be altered through the use of genetic engineering.

(i) **Release into the environment (environmental release):** The use of a regulated organism outside the physical constraints in a contained facility.

(j) **Responsible person:** The person who has control and will maintain control over a regulated organism during its movement and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. A responsible person must be at least 18 years of age and be a legal resident of the United States.

(k) **State:** Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, the Virgin Islands of the United States, or other Territories or possessions of the United States.

(l) **State or Tribal regulatory official:** State or Tribal official with responsibilities for plant health, or any other duly designated State or Tribal official, in the state or on the Tribal lands where the importation, interstate movement, or environmental release is to take place.

2.2.2.3.2 APHIS proposes to add the following new terms and definitions

(a) **Agent:** A person who is authorized to act on behalf of the responsible person to maintain control over a regulated organism during its movement and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States.

(b) **Contained facility:** A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the enclosed organisms. Examples include laboratories, growth chambers, fermenters, and containment greenhouses.

(c) **Genetically engineered organism (GE organism):**[32] An organism developed using genetic engineering. For the purposes of regulation, an organism would not be considered a genetically engineered organism if: (1) the genetic modification to the organism is solely a deletion of any size or a single base pair substitution which could otherwise be obtained through the use of chemical- or radiation-based mutagenesis; or (2) the genetic modification to the organism is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion); or (3) the organism is a "null segregant," that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient

[32] APHIS wishes to point out that its proposed definition for "genetically engineered organism" is limited to the regulations in 7 CFR part 340 and may not reflect the definition of genetically engineered organism that is in use by other Federal Agencies. The reason for this is that differences in regulatory scope, statutory authority, and potential risks have necessitated the collection of different data and terminology between Agencies.

organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

(d) **Import (importation):** To move into, or the act of movement into, the territorial limits of the United States.

(e) **Interstate movement:** To move interstate.

(f) **Noxious weed:** Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

(g) **Nucleic acid:** A chain or chains of nucleotides found in either DNA or RNA.

(h) **Plant pest risk assessment:** An assessment evaluating whether a GE organism is a plant pest.

(i) **Plant product:** Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of a plant or any manufactured or processed plant or plant part.

(j) **Regulated organism:** Any GE organism that is regulated pursuant to § 340.0.

(k) **Regulatory sequence:** A segment of a nucleic acid molecule that is capable of increasing or decreasing the expression of specific genes within an organism.

(l) **Secure shipment:** Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

(m) **Unauthorized release:** The intentional or accidental release of a regulated organism in a manner not authorized by a permit issued pursuant to 7 CFR part 340.

(n) **Weed risk assessment:** An assessment of the characteristics of a plant as these relate to weediness.

2.2.2.3.3 APHIS is proposing to retain the following terms and definitions in the current regulations, without change

Administrator, Animal and Plant Health Inspection Service (APHIS), donor organism, environment, organism, and person.

2.2.2.3.4 APHIS proposes to remove the following definitions from the regulations

Antecedent organism, courtesy permit, expression vector, introduce or introduction, product, regulated article, Secretary, stably integrated, vector or vector agent, and well-characterized and contains only non-coding regulatory regions. These definitions would be removed because the terms would no longer be used in the regulations. APHIS proposes to eliminate

the term "regulated article" partly because the use of the term "article" in current part 340 is not consistent with usage in the PPA. The term "regulated article" will be replace with "regulated organism".

2.2.2.4 Institute a More Efficient Risk Assessment Process for Determination of the Regulatory Status of GE Organisms

As previously discussed, the mere involvement of a plant pest in the genetic engineering process will no longer be the determining factor in APHIS's regulatory decision-making. Rather, GE organisms would be regulated as a plant pest or noxious weed based on a risk analysis that identifies such risks, the definitions for "genetic engineering," "GE organism," and "regulated organism," and those criteria described in the below subsections.

Under the Preferred Alternative, regulatory status determinations would be initiated in two ways: (1) APHIS would conduct a regulatory status determination on its own initiative, and (2) in response to requests for regulatory status determinations by developers or other individuals. In both instances, regulatory status determinations will be based on science-based risk assessments. These analyses would include a plant pest risk assessment (PPRA), a weed risk assessment (WRA), or both. Because the WRA system is new, APHIS is making the WRA system publicly available along with the proposed rule. To view the WRA system, go to http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule.

2.2.2.4.1 APHIS Risk Assessments and Regulatory Review

APHIS would proactively conduct plant pest risk assessments (PPRA) and weed risk assessments (WRA) on its own accord, absent of a regulatory status request described below, which would be used to determine whether a GE organism poses a risk as a plant pest or noxious weed, and should be regulated under 7 CFR part 340. APHIS would analyze plant pest and noxious weed risks first, and subsequently implement risk-appropriate regulatory controls over those GE organisms that are determined by APHIS to pose plant pest or noxious weed risks.

Once the risk analyses are completed by APHIS, the importation, interstate movement, or environmental release of GE organisms that were determined to pose plant pest or noxious weed risks, as documented and confirmed in the APHIS risk analysis, would be subject to APHIS permitting requirements. If APHIS determined that a GE organism is unlikely to pose a plant pest or noxious weed risk, that GE organism could be moved or introduced into the environment without APHIS oversight. However, it may still be subject to EPA requirements, as well as other applicable federal, state, and county requirements. For GE plants developed for food purposes, the developer would have the option to consult with the FDA for compliance with FSMA and FFDCA, as well as undergo early food safety evaluation with the FDA (US-FDA 2006).

All APHIS risk analyses and determinations of regulatory status would be published in the Federal Register for public review and comment (described below in 2.2.2.5.4). Proposed paragraph (c) of § 340.4 would describe the process for making evaluation of regulatory status available to the public.

If new information is obtained which indicates that a previously deregulated GE organism may present a plant pest and/or noxious weed risk, APHIS may reevaluate the GE organism and reconsider its regulatory decision.

2.2.2.4.2 Regulatory Status Evaluations (§ 340.4): Requests for Evaluation or Reevaluation

The current regulations in § 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. Under the Preferred Alternative the petition process would not be applicable, however, APHIS would provide a similar method of inquiry for individuals wishing to have the regulatory status of a GE organisms evaluated. The proposed revisions to § 340.4 would describe the process by which persons could request an initial evaluation or subsequent reevaluation of the regulatory status of a GE organism. The outcome of a regulatory status evaluation is a determination by the Agency that a GE organism is a non-regulated organism or a regulated organism subject to permitting.

Paragraph (a) of proposed § 340.4 would state that any person may submit a request to APHIS to have a GE organism's regulatory status evaluated, or to request the reevaluation of the regulatory status of a previously evaluated regulated organism. Regulations would describe the information that would have to be submitted with a regulatory status request in order for APHIS to evaluate the request (itemized below). Paragraph (b) would outline the actions the Administrator would take in response to a regulatory status request. If the request is complete, APHIS would conduct a risk analysis that includes an evidence-based, standardized approach to analyzing plant pest and/or noxious weed risks associated with the GE organism. APHIS envisions four types of inquiries from developers of GE organisms under the proposed revisions to regulations.

1. The first would be from developers of organisms that are uncertain of the regulatory status of their organism, but that consider it to either be outside the scope of regulated organisms or similar to an organism that APHIS has already evaluated and assigned non-regulated status. The developers would present what they consider to be the regulatory status of the organism, as well as the information on which the developers rely to support this consideration. In such instances, APHIS would review the information[7] and communicate to the developer whether the regulatory status that they presented to APHIS was accurate. This is substantially similar to the structure of APHIS' current "Am I regulated?" program.[8] That being said, because there would be some changes to that program based on the provisions of this proposed rule, if it is

[7] In evaluating the similarity between two GE plants, APHIS considers whether the mechanisms of action of the introduced traits are functionally equivalent. For example, one mechanism of action for resistance in plants to the herbicide glyphosate relies on an inability of glyphosate molecules to bind and inactivate an enzyme called EPSPS, which is responsible for an essential step in a biochemical pathway for the synthesis of certain amino acids. If glyphosate cannot bind to the EPSPS enzyme, the plant is resistant to the herbicide. APHIS has issued determinations of non-regulated status to two very similar types of GE plants which differed in the donor organism for the EPSPS genes: One version of the gene was derived from corn (mEPSPS) and the other from a strain of Agrobacterium (CP4 EPSPS). However, in both cases the added gene encodes an EPSPS protein which does not bind to glyphosate. Accordingly, these two glyphosate resistance traits have mechanisms of action which are functionally equivalent.

[8] See https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

finalized APHIS would make guidance available to aid developers in making such inquiries of APHIS.

2. The second type of inquiries that APHIS would expect to receive would come from developers of GE organisms that belonged to taxa that are listed in accordance with proposed § 340.2 prior to genetic engineering, or that have received DNA from such taxa during genetic engineering. The developers would provide information regarding the development of the GE organism, and would provide information regarding why they do, or do not consider, the GE organism to be a plant pest, or to have received DNA sufficient to produce an infectious entity or encode a pathogenesis-related compound that is expected to cause plant disease symptoms. Such requests would have to be made in accordance with proposed § 340.4.

3. The third category of inquiries would come from developers of GE plants that APHIS has not yet evaluated for plant pest and noxious weed risk and developers of other GE organisms, such as GE insects and other invertebrates, that were not plant pests prior to genetic engineering, but that APHIS has not yet evaluated for plant pest risk as GE organisms. These inquiries would request APHIS to evaluate the regulatory status of the GE organism. Such requests would also have to be made in accordance with proposed § 340.4.

4. The fourth category of inquiries would come from developers of GE organisms that APHIS have determined to be plant pests or noxious weeds, asking for a reevaluation of this determination. Such requests would have to be made in accordance with proposed § 340.4.

Requirements for Regulatory Status Evaluation Requests: The regulations would provide the necessary information that would be required to be submitted with a regulatory status request in order for APHIS to conduct its evaluation. Such information would include, among other information requirements:

1. A description of the recipient organism (including common name; genus, species, and any relevant subspecies information that would distinguish the organism; and, for microorganisms, the strain).

2. The genotype of the GE organism, including a detailed description of the differences in genotype between the organism subject to the request and the non-GE organism. If genetic material is inserted into the genome, the method of transformation would also have to be described and the following provided for each gene:

    a. For gene sequences, the name of the sequence, donor organism(s) or source, function of sequence, nucleic acid sequence, and publicly available sequence identification. If the genes have been modified, the nature of the modification and its purpose would have to be stated, and the request would have to identify and highlight the modifications by submitting an alignment of the modified sequence with the unmodified sequence. If the gene is not naturally occurring, the request would have to state whether the sequence is based on

that of a specific organism, and, if so, identify the organism and gene it was based on.

b. For regulatory sequences, the function of each regulatory sequence as it relates to the gene sequence and the source of each regulatory sequence. Promoters (sites on DNA to which the enzyme RNA polymerase can bind to initiate the transcription of DNA into RNA) would have to be identified as constitutive, inducible, developmental, or tissue-specific. If inducible, the inducer would have to be described. If developmental, stages at which the promoter is active would have to be described. If tissue-specific, the tissues in which the promoter is active would have to be described. The strength of the promoter would also have to be described. Finally, for microorganisms, descriptions of mobile genetic elements would also have to be included.

c. If the genome is edited, the following would also have to be provided: The nature of the edit(s) and the gene(s) and function(s) being modified, as well as what pathways are expected to be affected; for multiple substituted base pairs, the number of substitutions; the original unmodified sequence aligned to the modified sequence; and if the edits were created using genetic material which was integrated into the chromosome, but later eliminated through segregation, techniques used to confirm absence of the genetic material.

3. A detailed description of the intended phenotype(s) of the GE organism. This would include the purpose of the new phenotype and the mechanisms of action by which the intended phenotype is conferred; any new enzymes, other gene products, or expected changes in metabolism; if applicable, the protein accession number and the enzyme commission number; and the known and potential differences from the non-GE organism that would substantiate that the GE organism is unlikely to pose a greater noxious weed risk or plant pest risk than the non-GE organism from which it was derived.

4. For plants, any information that exists on known or likely changes that may affect any of the following would have to be provided: Weediness and plant pest characteristics of the plant; competitive growth ability; reproduction, spread, and persistence; stress tolerance, including a consideration of abiotic stresses such as cold and drought tolerance and biotic stresses such as herbivory (consumption of the plant) or diseases; and any other weediness or plant pest characteristics identified of the plant or other plants with which the plant can interbreed.

5. For non-plant, non-vertebrate organisms, any information that exists on known or likely differences to herbivory or virulence must be provided, including: Any observed or anticipated changes due to the genetic modification that might affect the ability of the organism to cause direct or indirect damage to plants; a description of any changes to known factors of pathogenesis and virulence factors such as polysaccharides (complex sugars consisting of multiple sugar molecules bonded together) and suppressors (genes that suppress expression of another gene); a

consideration of changes that might affect geographic distributions, host range, means of dissemination, horizontal gene transfer, reproductive cycle, and persistence; and a description of any characteristics introduced to mitigate harm to plants.

6. Any experimental data (including field tests) and publications that the developer believes might be relevant to APHIS's evaluation of the potential of the organism to affect plant health.

The current regulations require the petitioner to supply a detailed description of the genotype of the GE organism, but do not specify that a description of the gene sequences, regulatory sequences, or genome editing of the organism is required. Operationally, however, this information is helpful to conduct a substantive review of the genotype, and the revised regulations would reflect this operational need. With regard to the phenotype of the GE organism, APHIS requirements would also contain additional details that are considered necessary in order to evaluate the plant pest risk of microorganisms, insects, and other invertebrates. For GE plants, it would also include information that APHIS needs in order to prepare a weed risk assessment.

APHIS considers the categories of information specified above, which are drawn from current requirements for a petition for non-regulated status, to be sufficient to evaluate a GE organism and determine its appropriate regulatory status. That being said, APHIS is soliciting public comment on the adequacy of the above requirements, and whether additional or alternate requirements would be more appropriate.

2.2.2.4.3 Technical Evaluations

APHIS recognizes that many aspects of the proposed rule hinge on a determination by APHIS regarding the plant pest or noxious weed risk posed by a particular GE organism or class of GE organisms. Often, APHIS will be able to make a determination of plant pest or noxious weed risk based on its collective experience regulating genetic engineering and review of relevant scientific literature.

However, as genetic engineering evolves and new genetic engineering techniques are developed, APHIS may lack technical expertise to fully evaluate certain GE organisms or classes of GE organisms. This is particularly likely when new or emerging genetic engineering techniques are applied to recipient organisms that have not previously been subject to genetic engineering.

In such instances, APHIS may rely on researchers or other federal, state, tribal, or industry experts to provide information to help APHIS determine the organism's appropriate regulatory status. APHIS may solicit such information through a variety of means, including, but not limited to, working groups, workshops, peer review of documents (particularly risk analyses), or webinars.

2.2.2.4.4 Public Notices of Request for Evaluation of Regulatory Status

Public notices on regulatory inquiries, and all APHIS determinations of regulatory status, would be published in the Federal Register for public review and comment. APHIS would make both the request and the risk analyses available for public review. Proposed paragraph

(c) of § 340.4 would describe the process for making evaluation of regulatory status available to the public. The first notice would propose a regulatory status for the GE organism, and request public comment. If no comments are received on the notice, or if the comments do not affect the conclusions of the risk analysis or the proposed regulatory status of the organism, APHIS will provide notification through the APHIS stakeholder registry at the end of the comment period announcing that the proposed regulatory status has been finalized. APHIS will subsequently publish a notice in the Federal Register compiling these determinations. Alternatively, if comments lead APHIS to change its proposed regulatory status for the organism, APHIS will publish a subsequent notice in the Federal Register characterizing these comments and announcing the new regulatory status.

2.2.2.4.5 Regulatory Status Register

All regulatory status determinations made by APHIS will be listed and made publically available on a website. APHIS is making a draft list of such GE organisms available along with the proposed rule. APHIS encourages stakeholders to review this list and submit specific public comment regarding the listed plant/trait combinations.

For purposes of the proposed rule, the lists will be maintained at the following Web site: http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule. If the proposed rule is finalized, APHIS would use a different URL for maintenance of the regulatory status register, which will be publicly available.

2.2.2.5 Eliminate the Notification Procedure

The current option for authorization via notification provided for in 7 CFR § 340.3 would be eliminated. All authorizations for movement would be issued under permit. APHIS has determined that it would have a more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency if all regulated movements are authorized under the permitting procedure. Elimination of the notification procedure and singular use of the permitting procedure is respondent to the USDA OIG and Farm Bill recommendations.

2.2.2.6 Clarify APHIS Compliance and Enforcement Authorities under the PPA

APHIS is proposing to consolidate all record retention, compliance, and enforcement requirements, described the sections below, into a new 7 CFR § 340.5. APHIS is also proposing to strengthen its program in order to manage compliance with the regulations more efficiently, to augment the approaches used to prevent or remediate potential risks to plant health, and to utilize appropriate enforcement strategies. These proposed regulatory changes also reflect certain provisions of the 2008 Farm Bill and align with recommendations of the 2005 and 2015 OIG audits (USDA-OIG 2005, USDA-OIG 2015).

2.2.3 Authorization of Importation, Interstate Movements, and Environmental Releases

Permits: An APHIS permit would be required for the importation, interstate movement, or environmental release of all regulated organisms. An exception would be that a permit for interstate movement is not required for GE *Arabidopsis thaliana*, provided that such shipment meets APHIS requirements for exemption. Specific details on permitting on

provided in the proposed rule and the reader is referred to this document for a more in depth discussion. Provided below is an overview of proposed permitting requirements.

Paragraph (a)(3) of § 340.3 would state that, except as provided in paragraph (c) of § 340.3, a permit must be issued by APHIS for the importation, interstate movement, or release into the environment of all regulated organisms.

However, APHIS also envisions that there could be instances in which there would be an immediate need to import a regulated organism or move it interstate (but not for an environmental release), even though APHIS has not yet evaluated the risk it poses as a plant pest and/or noxious weed. This could occur when, for example, a developer consolidated research laboratories, and needed to move materials and supplies from one state to another. To allow for such instances, proposed paragraph (a)(2) of § 340.3 would provide that APHIS may issue a permit pursuant to the section for the importation or interstate movement of a regulated organism that has not been evaluated in accordance with § 340.4. For the purposes of permitting conditions, APHIS would assume that the regulated organism presents a risk as a plant pest and/or noxious weed. Accordingly, permitting conditions could be significantly more stringent for such unevaluated organisms than they would be for the same organisms, following evaluation in accordance with § 340.4. If the regulatory status of the organism is evaluated in accordance with § 340.4 during the duration of the permit, APHIS could amend the permit, or, if the organism is determined to pose no risk as a plant pest and/or noxious weed, terminate the permit and communicate this termination to the permittee. This considered, APHIS requests specific public comment on the provisions of paragraph (a)(2) of § 340.3.

Under the Preferred Alternative, courtesy permits would be eliminated as they are typically issued for organisms that are not regulated, by definition, to facilitate their movement through the ports of entry. The use of courtesy permits in the past led to the widespread misunderstanding by some researchers that they are actually required for the movement of certain organisms, or that issuance of a courtesy permit removes the requirement for applicants to follow all applicable regulations, including the plant pest regulations found in 7 CFR part 340. In an effort to alleviate confusion and to better focus and allocate APHIS' resources, APHIS is proposing to remove the regulations concerning courtesy permits.

Paragraph (b) of proposed § 340.3 would outline how to submit a permit application. Applicants would have to submit a permit application through a method listed at the Web address contained in the regulations; for purposes of this proposed rule, that address is http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule. That Web page specifies that permit applications must be submitted using APHIS' current electronic permitting system, ePermits, or the paper-based APHIS form 2000.

APHIS is proposing to list the methods for submitting a permit application on the Internet, rather than in the regulations, in order to make it easier to ensure they remain up-to-date. For example, APHIS is currently developing a new electronic permitting system to replace ePermits.

APHIS is also proposing to remove the specific requirements for what should be included in a permit application from the regulations. Instead, they would be listed on an APHIS Web site; for purposes of the proposed rule, that Web site is http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule.

That Website would first list general application requirements for all permit applications, and then break out additional requirements for specific permit applications. General information requirements that all types of permit applications would have to provide include the name, title, and contact information of the responsible person and agent, if possible; the country and locality where regulated organism was collected, developed, manufactured, reared, cultivated or cultured; the intended activity (i.e., importation, interstate movement, or release into the environment) for the regulated organism; and information regarding how the regulated organism was developed using genetic engineering.

For interstate movement or importation, the permit application would also have to contain the origin and destination of the regulated organism, including information on the addresses and contact details of the sender and recipient, if different from the responsible person; the method of shipment, and means of ensuring the security of the shipment against unauthorized release of the regulated article, to be used in the importation or interstate movement; and the manner in which packaging material, shipping containers, and any other material accompanying the regulated organism will be disposed to prevent the unauthorized release of the regulated article.

Permit applications for release into the environment would have to address the spread, persistence risk, and potential harm of the regulated organism in the environment, including but not limited to a description of how the phenotype of the regulated organism differs from the phenotype of the recipient organism, particularly with respect to potential interactions with, and its likelihood of spread and/or persistence in, the environment; and the location and size of all proposed environmental release sites, including area, geographic coordinates, addresses, land use history of the site and adjacent areas, and name and contact information of a person at each environmental release site, if different from the responsible person. In the even that additional release sites are requested after the issuance of a permit, APHIS would continue the practice of evaluating and amending permits to add new release sites.

Lastly, APHIS has occasionally received inquiries from stakeholders regarding whether a permit could authorize the commercial distribution of a regulated organism. Currently, most developers of GE organisms generally have not commercialized their products until after those products received a determination of non-regulated status. However, APHIS does not prohibit commercializing GE organisms that have not been determined to have non-regulated status. APHIS currently authorizes a small number of permits for such commercial production.

Under the proposed regulations, there may be some regulated organisms that an entity wishes to commercialize or grow on a large scale, under permit. As currently occurs, APHIS would evaluate these permit applications on a case-by-case basis, to determine whether permitting conditions can be developed that adequately address the risk associated with the permitted actions.

Permit Conditions: If a permit application is approved, permit conditions would be assigned to each permit commensurate with the risk associated with the regulated organism and activity. The use of permits and permit conditions gives APHIS and the responsible person an understanding as to what actions must be taken for the permit holder to comply with the regulations. General permit conditions, which would be described in the regulations, would be assigned to all permits. Additional or expanded permit conditions may also be assigned that are commensurate to the risk of the activities listed on the permit. Examples of such additional requirements include, but are not limited to, specific requirements for reproductive, cultural, spatial, and temporal controls; monitoring; post-termination land use; site security or access restrictions; management practices such as training of personnel involved in the movement; and practices to prevent articles associated with the movement of a regulated organism from becoming contaminated with plant pests or noxious weeds. APHIS would assign reporting requirements for all authorized activities.

All locations where regulated organisms are received, stored, distributed, or released into the environment would be identified within a permit or permits if movement occurs. This includes, but is not limited to, greenhouses; laboratories; growth chambers; field trial locations; and production, propagation, sale, distribution, and manufacturing locations.

Records: APHIS would increase the timeframes for record-keeping requirements because many of APHIS' investigations into instances of noncompliance involve activities that were conducted several years before noncompliance was discovered. APHIS would require that all records related to permit conditions, other than those demonstrating that a regulated organism that was imported or moved interstate arrived at its intended destination, be retained for 10 years following permit expiration, unless APHIS determines otherwise and documents an alternate record retention requirement. APHIS would extend the record retention requirement that demonstrates that a regulated organism that was imported or moved interstate arrived at its intended destination from 1 to 2 years. By example, in the event that there is uncertainty regarding whether a GE organism arrived at this destination, it may take APHIS more than 1 year to investigate the matter.

Maintenance of these records would facilitate the efficient enforcement of the regulations, as well as remediation measures and penalties in the event of an unauthorized release of a regulated organism (i.e., where a regulated organism was occurring in an area not authorized by APHIS).

Acknowledgement: Under the current regulations, the permitting procedure does not include a formal acknowledgement from the applicant prior to permit issuance that they are aware of and consent to the permit conditions. Such an acknowledgement, however, helps APHIS verify that applicants are aware of and willing to abide by the conditions. Accordingly, APHIS is proposing to add a requirement in § 340.3(d)(5) that, prior to permit issuance applicants must agree, in writing and in a manner prescribed by the Administrator, that they are aware of, understand, and will comply with all permit conditions. APHIS would deny applications of applicants who fail to comply with this provision.

Tribal and State Provisions: While the current regulations provide for review of permit applications by state regulatory officials, they do not include review by Tribal officials when

a permit application is submitted for the importation into, interstate movement through, or release into the environment on Tribal lands of a regulated organism. To correct this oversight, APHIS proposes to state in the regulations that APHIS will include appropriate Tribal officials when it provides copies of permit applications to state regulatory officials.

Denial, Revocation, and Amendment of Permit: APHIS would provide in §340.3 the circumstances under which a permit application may be denied. Such circumstances would include when the Administrator concludes that, based on the application or additional information, the actions proposed under the permit may result in the unauthorized release or dissemination of a regulated organism, or another plant pest or noxious weed; or when the Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any APHIS regulation or the conditions of any permit that has previously been issued in accordance with the regulations.

Procedures for revoking a permit would be contained in § 340.3. These procedures would state that a permit may be revoked if, following issuance of the permit, the Administrator receives information that would otherwise have provided grounds for APHIS to deny the permit application; if the Administrator determines that actions taken under the permit have resulted in the unauthorized release of a regulated organism, or another plant pest or noxious weed; or if the Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any APHIS regulation or the conditions of any permit issued.

APHIS is also proposing to clarify in the regulations the procedure to be used when amendment of existing permit conditions is sought by the responsible person or required by APHIS. Such amendments may include the transfer of the permit to a new responsible person. Currently, the administrative practices that APHIS uses to amend permits have not been explicit in the regulations, and these additions would provide increased transparency and efficiency.

Duration: It often takes considerably longer than 1 year for activities authorized under a permit to be completed. For example, with a perennial plant such as a tree, it may take much longer than a year to gather relevant data about the plant for the purpose of determining risk. Additionally, monitoring activities may be required for several years after a field test is complete. In other cases, multiyear research projects may require multiple shipments of regulated organisms for analysis.

APHIS is therefore proposing to eliminate the current limits in the regulations on the duration of permits for interstate movement and importation. APHIS would not specify a duration that an environmental release permit is valid in the regulations. The duration that a permit is valid would instead be specified on the permit itself, as a permitting condition. These changes should give APHIS the flexibility to issue these permits with suitable durations to meet individual circumstances.

2.2.3.1 Importation and Interstate Movement

The regulations in current § 340.7 and § 340.8 provide detailed requirements for identifying and securely shipping containers of regulated organisms. In the revised regulations, general

requirements, which apply to all shipments of regulated GE organisms under permit, would be now listed in paragraph (i) of § 340.3. These would specify that all shipments of regulated organisms must be secure shipments, which would be defined as shipments in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation. Specifics regarding labeling, marking, and the methods of secure shipment would be included as permit conditions. The proposed requirements would be generally applicable to all permits, with additional, shipment-specific conditions listed on individual permits as permitting conditions.

APHIS would specify that all regulated organisms must be shipped in accordance with the regulations in 49 CFR part 178. These regulations, which are administered by the Department of Transportation (DOT), provide packaging requirements for materials, including regulated organisms, which DOT has designated as hazardous materials. Following the completion of the shipment, all packing material, shipping containers, and any other material accompanying the regulated organism would have to be treated or disposed of in such a manner so as to prevent the unauthorized dissemination and establishment of regulated organisms.

Records: APHIS would require that records for importation or movement of a GE organism be retained for 1 to 2 years after completion of the importation or interstate movement. In the event that there is uncertainty regarding whether the organism arrived at this location, it may take APHIS more than 1 year to investigate the matter.

2.2.3.2 Environmental Release

Authorizations for environmental release of regulated GE organisms would be conducted subject to assigned permit conditions. Permit conditions would define the processes used to ensure confinement and containment of regulated organisms during environmental releases.

Containment: Permit applications for release into the environment would have to address the spread, persistence risk, and potential harm of the regulated organism in the environment, including but not limited to a description of how the phenotype of the regulated organism differs from the phenotype of the recipient organism, particularly with respect to potential interactions with, and its likelihood of spread and/or persistence in, the environment; the location and size of all proposed environmental release sites, including area, geographic coordinates, addresses, land use history of the site and adjacent areas, and name and contact information of a person at each environmental release site, if different from the responsible person; information about the ecology, agronomy, and local climatic or geologic conditions that could result in floods, fires, tornadoes, earthquakes, etc. at each site that could impact the integrity of the environmental release site; and the site management practices and control procedures designed to make it unlikely that there will be an unauthorized release of the regulated organism beyond the described environmental release site(s) and the permit time frame of the environmental release.

Reporting: APHIS is proposing to specify that regular reporting regarding any activities associated with environmental release of a regulated organism is a general permitting condition. As mentioned previously, the 2005 and 2015 OIG audits suggested that APHIS

exercise greater and more coordinated oversight over field tests of GE organisms. APHIS identified regular reporting regarding release site coordinates and details of the release as a key means of exercising such oversight. Adding this reporting requirement as a general permitting condition will ensure that it is communicated to all permittees. In addition, while the current general permitting conditions require a field test report following termination of a field test, in recent years, APHIS has required a more extensive report, an environmental release report, through permitting conditions. Our general permitting conditions would reflect this.

Records: The current regulations require a responsible person to retain records demonstrating that a regulated organism that was imported or moved interstate under a permit arrived at its intended destination for 1 year, but contain no record retention requirements related to environmental release of a regulated organisms. While APHIS has frequently added this record retention requirement as a permitting condition, both the 2005 and 2015 OIG audits and the 2008 Farm Bill recommended that APHIS specify the retention requirement in the regulations themselves. These recommendations are corroborated by our own experience administering the program.

APHIS would require that records for environmental releases be retained for at least 10 years after the permit expiration date, unless APHIS determined otherwise and documents an alternate record retention requirement. Maintenance of these records would facilitate the efficient enforcement of the regulations, as well as remediation measures in the event of an unauthorized release of a regulated organism (i.e., where a regulated organism was occurring in an area not authorized by APHIS).

2.2.4 Compliance, Enforcement, and Remediation

The Preferred Alternative will manage compliance with the regulations more efficiently, augment the approaches used to prevent or remediate potential risks to plant health, and clarify its enforcement authority under the PPA. These proposed regulatory changes also reflect certain provisions of the 2008 Farm Bill and align with recommendations of the 2005 and 2015 OIG audits. To improve the clarity of the regulations, APHIS is proposing to consolidate all compliance and enforcement requirements in 7 CFR part 340 into a new § 340.5.

Inspection: APHIS would require that the responsible person provide APHIS inspectors access to all relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other aspects related to the importation, interstate movement, and environmental release of organisms regulated under 7 CFR part 340. While this requirement is functionally the same as current inspection requirements, it clarifies which locations and regulated organisms may be subject to APHIS inspection, as well as reporting requirements. Failure to allow the inspection of premises prior to the issuance of a permit would be grounds for the denial of a permit application. Failure to allow an inspection after permit issuance would be grounds for revocation of the permit.

Enforcement and Remediation: Failure to comply with the regulations could include denial or revocation of permits, application of remedial measures in accordance the Plant Protection Act, and criminal and/or civil penalties. A responsible person could be held liable for the

violation of any APHIS requirement. Pursuant to sections 7714 and 7731 of the PPA, APHIS may seize, quarantine, treat, destroy, or apply other remedial measures to a regulated organism that is new to or not widely prevalent or distributed in within the United States to prevent dissemination of the organism. APHIS typically issues an Emergency Action Notification or administrative order to the owner of the regulated organism to specify these remedial measures.

2.2.5 Determinations of Regulatory Status

APHIS would determine the regulatory status of GE organisms by conducting the PPRAs and WRAs, and via procedure described above in Section 2.2.2.4. Any GE organism that APHIS has previously determined is not subject to regulation would continue to have non-regulated status under the Preferred Alternative. Any GE organism that APHIS determined to pose a risk as a plant pest or noxious weed, based on a risk assessment, or is a GE organism that has otherwise been determined by APHIS to pose a risk as a plant pest or noxious weed, would be regulated by APHIS.

Under the Preferred Alternative regulations would provide that any person may submit a request to APHIS to have a GE organism's regulatory status evaluated, or to request the reevaluation of the regulatory status of a previously evaluated regulated organism. It would also include the information that would have to be submitted with a regulatory status request in order for APHIS to evaluate the request, as detailed in Section 2.2.2.4.

2.2.5.1 Petition to Add or Remove a Plant Pest from the Regulations

Petitions to amend the list of taxa: The PPA provides that an individual may petition the Secretary to add or remove a plant pest from the list of taxa in the regulations. Currently, § 340.2 contains a list of taxa that are considered to be plant pests. This list has not been amended since it was established in 1987. To improve regulatory flexibility and help ensure the list remains current, APHIS is proposing to remove the list of taxa from § 340.2 and place it on the Internet at http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule. APHIS would advise the public of changes to the list through notices published in the Federal Register. These notices would request public comment.

Currently, § 340.5 contains provisions for petitioning the Administrator to amend the list of organisms in § 340.2 by either adding or deleting any genus, species, or subspecies. The list of requirements for petitioning the Administrator include formatting and submission procedures that are currently contained in § 340.5(b). However, these procedures have not been updated since 1994. Therefore, APHIS is proposing to remove the specific requirements related to formatting and submission procedures for petitions from the regulations. The procedures would instead be located on the Internet at http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule. APHIS is also proposing to revise the submission procedure to allow petitions to be submitted via email, and to update the address for postal submissions. These changes would update the submission procedure, and allow for greater flexibility in revising procedures, if, for example, the address for submissions changes in the future.

Following the receipt of a petition to amend the list of organisms in § 340.2, APHIS would publish a notice announcing the availability of the petition in the Federal Register and solicit public comment on the petition for 60 days. Following the close of the comment period, the Administrator would announce his or her decision to either approve the petition in whole or in part or deny the petition in a subsequent Federal Register notice.

Finally, APHIS is proposing to add an appeals process in the event that the Administrator denies a request to amend the list of taxa that are described in § 340.2. Any person whose petition has been denied would be able to appeal the decision in writing to the Administrator within 30 days after receiving the written notification of the denial. The appeal would have to state all of the facts and reasons upon which the person relies to assert that the petition was wrongfully denied. The Administrator would then grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow.

APHIS-initiated changes to listed taxa: APHIS may propose to add or remove taxa from the list of organisms in § 340.2 through a notice published in the Federal Register. The notice will state why APHIS has determined it necessary to add or remove a taxon from the list, and would request public comment. APHIS would review the comments received and publish its final decision in the Federal Register.

2.2.6 Exclusions and Exemptions from Regulation

As discussed earlier in this section, the regulatory framework would be structured around the terms and definitions for "genetic engineering", "genetically engineered (GE) organism", and "regulated organism". APHIS would exclude from the definition of genetic engineering traditional breeding techniques (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion) and chemical or radiation-based mutagenesis. By genetic engineering, APHIS means techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome. APHIS considers synthetic nucleic acids to be nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules. Consequently, organisms developed through traditional breeding and chemical or radiation-based mutagenesis would not be subject to 7 CFR part 340. Such organisms are essentially identical, despite the method of development, because while there may be small genetic differences, those differences are not phenotypically observable and these types of changes occur naturally in all organisms. APHIS has never considered traditional breeding and chemical or radiation-based mutagenesis to constitute genetic engineering, and they would continue to be excluded.

For purposes of the revised regulations under the Preferred Alternative, an organism would not be considered a "GE organism" if:

1. The genetic modification to the organism is solely a deletion or single base pair substitution that could otherwise be obtained through the use of chemical- or radiation-based mutagenesis.[33]

2. The genetic modification is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion).

3. The organism is a "null segregant," that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

Following is a summary of the rationale for these exemptions. A more detailed discussion of the rationale for these exemptions is provided in the proposed rule.

APHIS would exclude the first two types of organisms from the definition of GE organism for the following reasons. First, because the organisms could have been produced using traditional breeding techniques, chemical mutagenesis, radiation-based mutagenesis, or genetic engineering; not by genetic engineering alone as defined above. Genetic engineering is often used instead of traditional breeding practices or chemical or radiation-based mutagenesis in order to expedite the development of an organism with a desired genotype and/or phenotype. Examples from the realm of GE plants illustrate these practices. Chemical and radiation-based techniques create thousands of mutations in a single organism, and most of the plant breeders' subsequent efforts involve eliminating unwanted mutations by repeated crosses and selection of organism with desired traits; a process that months to years to complete. Using genetic engineering, single base pair substitutions and deletions can be precisely administered very quickly, avoiding the lengthy process of eliminating unwanted chemical or radiation-based mutations through traditional breeding. The resulting GE organism, however, remains identical to one that could otherwise have been developed using chemical or radiation-based mutagenesis.

The second reason for the exclusions is that GE plants, as a class, which constitute the vast majority of GE organisms developed to date, pose no greater plant pest or noxious weed risk than plants developed through traditional breeding techniques or chemical or radiation-based mutagenesis. Traditional breeding techniques, in the form of deliberate selection and breeding of those plants with desirable phenotypes, have been used since the advent of sedentary agriculture, and nearly every domesticated crop has, at one point, been subject to traditional breeding techniques. Chemical and radiation-based mutagenesis, in turn, have been used for nearly a century in the development of thousands of commodities, including such commercial commodities as ruby red grapefruit and many commercial varieties of wheat and rice. If APHIS were to regulate plants developed through traditional breeding

[33] A single base pair substitution is the most common type of substitution induced by chemical mutagenesis or natural variation and, therefore, most similar to the type of genetic variation that is possible through conventional breeding.

techniques or chemical or radiation-based mutagenesis as potential plant pests or noxious weeds, this would entail the regulation, at least provisionally, of almost every commercially available human or animal food crop. Hence, regulation of traditional breeding techniques and chemical and radiation-based mutagenesis for plant pest or noxious weed risk is considered impractical and unnecessary.

This same exclusion would apply to non-plant organisms. Non-plant organisms, which fall under the scope of the regulations as defined in § 340.0, are either plant pests, or organisms which have received genetic material sufficient to produce an infectious entity capable of causing plant disease or that encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms. Organisms of the latter type would not qualify for the exclusion, as receipt of genetic material capable of conferring the new properties could not be achieved through traditional breeding techniques, including chemical or radiation-based mutagenesis. However, it can be envisioned that plant pests might be altered in such a way that the exclusion would apply. In these cases, since the resulting plant pest would not be defined as a genetically engineered organism under 7 CFR part 340, they would be regulated, if needed, under APHIS's plant pest regulations in7 CFR part 330. This is appropriate since these organisms are biologically analogous to non-GE plant pests with mutations. It is important to note that, to date, APHIS has not encountered GE organisms of this type and that the GE plant pests that we do have experience with (e.g., pink bollworm expressing marker genes, citrus tristeza virus expressing antimicrobial compounds) would still be regulated under 7 CFR part 340 since this exclusion would not apply. The two APHIS program areas responsible for regulating under 7 CFR parts 330 and 340 are coordinating to ensure that together they are prepared to regulate any type of plant pest as needed.

The third proposed exclusion is for progeny of GE organisms where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, which was not passed to the recipient organism's progeny and did not alter the DNA sequence of the recipient organism's progeny. Such progeny are often referred to as null segregants. Traits are sometimes introduced by genetic engineering into breeding lines to simplify breeding, without altering the DNA sequence of progeny. The traits are eliminated with a simple cross and are no longer present in the final organism. An example of use of such techniques to facilitate traditional breeding would be the introduction of certain genes into trees solely to reduce the time to flowering, thereby speeding up a tree-breeding program. In this example, the progeny do not contain the early flowering gene and their DNA sequence has not been altered. Because the DNA of the progeny is no different from the DNA of the recipient organism prior to the use of genetic engineering, APHIS does not consider the progeny to be GE organisms for purposes of the proposed regulations.

The current § 340.2 contains a list of "exemptions" from the requirement for a permit for the interstate movement of certain GE strains of the microorganisms *Escherichia coli*, *Saccharomyces cerevisiae*, and *Bacillus subtilis*. One of the conditions for this exemption for the listed microorganisms is that the cloned material does not include the complete infectious genome of a known plant pest. The GE microorganisms mentioned above have been evaluated by APHIS and determined to present no risk as a plant pest. Consequently,

these microorganisms would not be regulated organisms, and APHIS would not need to retain specific permitting exemptions for them in § 340.2.

APHIS would continue to exempt *Arabidopsis thaliana* from permitting requirements for interstate movement. This is based on the organism's historically exempt status, which has not resulted in the dissemination of plant pests within the United States.

Note that APHIS is requesting specific comment on the appropriateness of the proposed exemptions, and whether commenters can identify any scenarios in which they would exempt from APHIS regulation an organism that presents a plant pest and/or noxious weed risk. APHIS also requests specific comment on whether any other types of organisms should be excluded from the definition of genetically engineered organism. Finally, APHIS is interested in whether the terms "traditional breeding techniques" and "chemical or radiation-based mutagenesis" should be defined, and whether the exclusions themselves are sufficiently delineated.

2.2.7 Regulation of GE Biological Control Agents

Biocontrol involves the reduction of plant pest and weed populations through the use of natural enemies such as parasitoids, predators, pathogens, antagonists, or competitors to suppress plant pest and weed populations. Under the Preferred Alternative, APHIS would regulate a GE organism that is intended for use as a biological control (biocontrol) agent if APHIS determines that it is a plant pest or noxious weed, with a limited exception; GE vertebrate biocontrol agents. Although such organisms could fall within the scope of the PPA's definition of plant pest, particularly if they are herbivores, it is long-standing APHIS policy not to regulate vertebrates as plant pests.

2.2.8 Regulation of GE Plants That Produce Pharmaceutical or Industrial Compounds

Certain varieties of plants, to include crop plants, are genetically engineered to produce pharmaceutical or industrial compounds, termed plant-made pharmaceutical and industrials (PMPIs). Under current 7 CFR part 340, APHIS regulates plants genetically engineered to produce pharmaceutical or industrial compounds (GE P/I-producing plants) because they were developed using genetic material from plant pest, or a plant pest was part of the development process. Under the Preferred Alternative, it is expected that most of the GE P/I-producing plants that APHIS evaluates will be found unlikely to pose a plant pest or noxious weed risk. Consequently, federal oversight of PMPIs and GE P/I-producing plants will require adjustments in oversight among APHIS, the FDA, and EPA. APHIS has identified several options that have the potential for adequate federal oversight of outdoor plantings of GE P/I-producing plants. These are discussed in greater detail in Section 4.8.1 – Federal Oversight.

2.2.9 Regulation of Small Scale Field Testing – Plant Incorporated Protectants

Plant-incorporated protectants (PIPs) fall under the regulatory oversight of the EPA and APHIS. Currently, the EPA requires experimental use permits (EUPs) for small scale field testing of PIP containing GE plants when field tests are over 10 acres in size, and APHIS

exercises regulatory oversight of field testing of GE PIP producing plants on or under 10 acres. The Preferred Alternative would shift federal oversight of small-scale (10 acres or less) outdoor plantings of GE PIP producing plants (or rather, the PIP itself) to the EPA. APHIS is fully committed to coordinating with EPA in order to give the EPA sufficient time to stand up a program for federal oversight of small scale field testing of GE PIP producing plants, if the Preferred Alternative is implemented (the proposed rule is finalized). APHIS and EPA oversight of GE PIP producing plants is discussed in Section 4.8.1 – Federal Oversight.

2.2.10 Regulation of GE Herbicide Resistant Plants

The EPA registers and has oversight of the herbicides used on herbicide resistant (HR) crop plants, but does not regulate GE HR plants themselves. Rather, GE HR plants are regulated by APHIS under 7 CFR part 340 To date, GE HR plants have been regulated by APHIS because they were developed using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current 7 CFR part 340. However, under the Preferred Alternative, APHIS expects that many of the GE HR plant-trait combinations it evaluates will not be found to present plant pest or noxious weed risks. Due to the more efficient regulatory review process for GE organisms that APHIS is proposing to implement, it is important that regulatory status determinations made by APHIS are in synchrony with the EPA's herbicide registration and review procedures. APHIS will work with the EPA to explore possible solutions to better coordinate the commercial availability of seed for GE HR crops concomitant with the registration of herbicides intended to be used on those crops. Synchrony in regulatory decisions between APHIS and the EPA is further discussed Section 4.8.1 – Federal Oversight.

2.3 Program Alternative 3: Comprehensive Regulation to Facilitate Coexistence

Revise the current APHIS regulations to provide for the comprehensive regulation of GE organisms as potential plant pests or noxious weeds, inclusive of previously deregulated GE organisms. APHIS would adopt the revisions considered under Alternative 2 and expand noxious weed harms to include the potential adverse economic impacts that could derive from the mere presence of GE plant material in non-GE crops or crop products.

2.3.1 Overview

Under Alternative 3, APHIS would substantially increase oversight of GE organisms relative to the No Action and Preferred Alternative. Alternative 3 is similar to the Preferred Alternative in that it incorporates noxious weed authority, uses the revised definitions for "genetic engineering" and "GE organism," and conducts risk analyses via a PPRA and WRA. However, it expands the scope of regulation to encompass the potential economic impacts of GE crop plants on non-GE crops. The mere presence of GE plant materials (e.g., pollen, seed, grain dust) in non-GE crops and their products would be considered a harm to agricultural interests and subject to regulation under 7 CFR part 340. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the

commercial GE crops currently grown, and those that would be grown under this Alternative, including GE organisms regulated under the Preferred Alternative.

2.3.2 Regulatory Scope

Under Alternative 3, APHIS' proposed regulatory framework would implement many of the revisions described for the Preferred Alternative. However, under this Alternative APHIS would incorporate the noxious weed authority under the PPA as inclusive of GE plants that cause economic harms due to the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. This is a broader interpretation of the definition of noxious weed than has typically been applied in the PPA's implementing regulations.

The terms "injure" and "damage" in the PPA's definition of noxious weed would be interpreted to include any adverse impacts that could result from the mere presence of GE plant material where it is not wanted. In evaluating a GE plant under a WRA, APHIS would assess the likelihood that the modifications made to the genome of the plant alter its ability to cause notable harm or injury. If so, these types of GE plants would be regulated as under the Preferred Alternative. In addition, APHIS would consider the economic harms that may result from commingling or cross pollination of the GE plant with a non-GE crop plant or its products. Based on the WRA, APHIS would distinguish those GE organisms that could potentially cause economic impacts from those GE organisms that did not.

Under this regulatory framework, APHIS would likely find many of the GE plants under regulation are unlikely to pose a plant pest or noxious weed risk in the traditional sense, but do pose a noxious weed risk if implementation of "injure" or "damage" includes potential economic impacts resulting from the mere presence of GE materials in non-GE agriculture, marketing, or shipping. In essence, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and those that would be grown. Under Alternative 3, only those GE crops that did not present a risk to plant health based upon a PPRA and/or WRA and had no potential economic impacts would not be regulated. In effect, the only GE organisms that would not require permits for interstate movement, importation, and environmental release would be those that are unlikely to pose plant pest or noxious weed risks, and did not cause economic harms due to mere presence.

For the purposes of this dPEIS, and discussion of Alternative 3, GE plants that pose a noxious weed risk absent of economic effects will be termed plant health noxious weeds (PHNW), equivalent to the Preferred Alternative. Those GE plants determined by APHIS to potentially cause economic harms to non-GE crop producers, their products, or agricultural commodity markets are termed mere presence noxious weeds (MPNW).

2.3.3 Authorization of Imports, Interstate Movements, and Environmental Releases

Permitting: As with the Preferred Alternative, the importation, interstate movement, and environmental release of all regulated GE organisms would be conducted solely under

APHIS permit; the notification procedure and courtesy permits would be eliminated. Under this Alternative, permitting procedures and requirements for environmental releases would be the same as that described for the Preferred Alternative for those organisms that posed plant pest and noxious weed risks as defined under the Preferred Alternative. Those GE organisms deemed to present risks as MPNWs, including those previously deregulated, would have different permitting requirements aimed at promoting coexistence and minimizing incidents of unauthorized and unintended presence.

2.3.3.1 Importation and Interstate Movement

Requirements for the importation and movement of regulated organisms would be the same as those under the Preferred Alternative. However, permits would not be required for the importation and interstate movements of GE organisms that presented MPNW risks, although their environmental release would.

2.3.3.2 Environmental Releases

Under Alternative 3, all GE crops that were previously deregulated and any new GE crops would require permits for environmental release under 7 CFR part 340 if they presented risks to agricultural markets as MPNWs. Permitting procedures and requirements for regulated organisms that were not MPNWs would be the same as that described under the Preferred Alternative. Permitting requirements for MPNWs would have the following provisions.

Permits for MPNWs would be designed to facilitate coexistence among conventional, organic, and GE crop producers. Under this Alternative, developers and growers of GE crops would be assigned permits with terms and conditions requiring the management of coexistence among GE and non-GE crops, and protection of crop product identity across GE non-GE crops. The permit conditions for MPNWs would be specifically designed to limit cross-pollination and commingling among GE and non-GE crops by specifying isolation distances; management of volunteer plants to prevent GE crops from flowering in abandoned, fallow and rotated fields; and other measures that would address and mitigate potential economic impacts that could result from cultivation of MPNWs.

Further, the only regulated GE crop plants that would be permitted for commercial-scale cultivation in the United States would be those crop plants that have received international approval in the major export markets. This requirement would be instituted to reduce the potential for low level presence (LLP)[34] occurring in countries importing U.S. agricultural commodities.

Registration and Pinning System: All non-GE crop producers (conventional and organic) that wish to receive protections from injury or harm from MPNWs provided under the regulations would need to be registered with APHIS to confirm that they are legitimate business entities. A voluntary registration system for non-GE crop producers would be developed, and non-GE crop producers would need to register their production systems with

[34] Low level presence (LLP): Once a GE crop is authorized for commercial use in a given country, trace amounts of that GE crop may become mixed with other crop varieties in that country during processing or transit. As a result, a GE crop that is authorized in an exporting country may be present at low levels in grain, human and animal food, or seed that is imported into another country, where that particular variety of GE crop has not been authorized.

APHIS to establish authenticity and qualify for protections from APHIS's regulatory program. This requirement would prevent non-legitimate interests from unfairly imposing heavy requirements on neighboring GE producers by spuriously claiming non-GE crop status.

In addition, a voluntary national web-based pinning map would be developed by APHIS to identify the location and acreage of GE and non-GE crops cultivated in the United States. Non-GE crop producers who wished to receive protections provided under 7 CFR part 340 could identify the GPS coordinates of their production fields using this system. In order to ensure that legitimate interests were reflected in the pinning system, only registered organic and non GE growers would be allowed to participate.

Tracking and reporting: GE plant developers would be required to maintain and provide to APHIS a list of regulated crop plants they offered for sale each year and verify whether these crops have been approved for import into major international export markets. Biotechnology developers and producers of regulated GE crop plants would be required to track and record the planting locations and acreage of all regulated crop plants and submit that information to APHIS as requested. All registered producers of non-GE crops would likewise need to track, record, and report the location and acreage of their crops on a national pinning map in order to receive protections under part 340.

Isolation distances: Biotechnology developers and producers would need to verify that all regulated GE crops maintained the isolation distances from non-GE crops specified in the permit. Permits would specify the isolation distance necessary to separate the GE and non-GE crop to achieve less than 0.1% cross pollination for seed production and 1% for grain production. Established isolation distances would be based on the best available science.

Producers of regulated GE crops would share the responsibility for meeting the isolation distance with non-GE crop producers; producers of both non-GE and regulated GE crops would need to contribute equally to the isolation distances required for maintenance of registration and permit requirements, respectively. Biotechnology developers would have the responsibility for obtaining permits and ensuring isolation distances and volunteer plant management requirements were met. Similarly, non-GE crop producers would be required to maintain their registration with APHIS and adhere to registration requirements.

Volunteer plant management: Permits would require volunteer plant management plans be developed and implemented to prevent regulated GE crop plants from flowering in abandoned, fallow, and rotated fields. All land used for regulated GE crop production must be monitored pursuant to permit requirements to ensure that crops are harvested and volunteers are managed in abandoned, fallow, and rotated fields.

2.3.4 Compliance, Enforcement, and Remediation

APHIS' compliance and enforcement program would be the same as that described for the Preferred Alternative, with additional provisions for oversight of MPNWs, summarized below.

Isolation distances: Biotech developers and growers of regulated GE crops can be held accountable for harm to non-GE producers if isolation distances and other permit conditions are not followed. Non-GE crop producers who felt that isolation distances were not maintained could request an inspection by APHIS. If the APHIS inspection revealed that the isolation distance was in violation of permit requirements, or there were demonstrated losses to non-GE crop producers due to the unintended presence of the regulated GE crop material, the biotechnology developer would be subject to civil penalties authorized under the PPA (§ 7734 - Penalties for violation). If required isolation distances were found to be maintained and all other permit conditions were followed, the biotechnology developer would not be subject to penalties.

Volunteer plant management: Non-GE crop producers who felt that GE volunteer crop plants were growing in abandoned, fallow, or rotated fields could request an APHIS inspection. If the volunteer plants were identified in areas that violated permit requirements, APHIS would conduct available tests to determine if a violation existed. If so, the biotechnology developer and grower would be subject to penalties authorized under the PPA (§ 7734 - Penalties for violation).

Records: APHIS would also include revised requirements for the establishment and maintenance of records, and the provision of APHIS inspectors with all required records upon request. Permits would require plant biotechnology developers to track and record the plantings, acreage, and location of their regulated organisms being grown, as well as GE plant volunteer management records. Records required to be maintained would include all locations and acreage where the regulated organism was planted; and copies of contracts between the responsible person and all of his/her agents, as well as copies of other records (e.g., emails, telephone records).

2.3.5 Determination of Regulatory Status

As with the Preferred Alternative, the current petition process (7 CFR § 340.6) would be eliminated, and APHIS would conduct a PPRA and/or WRA to determine whether the GE organism should be regulated under 7 CFR part 340. Because APHIS would also consider potential market impacts as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause market impacts to non-GE crop producers, and those GE organisms that were determined to present no plant pest or noxious weed risk. Regulated organisms would include those that presented a risk to plant health as a plant pest or noxious weed, and those that presented potential economics risks to non-GE crop producers and agricultural markets due to the mere presence of GE plant materials in non-GE agriculture, shipping, processing, or marketing. GE organisms not subject to regulation under 7 CFR part 340 may be subject to EPA requirements, as well as all other federal, state, and county requirements. For GE plants developed for human or animal food purposes, the FDA recommends that developers of GE plant varieties intended for food use consult with the FDA about the safety and composition of the GE plant variety prior to its introduction into the food supply (US-FDA 2006).

If APHIS determined that a GE organism was not subject to regulation, and it was later found to present potential plant pest risk or noxious weed risks, or other agricultural harms, APHIS

would have the authority to bring that GE organism under 7 CFR part 340 regulation or other APHIS regulations as appropriate.

As with the Preferred Alternative, regulations under Alternative 3 would provide that any person may submit a request to APHIS to have a GE organism's regulatory status evaluated, or to request the reevaluation of the regulatory status of a previously evaluated regulated organism. It would also include information that would have to be submitted with a regulatory status request in order for APHIS to evaluate the request. Likewise, provisions for petitions to amend the list of organisms in § 340.2 and APHIS-initiated changes to the list of organisms in § 340.2, would remain the same as those described for the Preferred Alternative.

2.3.6 Exemptions from Regulation

APHIS would exempt the same categories of GE organisms as outlined under the Preferred Alternative, unless that GE organism was identified as a potential MPNW.

2.3.7 Regulation of GE Biological Control Agents

Under Alternative 3, APHIS would regulate a GE organism that is intended for use as a biological control (biocontrol) agent the same as described for the Preferred Alternative. Although such organisms could fall within the scope of the PPA's definition of plant pest, particularly if they are herbivores, it is long-standing APHIS policy not to regulate vertebrates as plant pests.

2.3.8 Regulation of GE Plants That Produce Pharmaceutical or Industrial Compounds

Under Alternative 3, GE P/I-producing plants would be regulated by APHIS, similar to APHIS' current oversight of such GE plants. This is due to the expanded interpretation of noxious weed authority under Alternative 3, and regulation of GE plants APHIS determines to present MPNW risks. Accordingly, APHIS would exercise oversight of all field trials and commercial production of regulated GE P/I-producing plants; this oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring. This would not preclude the FDA or EPA from exercising their authorities over the pharmaceutical (FDA) or industrial (EPA) compounds produced by such GE plants.

2.3.9 Regulation of Small Scale Field Testing – Plant Incorporated Protectants

Under Alternative 3, all GE plants that meet the definition of a regulated organism and produce plant-incorporated protectants (PIPs) would be regulated by APHIS. By virtue of inclusion of those GE organisms APHIS determines to present MPNW risks, this would include the small scale field testing (on or under 10 acres) of GE PIP producing plants determined to present MPNW risks. In effect, APHIS would continue oversight of the small-scale field testing of GE PIP producing plants, with such plantings subject to the permitting, inspection, reporting, compliance, and other requirements described for Alternative 3.

2.3.10 Regulation of GE Herbicide Resistant Plants

In contrast to the Preferred Alternative, under Alternative 3 the need for coordination between APHIS and the EPA regarding the timing of deregulation/determination of non-regulated status of GE HR crops and the EPA registration of herbicides used on these crops would not be an issue. It is expected that APHIS would regulate the vast majority, if not all of the GE HR crops produced in the United States. Consequently, the permitted planting of regulated GE HR crops would be under APHIS authority, and coordination with EPA facilitated by APHIS oversight of the commercial production of GE HR crop plants.

2.4 Alternatives Considered But Dismissed from Further Consideration

APHIS considered various alternatives for revision of 7 CFR part 340. APHIS evaluated these alternatives relative to the Agency's PPA authorities, and their potential efficacy and feasibility in fulfilling the purpose and need for revisions of the regulations. Based on these evaluations, APHIS dismissed several of the alternatives considered in revision of part 340 as plausible paths forward. These alternatives were not evaluated in this dPEIS, but are discussed briefly below along with the specific reasons for dismissing the alternative from further consideration.

2.4.1 Withdraw 7 CFR part 340 and Regulate Plant Pests under part 330, and Noxious Weeds under part 360

In the notice of intent (NOI) to prepare this dPEIS, which APHIS published in the Federal Register on February 5, 2016 (85 FR 6225-6229, Docket No. APHIS-2014-0054), APHIS proposed to examine a fourth alternative in this dPEIS. For this fourth alternative, based on the assumption that most GE crop plants are unlikely to pose a noxious weed or plant pest risk, APHIS considered rescinding its current regulations at 7 CFR part 340 and regulating GE organisms under existing 7 CFR part 330 (Federal Plant Pest Regulations; General; Plant Pests; Soil, Stone, and Quarry Products; Garbage) and part 360 (Noxious Weed Regulations) if they posed a plant pest or noxious weed risk, respectively.

Under this alternative, any GE organism that poses a plant pest or noxious weed risk would be managed by APHIS using 7 CFR parts 330 and 360. Those regulations, if used to regulate any GE organisms, would provide for regulation of GE organisms under a framework that differs from that of current 7 CFR part 340 regulations, and the regulatory frameworks described for the Preferred Alternative and Alternative 3. Under this alternative regulated organisms would include all those listed as plant pests under 7 CFR parts 300-399 and noxious weeds under 7 CFR § 360.200. APHIS would have the ability to expand or refine the lists of regulated organisms at its own discretion, and in response to inquiries as described in 7 CFR § 360.500.

Implementing this alternative biotechnology developers, growers of GE crops, and anyone using a GE organism would need to determine whether the GE organism poses a plant pest or noxious weed risk before planting, or otherwise using a GE organism, and comply with parts 330 and 360. No one would be required to consult with APHIS. However, biotechnology developers, growers, and anyone using a GE organism could voluntarily consult with APHIS regarding the regulatory status of a GE organism and permitting requirements if they wished

to do so. APHIS would agree to conduct courtesy PPRAs and WRAs as requested to assist with compliance. Biotechnology developers would still be responsible for satisfying the regulatory requirements of the EPA, as well as complying with all other federal and state laws and regulations governing the importation, interstate movement, and environmental release of GE organisms. This includes all laws and regulations providing protections for the environment and natural resources. For GE plants developed for food purposes, the FDA recommends that developers of GE plant varieties intended for food use consult with the FDA about the safety and composition of the GE plant variety prior to its introduction into the food supply. Developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006).

While the merit of this regulatory framework, in principle, was recognized, stakeholders' concerns expressed in comments on the NOI, APHIS review of these concerns, and APHIS' initial examination of this fourth alternative in the dPEIS prompted APHIS to dismiss this alternative as a plausible path forward. Commenter concerns, shared by APHIS, were that implementing this alternative regulatory framework there could be unintended deleterious effects associated with it, such as lack of international acceptance for provision of voluntary consultation with APHIS and potential adverse impacts on trade, or creation of a regulatory vacuum that another federal or state agency may feel compelled to fill. APHIS also identified several issues with the existing regulations that could adversely impact operational feasibility. For example, while 7 CFR part 330 provides for the permitted movement of regulated organisms, it does not contain provisions for permitting the environment release of regulated organisms, as the regulations are written, and contains no clear mechanisms by which to issue a determination of non-regulated status to an organism APHIS determines unlikely to pose a plant pest. Similarly, the regulations in 7 CFR part 360 have no clear provision for permitting of environmental releases.

Based on APHIS' reevaluation, it was determined that this alternative is not operationally feasible without substantial changes to the regulations in 7 CFR part 330 and 360. For this reason, and those stated above, APHIS decided not to evaluate this alternative, which was proposed in the NOI, any further.

2.4.2 Revise 7 CFR part 340 for APHIS Regulation of GE Organisms as Plant Pests, but without incorporating Noxious Weed Authority

One regulatory alternative that APHIS considered but dismissed was to revise the current 7 CFR part 340 as to how it determines what may be a plant pest and regulated under PPA authority, without incorporating the noxious weed authority provided by the PPA. Under this alternative, APHIS considered (a) updating the definition of "genetic engineering"; (b) eliminating the concept of "regulated article"; (c) defining a regulated GE organism; (d) removing the stipulation that regulation of GE organisms to protect plant health is based on the use of a plant pest as a donor, recipient, or vector of genetic material; and (e) conducting an upfront PPRA of the GE organism. Hence, this alternative shares many of the revisions considered under the Preferred Alternative.

Under this regulatory framework, APHIS would determine the regulatory status of a GE organism prior to it being permitted by conducting an upfront PPRA as described in the

Preferred Alternative. The regulatory "trigger" for risk analysis would not be based on whether the GE organism contained a gene sequence from a plant pest, as is currently done, but whether the GE organism poses a risk as a potential plant pest pursuant to the revisions described in items (a) through (d) above, and an upfront risk analysis. This alternative may not encompass a sufficient range of current and future GE organism-trait combinations that could pose risks to resources protected under the noxious weed authority of the PPA. Consequently, this alternative was dismissed from further consideration.

2.4.3 Revise the Regulatory Framework in 7 CFR part 340 that Describes APHIS's Ability to Determine a GE Organism as a Plant Pest, but Keep Notifications

Under this alternative APHIS would revise 7 CFR part 340 regulations as proposed under the Preferred Alternative, but would retain the current notification procedures. As described under the Preferred Alternative, APHIS would conduct an upfront PPRA and/or WRA to determine the regulatory status of a GE organism prior to it being regulated by APHIS.

The term "notification" can be misleading to the public, as sending a notification does not mean automatic authorization by APHIS. In many ways, APHIS' evaluation and approval of notifications is very similar to those done for permit applications. The notification procedure, however, relies on applicants agreeing to performance standards described in the regulation rather than submitting an application for APHIS' review describing the specific measures they will employ for the activity (as is the case for permits). Because the notification procedure uses only the performance standards in the regulations, it is more administratively streamlined. However, the general nature of the standards has made it difficult for APHIS inspectors to determine if a notification holder is in compliance, and can also make enforcement more difficult. While the use of performance standards under the notification procedure has some benefits, such as providing the responsible person with flexibility in how the standard is met (e.g., allowing for appropriate changes in protocols used during the growing season), there are some disadvantages in not specifically listing measures that constitute compliance with the regulations. The permitting procedure does not have this disadvantage because the permit conditions specify which actions need to be taken by the responsible person to be in compliance. Because of this, APHIS has determined that it would have more flexible, risk-appropriate oversight, better regulatory enforcement, and improved transparency if all regulated importations, interstate movements, and environmental releases are authorized under the permitting procedure. Consequently, this consideration was dismissed from further evaluation.

2.4.4 Regulate Based on the Concept of "Novelty"

APHIS considered but dismissed an alternative where APHIS would regulate potential plant pests and noxious weeds based on the novelty of the introduced trait in the organism, regardless of the method used to introduce that trait. Novel traits can be developed through various techniques, such as traditional selective breeding, chemical or radiation based mutagenesis, cell fusion, or using more modern genetic engineering methods. Regardless of the method or technology used, APHIS, under this alternative, would regulate the potential plant pest and noxious weed risk of organisms based singularly on the novelty of the introduced trait itself. This approach would result in APHIS regulation of all organisms with novel traits that presented a risk to plant health, both GE organisms and non-GE organisms.

Applying the concept of novelty to trigger regulatory oversight would enable the regulation of a wide array of potential plant pests and noxious weeds; however, this alternative was dismissed from further consideration because 7 CFR part 340 would need to be replaced entirely by new regulations. Applying the concept of novelty as a trigger for regulatory oversight would be a paradigm shift, and would likely require a new Act of Congress or discovering authority elsewhere in existing USDA statutes.

2.5 Summary: Comparison of Alternatives Considered in Revision of 7 CFR part 340

340 dPEIS Alternatives Summary			
	ALT 1: No Action	**ALT 2: Preferred Alternative**	**ALT 3: Comprehensive Regulation**
Statutory Authority	PPA	PPA	PPA
Implementing Regulations	7 CFR 340	7 CFR 340	7 CFR 340
Risk Evaluated	PP	PP & NW	PP, NW, MPNW
Definition for Regulatory Determination	"Regulated article" per current part 340 [a]	"Regulated organism" is any GE organism that is regulated pursuant to § 340[b] (as revised).	Same as ALT 2
Regulatory Scope GE organism is subject to regulation if [c]-	The donor organism, recipient organism, vector, or vector agent is listed in § 340.2 and meets PP definition, or APHIS has reason to believe the GE organism is a plant pest. [d]	(1) Is listed in § 340.2 and meets PP definition[e]; (2) Has DNA from taxon listed in § 340.2 and the DNA from the donor is sufficient to produce an infectious entity or encodes a pathogenesis-related compound that is expected to cause plant disease symptoms; (3) A plant-trait combination that has not been evaluated for PP or NW risk; (4) Is any of the foregoing that has been evaluated for PP or NW risk[f], or is a GE organism that has otherwise been determined by the Administrator to pose a risk as a plant pest or noxious weed.	(1) Same as ALT 2 (2) GE organisms that have potential economic impacts resulting from the mere presence of GE plants determined to be noxious weeds in non-GE crops (MPNW). [g] Same definitions for "genetic engineering" and "GE organism" as ALT2.
Risk Assessment	PPRA	PPRA and/or WRA [h]	PPRA and/or WRA
Regulatory Determination	Via Petition for non-regulated status [i]	Via (1) APHIS initiated regulatory review and (2) requests for evaluation or reevaluation of regulatory status [j]	Same as ALT 2 + MPNW
Authorization Requirements	Notification or Permit	Permit only [k]	Permit only
Import/ Interstate Movement	PP	PP & NW	PP & NW
Environmental Release	PP	PP & NW	PP, NW, MPNW
Compliance	Inspections, reporting, enforcement per current part 340	Increased inspections & reporting requirements relative to No Action Alternative. Clarified enforcement actions.	Significantly increased inspections & reporting requirements relative to No Action and ALT 2. Clarified enforcement actions.
Basis of Determination	PPRA under definition of regulated article, NEPA as required	PPRA and/or WRA under definition of regulated organism, NEPA as required	PPRA and WRA under definition of regulated organism, NEPA as required
Summary of Changes		Refines regulatory review, inquiry, and determination process for greater efficiency. Focuses regulation on GE organism that pose a PP or NW risk.	APHIS functions as a wide-scale permitting authority regulating the production of many commercial GE crops, in addition to GE organisms that may be regulated under ALT 2. APHIS mandates isolation

340 dPEIS Alternatives Summary	
	distances and volunteer management for GE crops to promote coexistence and restricting the commercialization of GE crops until international approvals are completed.

* PP – GE Plant Pest; NW –Noxious Weed; MPNW – Mere Presence Noxious Weed (economic impacts); PPRA – Plant Pest Risk Assessment; WRA – Weed Risk Assessment.

Notes:

(a) Regulated article (ALT 1): Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

(b) Regulated organism (ALT 2 & 3): Any GE organism that is regulated pursuant to § 340.0 (as revised).

(c) GE organism (ALT 2 & 3): An organism developed using genetic engineering; techniques that use recombinant or synthetic nucleic acids to create or alter a genome. Genetic engineering does not include traditional breeding techniques (including, but not limited to, marker-assisted breeding and chemical or radiation-based mutagenesis, as well as tissue culture and protoplast, cell, or embryo fusion).

(d) Plant pest (ALT 1, current in part 340)**:** Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

(e) Plant pest (ALT 2 & 3): Any living stage of a protozoan, invertebrate nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product. [This change aligns the definition of "plant pest" in 7 CFR part 340 with the definition of "plant pest" used in the PPA].

(f) Noxious weed (ALT 2 & 3)**:** Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

(g) Mere Presence Noxious weed (ALT 3): APHIS would interpret the noxious weed authority under the PPA to include potential economic impacts resulting from the mere presence of GE materials (e.g., pollen, seed, grain dust) in products marketed as organic or non-GE. This is a broader interpretation of the definition of noxious weed than has been typically understood, and PPA implementing regulations.

(h) PPRA and WRA: APHIS will conduct, proactively, absent of regulatory status inquiries, plant pest risk assessment (PPRA) and noxious weed risk assessment (WRA) on GE organisms to make a regulatory status determination. APHIS will also conduct PPRAs and WRAs in response to a regulatory status inquiry. APHIS may initiate a regulatory status determination for a GE organism at any time. Under Alternative 3, the WRA risk assessments would also evaluate noxious weed risk to include potential economic harms. In this case, new APHIS policy will interpret noxious weed risk to include economic harms from unwanted cross pollination and unintended presence of GE organisms in exported commodities. The new system will likely find many of the current GE organisms under regulation are unlikely to pose a plant pest or noxious weed risk in the traditional sense, but have potential economic impacts resulting from the mere presence of GE materials.

(i) 7 CFR part 340.6 - Petition for determination of non-regulated status.

(j) The proposed revisions to § 340.4 would describe a formal process by which persons could request an initial evaluation or subsequent reevaluation of the regulatory status of a GE organism.

(k) Permit (ALT 2 & 3) APHIS would issue core permit conditions in § 340.4 and may add further conditions as necessary to make it unlikely that actions under the permit would result in the release or dissemination of a plant pest or noxious weed. Alternative 3 would have same basic requirements as Alternative 2, with added permitting and reporting requirements relative to MPNW considerations.

3 AFFECTED ENVIRONMENT

As part of APHIS' larger mission to protect the health and value of American agriculture and natural resources, APHIS-BRS is charged with protecting plant health by ensuring the safe importation, interstate movement, and environmental release of GE organisms. APHIS regulates these activities under 7 CFR part 340, which it is seeking to revise, as discussed in Chapters 2 & 3. APHIS is evaluating three regulatory options, or Alternatives, in revision of 7 CFR part 340. This chapter describes those aspects of the human environment[35] potentially affected by the Alternatives under consideration with emphasis on:

(1) how and where GE plants and other organisms subject to 7 CFR part 340 regulations have been, and are likely to be field tested, transported, and used in agriculture;

(2) the known and potential impacts on the human environment that may derive from the importation, interstate movement, and environmental release of regulated GE organisms;

(3) the known and potential impacts on the human environment that may derive from agricultural activities in the United States and U.S. territories, inclusive of conventional, organic, and GE cropping systems; and

(4) the known and potential impacts on the human environment that may derive from GE plants and other organisms developed for uses other than food or fiber, such as ornamental plants, microbial pesticides, and those developed for pharmaceutical and industrial purposes.

3.1 Acreage and Areas Used for Agriculture and Forestry

Lands in the United States and its territories that are affected by 7 CFR part 340 are largely those used for cropland, rangeland, and forestland. APHIS may authorize the importation, interstate movement, or field testing of a regulated GE organism in any of the 50 states or U.S. territories. Historically, the vast majority of GE organisms APHIS has regulated are plants, and most environmental introductions have taken place on lands used for agriculture or forestry. Once APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories without APHIS authorization, subject to EPA requirements, as well state and local requirements. For GE plants developed for human or animal food purposes, the FDA recommends that developers of GE plant varieties intended for food use consult with the FDA about the safety and composition of the GE plant variety prior to its introduction into the food supply. Sponsors and developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006).

This section describes the areas, acreage, and types of land uses in the United States and its territories that are affected, directly or indirectly, by APHIS regulatory oversight of GE organisms. The areas and acreage described are those where both regulated and non-regulated GE food and fiber crops have been and may be grown, or animal food derived from GE plants is

[35] The human environment includes the natural and physical environment and the relationship of people with that environment.

used for livestock production. This section does not include a detailed discussion of non-GE farms. However, production of non-GE crops and those using organic procedures (USDA-AMS 2015b) can occur in general areas where GE crops are produced. Hence, where the focus is on GE crop production, agricultural production in the United States and its territories, inclusive of GE and non-GE production, is addressed.

Various federal agencies produce land use or land cover estimates, namely the U.S. Forest Service (USFS), Bureau of Land Management (BLM), USDA National Agriculture Statistics Service (NASS), Census Bureau, USDA Economic Research Service (ERS), and USDA Natural Resources Conservation Service (NRCS). Some agencies produce estimates for the entire United States, while other agencies produce estimates covering fewer land or ownership types. For many agencies, the scope and scale of the land use or land cover estimates developed are to meet specific Agency responsibilities in legislated mandates passed by Congress. As the scope and scale of Agency mandates will differ, so do the resulting estimates that are produced by the various agencies (USDA-ERS 2015e).

This draft programmatic environmental impact statement (dPEIS) primarily uses ERS and USFS data in evaluation of land uses. The ERS Major Land Use series, started in 1945, is the longest running, most comprehensive accounting of all major uses of public and private land in the United States. The ERS data can be used to identify long-term trends in land uses at the state level. The USFS monitors and reports on national forests (to include 154 national forests), private lands, urban forest, and forest resources. The USFS reports served as resources on land uses, human-environment conflicts, habitat fragmentation, invasive species, and biodiversity.

3.2 Major Land Uses in the United States

The United States is comprised of approximately 2.3 billion acres of land allocated to various uses supporting social, economic, national defense, and conservation needs (Nickerson, Ebel, Borchers et al. 2011) (Figure 3-1). As the primary source of the Nation's food and fiber, as well as a source of biofuel, agriculture comprises a substantial area of land use in the United States, currently accounting for over half of the U.S. land base. Where total U.S. land area amounts to approximately 2.3 billion acres, around 1.2 billion acres of this is used for agricultural purposes (Nickerson, Ebel et al. 2011, USDA-NASS 2014c).

The largest shares of land over the last several decades have been allocated to federal uses, forestland, grassland pasture and rangeland, and cropland. Among these, agricultural lands used for livestock and crop production comprise the largest use, accounting for 40% to 50% of the U.S. land base, depending on annual fluctuations, and relative to how farmland is defined and categorized by federal agencies.[36]

As of 2007 (latest compiled data for all land uses, yet reflective of land uses over the last several decades), approximately 408 million acres (18%) of U.S. land area was cropland, 614 million acres (27%) permanent grassland pasture and rangeland, and 671 million acres (30%) forest-use

[36] For example, ERS estimated for 2007 that land used for agricultural purposes totaled 1.16 billion acres, about 51% of total U.S. land area. By comparison, the NASS estimated 921 million acres of "land in farms" in 2007. The difference between the two estimates is mostly accounted for by grazing lands (both forested and nonforested) that are not included in the NASS definition of a farm.

land. Urban areas accounted for around 3% (61 million acres), while special uses, which include parks, wilderness areas, transportation, and national defense areas, accounted for around 313 million acres (14%). Miscellaneous other uses (e.g., tundra or swamps) comprise around 197 million acres (~9%). Lands in the Conservation Reserve Program (CRP) comprise around 1%. The CRP is a land conservation program administered by the Farm Service Agency (FSA) where farmers enrolled in the program agree to remove environmentally sensitive land from agricultural production and plant species that will improve environmental health and quality (Nickerson, Ebel et al. 2011).

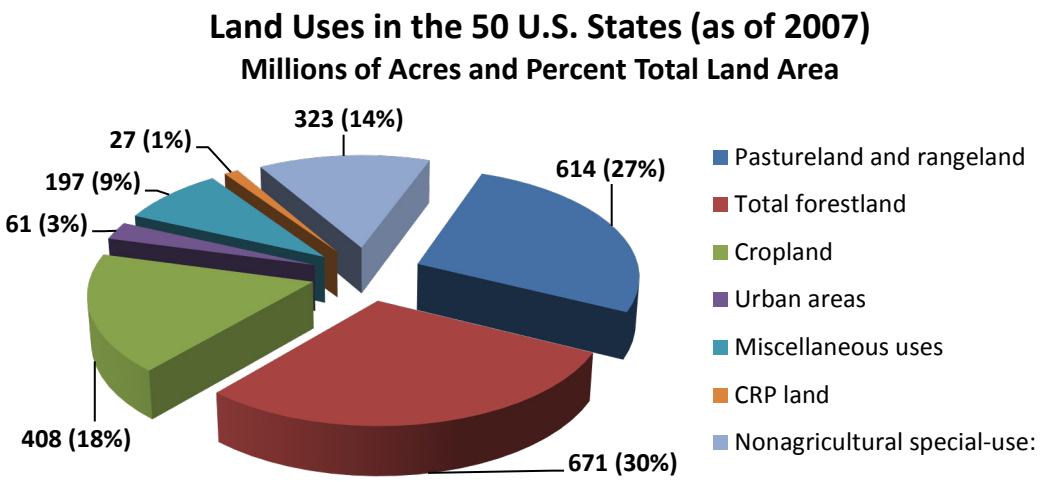

Figure 3-1. Major Land Uses in the United States

Source: (Nickerson, Ebel et al. 2011)

Notes: Cropland includes land used for crops, idle cropland, and cropland used only for pasture. Grassland pasture and range includes permanent grassland and other non-forested pasture and range. Forestland is total forestland as classified by the USFS, excluding an estimated 80 million acres used primarily for parks, wildlife areas, and other uses. Special-uses land includes areas for rural transportation, recreation and wildlife, and public installations and facilities, including the 80 million acres of forested land. Miscellaneous land includes areas in various uses not inventoried, marshes, open swamps, desert, and other land of low agricultural value. The percentages of allocated land uses described are significantly affected by the land area of Alaska, which, relative to the contiguous 48 States, has limited amounts of cropland and pasture but large areas of forest, special use lands, and miscellaneous other land uses

Historical land-use trends are shown in Figure 3-2, along with the projected uses through 2062. Though areas of cropland, forest, and rangeland are expected to marginally decline over the next several decades, these three uses will continue to be the dominant land uses in the United States. The most significant change is projected to be urban land uses, which are projected to substantially increase, in line with increases in U.S. population. In fact, the largest net loss in cropland will come from urban expansion; USFS modelling projects that 21 million acres of cropland will be developed for urban use by 2062 (Alig, Plantinga, Haim et al. 2010).

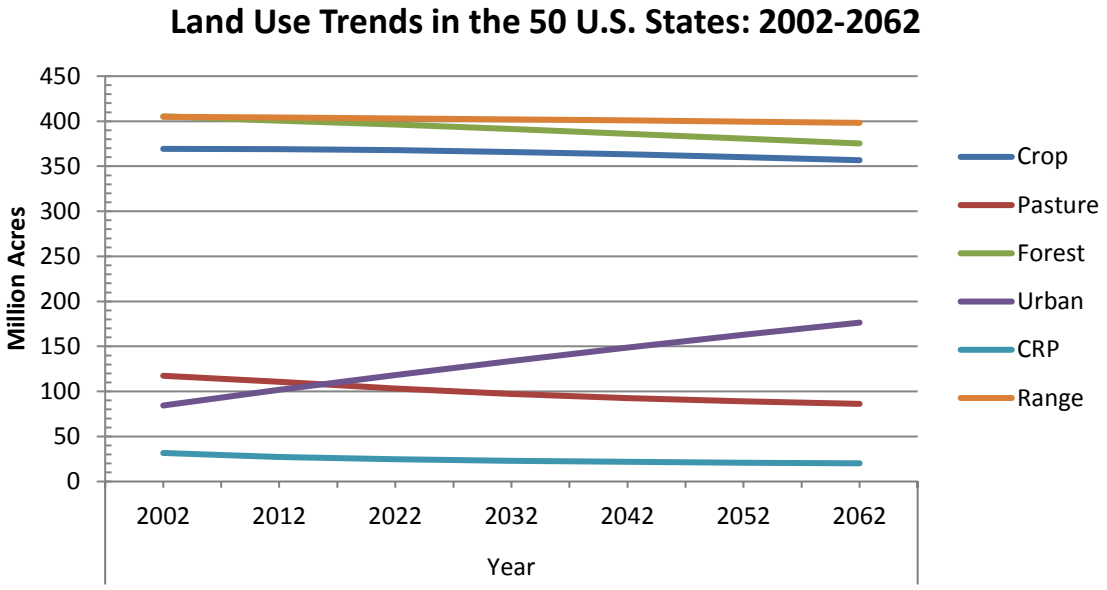

Figure 3-2. Historic and Projected Land Use Trends in the United States
Source: (Alig, Plantinga et al. 2010)

3.2.1 Land in Farms

3.2.1.1 Historic and Projected Trends

The number of U.S. farms and amount of land in farms has declined steadily since 1935 while the average size of farms increased (Figure 3-3)(USDA-NASS 2014d).[37] This trend is accompanied by the growing productivity of U.S. agriculture due to advances in agronomy, genetics, and plant biotechnology. These advances have contributed to better soil, nutrient, water, and pest management, as well as more efficient methods of planting and harvesting. Such increased efficiencies in agricultural production have led to increased yields per acre for many of the primary crops such as corn, cotton, and soybean. Consequently, the amount of land required to meet market demand for agricultural products steadily declined over the last 70 or so years, even in the face of an increasing population.

[37] The statistics collected in the census relate to places with agricultural operations qualifying as farms according to the census definition. In Puerto Rico, this included all places from which $500 or more of agricultural products were produced and sold, or normally would have been sold, during the 12-month period between January 1, 2012 and December 31, 2012.

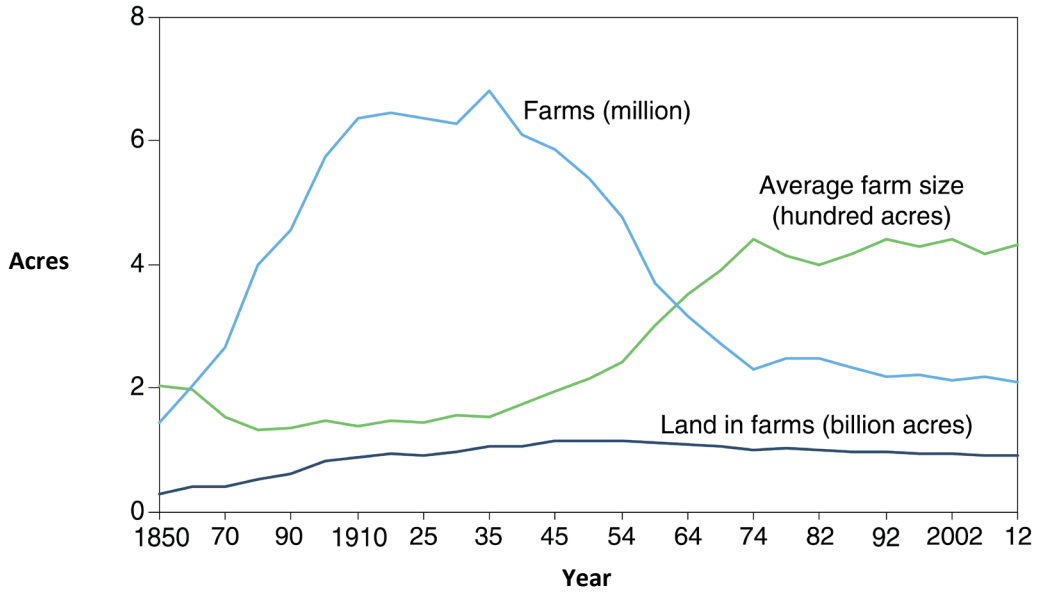

Figure 3-3. Land Use Trends: Farms, Land in Farms, and Average Acres per Farm, 1850-2012
Source: (USDA-ERS 2013)

Since the 1970s, the trend in decline in the number of farms and increase in the size of farms has relatively stabilized. Despite slight declines in the number of farms and total farmland acreage in recent years, with acreage dropping from 922 million acres in 2007 to 915 million acres in 2012 (Table 3-1) (USDA-NASS 2014d), [38] total acreage and the areas used for agricultural production of major crops are not expected to significantly deviate from current levels through 2024 (Westcott and Hansen 2015). Minor fluctuations in total farmland will occur on an annual basis relative to market demand and pricing for given agricultural products, although USDA projections have farmland remaining fairly steady over the next decade for the eight major crops produced in the United States (Figure 3-4).

Table 3-1. Farmland and Farms in the Continental United States and Hawaii

	2007	2012	% Change
Number of Farms	2,204,792	2,109,303	-4.3
Farmland (acres)	922,095,840	914,527,657	-0.8
Average Farm Size (acres)	418	434	+3.8

Source: (USDA-NASS 2014c)

[38] The USDA census definition of a farm is any place from which $1,000 or more of agricultural products were produced and sold, or normally would have been sold, during the census year.

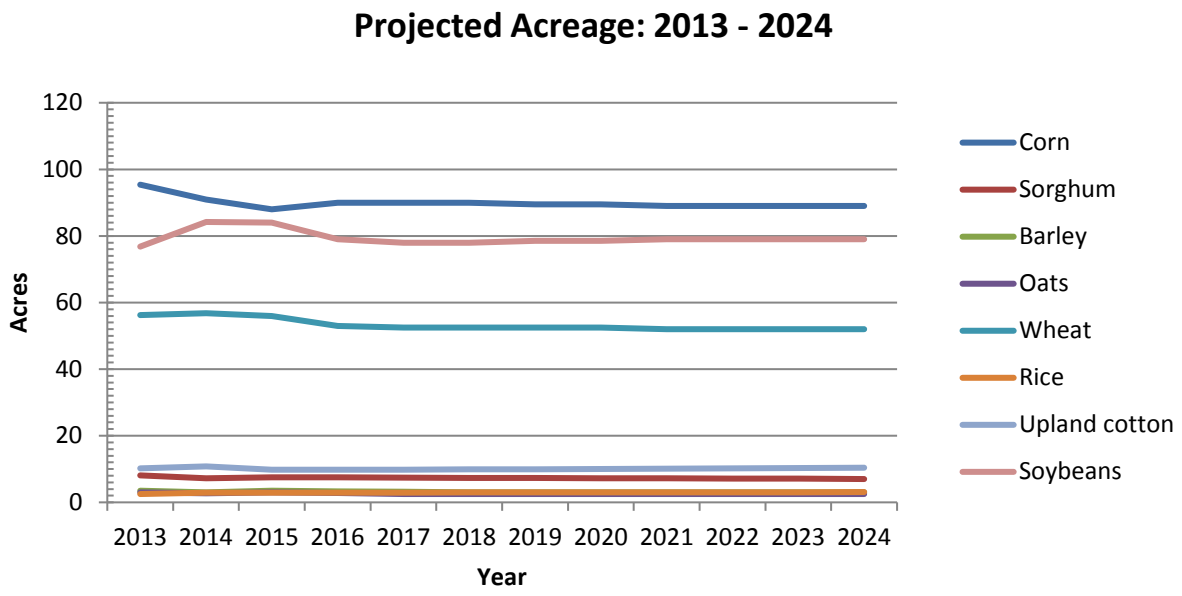

Figure 3-4. Projected Acreage for the Eight Major Crops: Continental United States and Hawaii
Source: (Westcott and Hansen 2015)

Farmland continues to be most heavily concentrated in the central United States, although production of various crops occurs in all states to some degree (Figure 3-5). In Puerto Rico (2.2 million total acres of land), farmland comprises approximately 26% of total land; around 585 thousand acres.

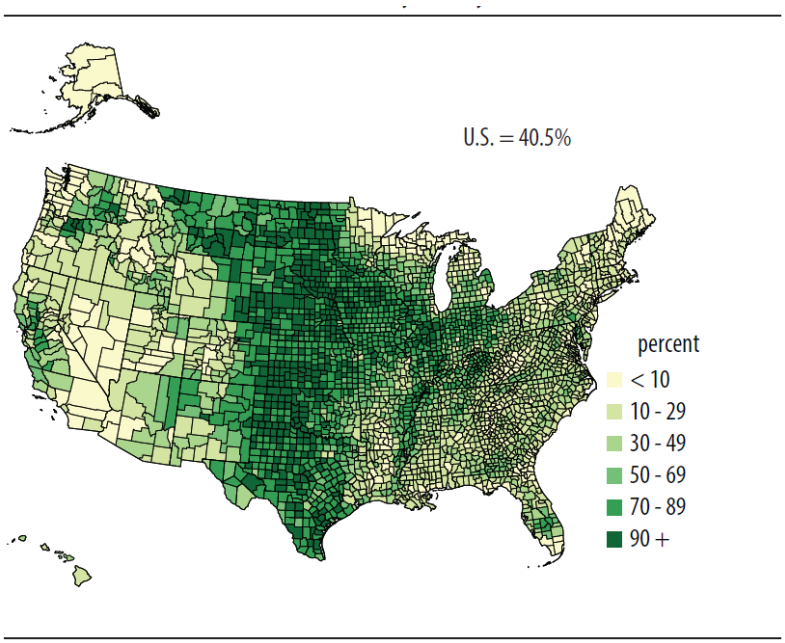

Figure 3-5. Farmland as Percent of Land Area in the Continental United States and Hawaii: By County, 2012
Source: (USDA-NASS 2014d)

3.2.2 Agricultural Land Uses

Table 3-2 summarizes the primary uses of farmland in the United States for 2007 and 2012. As with total farmland, variance in these uses is not expected to significantly change through 2024-25. Minor annual fluctuations in the types of farmland uses will occur respondent to market demand for specific agricultural products, although substantial changes in cropland, pasture and rangeland, and woodland are not anticipated through 2024-25 (Westcott and Hansen 2015).

Table 3-2. Farmland Uses in the Continental United States and Hawaii, 2007-2012

	2007	2012	% Change
	Million Acres		
Total	922.1	914.5	-0.8
Permanent Pasture	408.8	415.3	+1.6
Total Cropland	406.4	389.7	-4.1
Harvested Cropland	309.6	315	1.7
Woodland	75.1	77	+2.5
Other Land*	31.7	32.5	+2.4*

* Other land: Remaining 3.6% was land in farmsteads, buildings, ponds, livestock facilities, etc.

Source: (USDA-NASS 2014d)

Table 3-3 summarizes the primary uses of agricultural lands in U.S. Caribbean territories (including Puerto Rico and the U. S. Virgin Islands), which comprise a total area of 2,259,000 acres. The three main inhabited islands of the U.S. Virgin Islands include St. Croix (53,760 acres total land), St. John (12,800 acres), and St. Thomas (20, 480 acres). Crop, rangeland, and pastureland for Caribbean territories in aggregate have declined over the last few decades (USDA-NRCS 2012b). Puerto Rico has experienced the same trends in the declining number of farms and increasing farm size as seen in the continental United States. Farmland in Puerto Rico increased around 5% from 2007 to 2012, and total cropland around 10%. As with the continental United States, these trends are commensurate with agronomic advancements in agricultural production (Table 3-4) (USDA-NASS 2014b). The most recent data available for farmland uses in the U.S. Virgin Islands is summarized in Table 3-5.

Table 3-3. Farmland Uses in Caribbean Territories

Year	Cropland	Pastureland	Rangeland	Forest Land	Other Rural Land
			Thousands of Acres		
1982	396.7	751	154.6	520.1	49.6
2007	255.3	448.9	128.5	683.4	63.3

Source: (USDA-NRCS 2012b)

Table 3-4. Puerto Rico Farms and Farmland, 2007 and 2012			
	2007	**2012**	**% Change**
Number of farms	15,745	13,159	-16.4
	Cuerdas		
Farmland	557,530	584,988	+4.9
Average Farm Size	35.4	44.5	+25.7
Pasture and Rangeland	87,951	67,150	-23.7
Total Cropland	392,728	433,563	+10.4
Harvested Cropland	116,198	127,372	+9.6
Woodland	38,390	42,712	+11.3
Other Land	38,461	41,563	+8.1

Source: (USDA-NASS 2014b)

*Note: Figures are in cuerdas,1 cuerda = .97 acre

Table 3-5. U.S. Virgin Islands Farms and Farmland Uses, 2002 and 2007			
	2002	**2007**	**% Change**
Number of farms	191	219	+14.7
	Acres		
Total Land in Farms	9,168	5,881	-35.9
Average Farm Size	48	26.9	-44.0
Permanent pasture	7,482	5,209	-30.4
Total Cropland	911	493	-45.9
Harvested Cropland	602	304	-49.5
Woodland	541	95	-82.4
Other Land	234	83	-64.5

Source: (USDA-NASS 2009)

3.2.2.1 Principal Crops

The principal crops in the United States are summarized in Table 3-6. As of 2012, soybeans and corn grown for grain together accounted for over 50% of all cropland harvested (163.5 million acres). Of the principal crops harvested, soybeans and corn for silage exhibited the largest percentage increases in acres from 2007 to 2012. Corn for grain and land in orchards also increased, while fewer acres were devoted to other crops such as forage, cotton, and vegetables. Detailed data for all U.S. crops is provided in the USDA 2012 Census of Agriculture (USDA-NASS 2014c).

In Puerto Rico, major crops include coffee, pineapple, plantains, bananas, root crops or tubers, fruits, grains and field crops, and vegetables and melons. Livestock, poultry, and their products are also a substantial part of agricultural production in Puerto Rico. In the U.S. Virgin Islands, cassava (arrowroot), sugarcane, corn, dry beans, sweet potatoes and yams, a variety of common vegetables and tropical fruits, and livestock and poultry are each significant areas of production.

Table 3-6. Principal U.S. Crops Harvested, 2007 and 2012			
	2007	2012	% Change
	Millions of Acres		
Corn for Grain	86.2	87.4	+1
Soybeans	63.9	76.1	+19
Forage	61.5	55.8	-9
Winter Wheat	35.8	34.7	-3
Spring Wheat	13.0	12.2	-6
Cotton	10.5	9.4	-11
Corn for Silage	6.0	7.2	+20
Orchard Crops	5.0	5.2	+3
Sorghum for Grain	6.8	5.1	-24
Vegetables	4.7	4.5	-4
Barley	3.5	3.3	-7
Rice	2.8	2.7	-2
Durum Wheat	2.1	2.1	0
Sunflower Seed	2.0	1.9	-6

Source: (USDA-NASS 2014c)

3.2.3 Forest Use Lands

Forest lands potentially affected by 7 CFR part 340 regulations are primarily limited to timberlands, where trees are grown specifically for use in commercial wood-based products. GE trees used for the production of commercial wood products could include those that are more tolerant of climates that would otherwise be inhospitable (i.e., cold tolerant, drought resistant), trees genetically engineered for greater wood density to provide more strength and insect resistance, or lignin modified trees that facilitate paper and paperboard production. [39]

The environmental introduction of GE trees would not necessarily be limited to timberlands, however. Certain GE trees could be introduced into unmanaged forested areas for the purposes of restoration. For example, there are current efforts to develop a blight resistant American chestnut for reintroduction into forest ecosystems of the Eastern United States. The American chestnut, once one of the most dominant trees in the Eastern United States, is effectively extinct as a result of a pathogenic fungus (*Cryphonectria parasitica*) that has destroyed most of the U.S. population.

3.2.3.1 Current and Projected Uses

The United States is one of the world's leading producers of wood products, such as industrial round-wood used for furniture, and lumber, paper, and paperboard (FAO 2014a). These

[39] The removal of lignin from wood requires caustic chemicals, is energy intensive, and produces waste. Lignin modified GE trees could potentially reduce current chemical and energy requirements for production of wood pulp used in paper and paperboard manufacturing.

comprise the primary wood products derived from U.S. timberlands,[40] accounting for around 94% of all timberland removals (USDA-FS 2015).

The United States has approximately 751 million acres of forest land, 623 million of which are in the contiguous United States (Figure 3-6) (Nickerson, Ebel et al. 2011). Timberlands, including natural stands and planted forests, comprise the largest category of forest at 514 million acres, nationally; around two-thirds of total forested land (DOI 2013). The greatest proportion of timberland is in the Southeast, Appalachian, and Northeast and Mountain regions. Planted forests comprise only around 63 million acres of all U.S. timber land, or 12% of total timberlands.

The remainder of total forested land is a combination of reserved forestland and other forestland, which provide recreation, watershed protection, wildlife habitats, and other special purposes depending on the region. Other forestland also includes land that is less useful for commercial wood products, but is used for other wood and tree products such as fuel (Nickerson, Ebel et al. 2011). About 43% of the reserved and other forestlands are in the Mountain and Pacific regions, where they account for over 44% of all forestland in those regions. Acreage of reserved and other forestland in the Eastern States is relatively small, accounting for approximately 8% of all forested land in all regions east of the Mississippi River (Alig, Plantinga et al. 2010, Nickerson, Ebel et al. 2011).

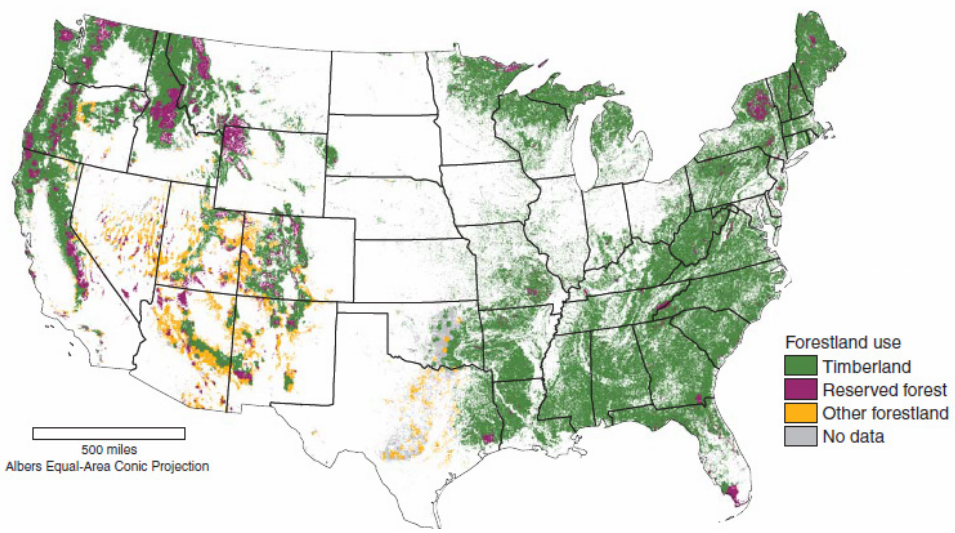

Figure 3-6. Timberland, Reserved Forests, and other Forest Lands in the 48 States, 2007
Source: (Nickerson, Ebel et al. 2011)

Forest area in the United States is projected to decline from 400.7 million acres in 2012 to 375.3 million acres in 2062. The largest anticipated cause of forest loss is urban development, which is projected to lead to the conversion of 49.7 million acres of forest to urban uses by 2062 (Table 3-7) (Alig, Plantinga et al. 2010). Timber harvesting over the past 50 years has remained well

[40] Forest is classified as timberland if the forest is capable of growing 20 cubic feet of commercial wood per year. Timberlands can be used for the repeated growing and harvesting of trees. Traditionally, commercial timber production has been among the primary uses of these lands.

within sustainable limits. For example, timber removals have remained below 2% of standing tree inventory, while net tree growth has been near 3% (Alvarez 2007). Currently, the volume of annual net timber growth is 36% higher than the volume of annual timber removals (Alvarez 2007).

Table 3-7. Projected Areas for Major Land Uses on Non-Federal Land in the Contiguous 48 States, 2012 to 2062

Year	Crop	Pasture	Forest	Urban	CRP*	Range
			Million Acres			
2012	368.9	110.6	400.7	101.8	27.3	404.0
2062	356.7	86.2	375.3	176.4	20.2	398.2

Source: (Alig, Plantinga et al. 2010)

*CRP = USDA Conservation Reserve Program

Forestland in U.S. territories is generally projected to increase in coming years due to conservation efforts in the U.S. Virgin Islands and Puerto Rico. Puerto Rico consists of approximately 1.2 million acres (53%) of forest, on both public and private lands (PR-DNR 2010). In general, there is little potential in Puerto Rico for full scale industrial timber production due to limited acreage, topographical factors, land holdings, and local laws. However, small-scale industries exist that serve domestic markets (PR-DNR 2010). Commercial timber species include mahogany, teak, eucalyptus, Caribbean pine, maría, and mahoe.

Commercial forestry is not a significant activity in the U.S. Virgin Islands; there are no forests in the U.S. Virgin Islands owned by the forest industry. The U.S. Virgin Islands timberland is owned by nonindustrial private entities and local government (Brandeis and Turner 2009). The inventory of forest covers about 45,163 acres, or about 45% of the islands, a very small percentage of which is saw timber. The majority of forested land is privately owned (89%) and most is not managed for forest activities, with the exception of properties in the Forest Stewardship Program of the U.S. Virgin Islands Department of Agriculture. The last published data has timber production at 188,500 board feet per year (Chakroff 2010), which is used almost exclusively on-island, primarily for custom house building. Secondary forest products, or non-timber forest products, are wooden arts and crafts, medicinal items, and cultural items. There is no export market for timber products (Chakroff 2010).

3.2.4 Regional Agricultural and Forestry Land Uses in the United States

In the United States, regional variations in production of agricultural/forestry products are reflective of differences in soil types, climate, topography, and population. Major stresses such as temperature extremes, water availability, pest pressures, and unsuitable soil quality preclude production of agricultural and forestry commodities in certain regions.

Basic land use patterns (latest 2007 data) attributed to agricultural uses across cropland, pastureland, rangeland, and forestry are summarized in Figure 3-7. Nearly half of the Nation's cropland is concentrated in 2 of the 10 Farm Production Regions, the Corn Belt, and the Northern Plains. These regions combined contain 24% of U.S. cropland.

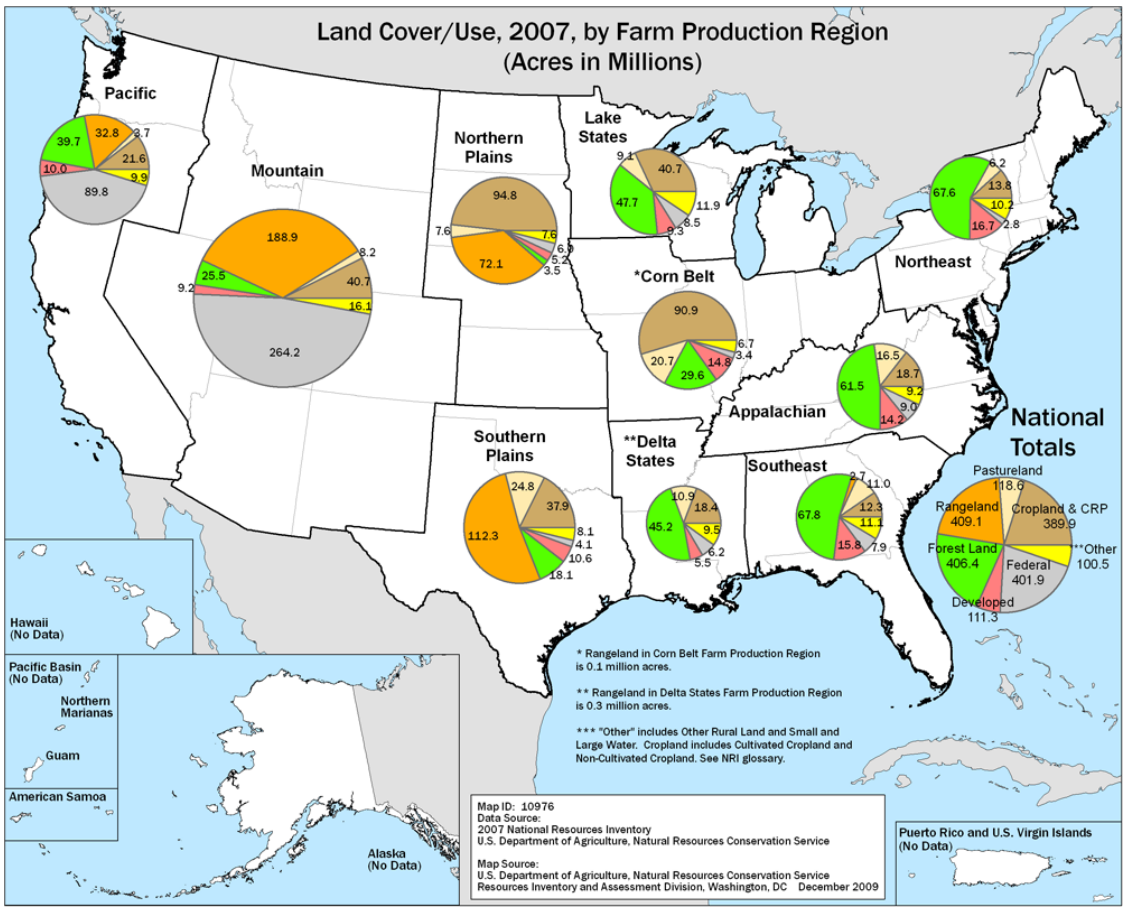

Figure 3-7. Regional Agricultural and Forestry Land Use Types in the United States, 2007
Source: (USDA-NRCS 2010)

3.2.4.1 Land Resource Regions and Agricultural Activities in the United States Caribbean, and Pacific Basin

To further categorize the specific types of agricultural activities that occur across the United States and its territories, the USDA uses land resource units, major land resource areas, and land resource regions (LRRs). LRRs are geographically delineated areas that approximate the primary agricultural activities in these regions (Figure 3-8). The agricultural activities occurring in LRRs and associated environmental concerns are summarized in Table 3-8.

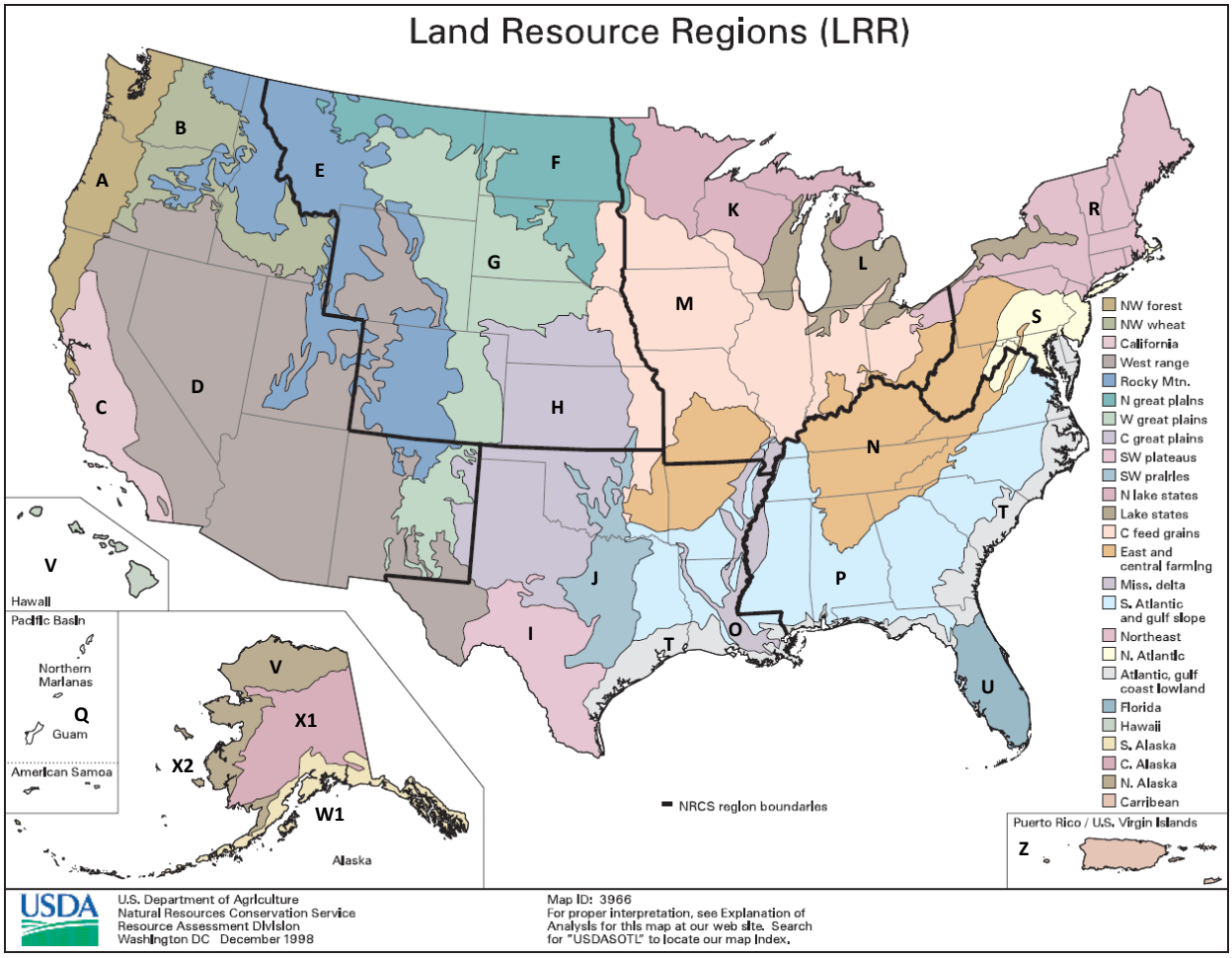

Figure 3-8. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

Table 3-8. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

Region		Agricultural Activities		Environmental Issues
A	**Northwestern Forest, Forage, and Specialty Crop**	• grain crops • grass and legumes • fruits	• orchards • vineyards • horticultural specialty crops	Water erosion in orchards, vineyards. Sediment from logging.
B	**Northwestern Wheat and Range**	• grazing land (primary) • wheat (major crop) • oats • barley • lentils • peas • potatoes	• apples • sugar beets • beans • forage crops • vegetables • vegetable seeds • mint and hops	Water and wind erosion, surface compaction, maintenance of soil organic matter, conservation of soil moisture are major resource management concerns on cropland. Overgrazing and invasion of undesirable plant species are resource management concerns on grazing lands.

Table 3-8. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

C	**California Subtropical Fruit, Truck, and Specialty Crop**	• citrus fruits and other subtropical and tropical fruits • nuts (major crop) • vegetables • rice • sugar beets	• cotton • grain crops • hay • dairying (major enterprise) • beef cattle production on feedlots and rangeland also is important	Soil erosion and maintenance of the content of soil organic matter throughout this agriculturally rich region. Wind erosion is a hazard in the valley. Irrigation water management is a priority, where agriculture and urban areas compete for good-quality water. Salinity and the intrusion of saltwater into aquifers are management concerns in the coastal valleys.
D	**Western Range and Irrigated Region**	• grazing • irrigated crops are grown in areas where water is available and the soils are suitable • crops for livestock are grown on much of the irrigated land	• peas • beans • sugar beets • cotton and citrus fruits are important crops in Southwestern Arizona	Soil productivity and the content of salts and sodium in the soils. Overgrazing is a concern on rangeland.
E	**Rocky Mountain Range and Forest Region**	• grazing is the leading land use • timber production is important on some of the forested mountain slopes	• grain and forage (main crops) • beans • sugar beets • peas • seed crops	The major soil resource concerns are water erosion; steep slopes; shallow, rocky soils; and a short growing season.
F	**Northern Great Plains Spring Wheat Region**	• spring wheat (major crop) • grains • flax • hay	• potatoes • sugar beets • soybean • corn	The main management concerns are a reduced soil nutrient content, increasing salinity, and susceptibility to water erosion and wind erosion.
G	**Western Great Plains Range and Irrigated Region**	• dominant land use is grazing by cattle and sheep • winter wheat • small grains	• corn • alfalfa • forage crops • sugar beets	Overgrazing, wind and water erosion, maintenance of soil organic matter are major resource concerns on cropland. Surface water quality also is a concern. Sediment, nutrients, pesticides, and organic material are the major nonpoint source pollutants of surface- and groundwater pollution. Control of saline seeps on rangeland and salt management on irrigated land are needed in some areas.
H	**Central Great Plains Winter Wheat and Range**	• production of beef cattle is the dominant enterprise • winter wheat and other small grains	• corn • alfalfa • forage crops	Overgrazing and the spread of invasive plants and noxious weeds. Wind erosion, water erosion, maintenance of soil organic matter, and soil moisture management. Surface water quality is also a concern. Sediment, nutrients, pesticides, and salinity are the major nonpoint sources of surface- and ground-water pollution. Control of saline seeps on rangeland and salt

Table 3-8. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

				management on irrigated land are concerns in some areas of the region.
I	**Southwest Plateaus and Plains Range and Cotton**	• grazing is the dominant land use • wheat • grain	• Irrigated cotton • citrus fruits • winter vegetable • sorghum, and other small grain crops	The major resource concern is overgrazing. The invasion of undesirable species also is a concern.
J	**Southwestern Prairies Cotton and Forage**	• grazing by beef cattle is the dominant land use in most of the region • hay • grain • sorghum and small grains	• corn • cotton • peanuts • pecans • vegetables where irrigation is available	Overgrazing and the invasion of undesirable plant species. Soil erosion, surface compaction, moisture management, and maintenance of the content of organic matter in the soils are additional concerns in areas of cropland
K	**Northern Lake States Forest and Forage**	• corn • wheat • alfalfa • oats • barley • soybeans • dairy and beef cattle	• sunflowers • potatoes • edible beans • sweet corn • peas • berries and fruit	Soil erosion, especially on cropland, is a major resource concern. Wind erosion is a hazard in areas of silty and sandy soils. Soil wetness, fertility, and tilth and protection of water quality are additional resource concerns
L	**Lake States Fruit, Truck Crop, and Dairy**	• dairy farming and beef cattle • corn • winter wheat	• beans • sugar beets • fruits, especially sour cherries	The major soil resource concerns are controlling the pollution resulting from the movement of sediment and pesticides by water and wind, preserving water quality, wetlands, habitat for fish and wildlife.
M	**Central Feed Grains and Livestock**	• corn • soybeans • grains for animals and hay		Soil erosion, wetness, and maintenance of soil organic matter. Wind erosion is a hazard in some of the Northern parts of the region. Protecting wildlife habitat and preserving the quality of surface water and groundwater.
N	**East and Central Farming and Forest**	• forestry is an important industry. Oak, yellow-poplar, and pine are the dominant trees harvested	• cotton • soybeans • corn • wheat	The major management concerns in areas of forestland are soil erosion resulting from harvest practices and maintenance of forest productivity. The concerns on cropland include soils quality, erosion, and prevention of ground-

Table 3-8. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

				water contamination.
O	**Mississippi Delta Cotton and Feed Grains**	• cotton • soybeans • milo • corn	• rice • sugarcane • wheat	The major management concerns on cropland include flooding, excess water, and contamination of groundwater.
P	**South Atlantic and Gulf Slope Cash Crops, Forest, and Livestock**	• cotton • soybeans • peanuts • corn	• rice • sugarcane • wheat	The major management concerns on cropland include maintenance of soil quality, control of erosion, and prevention of ground-water contamination.
Q	**Pacific Basin**	• most of the agriculture in this region is at the subsistence level: gardens, free-ranging pigs and poultry	• small but profitable commercial farms in the Marianas produce cabbage, taro, sweet potatoes, cucumbers, melons, papaya, and other fruits and vegetables for local consumption	Steep slopes, low soil fertility, stoniness, and high acidity reduce the variety of agriculture on most soils throughout the region. High humidity and rainfall also are important management concerns.
R	**Northeastern Forage and Forest**	• lumber and pulpwood • Christmas trees • maple syrup • forage and grains	• fruits • tobacco • potatoes • vegetables	Wildlife habitat and recreation are important land uses. Stoniness and steep slopes limit the use of many of the soils.
S	**Northern Atlantic Slope Diversified Farming**	• fruits • poultry • forage crops	• soybeans • grain for dairy and beef cattle	Throughout the region, urban areas are encroaching on farm land.
T	**Atlantic and Gulf Coast Lowland Forest and Crop**	• lumber and pulpwood		The loss of wetlands, cropland, and forestland to urban development. Soil erosion, maintenance of soil organic matter and productivity of the soils, salinity, and coastal flooding also are major resource concerns.
U	**Florida Subtropical Fruit, Truck Crop, and Range**	• only about 10% is cropland, which is used mainly for citrus fruits	• truck crops and some sugarcane are important sources of income	Soil erosion and maintenance of soil organic matter, management of soil moisture. Water quantity can be a problem in a few parts of this region, and maintaining the quality of surface water and groundwater is a concern.

Table 3-8. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

V	**Hawaii**	• pineapples • coffee • macadamia • papaya • floral products • tomatoes • cucumbers • head cabbage • lettuce	• green peppers • snap beans • bananas • specialty crops as ginger and taro, also are important. • cattle ranching is important to the local economy	The most significant resource concern is the invasion of foreign plants and animals. Other concerns include water erosion and nutrient and pesticide runoff and leaching.
W1	**Southern Alaska**	• land use is very diverse and includes urban and rural development, agriculture forestry, commercial fishing, mining, livestock grazing, subsistence hunting and fishing, recreation		No significant environmental issues
W2	**Aleutian Alaska**	• major land uses in the region are subsistence hunting, fishing, and gathering. Small communities with fishing operations are located in the few good harbors. A few areas are used for recreation or some livestock grazing		No significant environmental issues
X1	**Interior Alaska**	• much of this region is sparsely populated. Land use in some parts of the region includes urban development and rural settlement, agriculture , forestry, mining, subsistence hunting and fishing, and wildlife habitat		No significant environmental issues
X2	**Western Alaska**	• land use throughout the region includes reindeer herding, mining, wildlife habitat, and subsistence hunting, fishing, and gathering		No significant environmental issues
Y	**Northern Alaska**	• reindeer grazing, wildlife habitat, mineral and petroleum extraction, and subsistence hunting, fishing, and gathering are the major land uses in this region		No significant environmental issues

Table 3-8. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

Z	**Caribbean**	• dairy and beef enterprises are the main land use • plantains • bananas • yams • mangos	• tanier • vegetables • citrus fruit • coconuts • pineapples • rice	Urban developments, highways, and recreational areas are encroaching on the better farmland, especially near metropolitan areas. The main limitations of the soils in the region are shallowness to bedrock and steepness of slope.

3.3 Genetically Engineered Organisms in Agriculture, Forestry, and Industry

Since the introduction of GE crops in the mid-1990s, GE crops have expanded to comprise around 90% of the planted acres of corn, soybeans, and cotton (Fernandez-Cornejo, Wechsler and Livingston 2014b). For example, herbicide resistant (HR) soybeans expanded from 17% of U.S. soybean acreage in 1997 to 94% in 2015; HR cotton from about 10% of U.S. acreage in 1997 to 89% in 2015; and HR corn from about 6% of U.S. acreage in 1997 to around 89% of U.S. corn acreage in 2015. Insect resistant *Bacillus thuringiensis* (Bt) corn grew from about 8% of U.S. corn acreage in 1997 to 81% in 2015 (Fernandez-Cornejo, Wechsler, Livingston et al. 2014a). These 3 crops (corn, cotton, and soybeans) comprise the bulk of the acres planted to GE crops, and U.S. farmers planted about 169 million acres of these GE crops in 2013. Together, these GE crops accounted for almost half of total land used to grow crops in 2013 (Fernandez-Cornejo, Wechsler et al. 2014a). Other GE crops commercially grown in the United States are HR canola, HR sugar beets, HR alfalfa, virus-resistant papaya, and virus-resistant squash.

Due to the potential benefits provided by certain GE crop plants (e.g., reduced need for insecticide use, expansion of options in sustaining maximum yields to meet growing domestic and international demand for agricultural commodities) (Fernandez-Cornejo, Wechsler et al. 2014a, Brookes and Barfoot 2015), development and grower adoption of GE plants is expected to increase. Apart from food and fiber based crops, GE trees (i.e., faster growing, improved product quality, cold tolerant, and disease resistant) are also being explored as potentially beneficial options for commercial wood and paper production.

Prior to the commercial use of GE plants or other organisms, APHIS regulates the importation, interstate movement, and environmental release of GE organisms if (1) any of the recipient, genetic donor, or vector organisms are plant pests or of unknown classification or (2) the Administrator has determined or has reason to believe the GE organism is a plant pest. The 7 CFR part 340 applies to any living GE organism listed in current § 340.2.

In addition, a GE organism is regulated if any organism from the foregoing list that is a plant pest serves as a donor organism or vector agent used in the creation of a GE organism. Taxa containing "known plant pests" are those listed in current § 340.2. Current regulations also include a petition procedure (§ 340.5) that allows petitioners to ask APHIS to add or subtract taxa from the list in § 340.2. Specifically excluded from the regulatory scope are GE microorganisms such that the recipient microorganism is not a plant pest but is a GE microorganism that has resulted from the addition of genetic material from a donor organism

where the material is well characterized and contains only non-coding regulatory regions. Current 7 CFR part 340 regulations do not extend to the regulation of nonviable material derived from GE organisms.

APHIS currently takes two major types of actions in the regulation of GE plants and other organisms, and they are: (1) authorizing the importation, interstate movement, or environmental release of regulated GE organisms and (2) determinations of GE organisms regulatory status. APHIS activities relative to these actions are summarized below.

3.3.1 Permits and Notifications under 7 CFR part 340

When appropriate, APHIS authorizes the importation, interstate movement, and environmental release of regulated GE organisms through a permit or notification process (USDA-APHIS 2011, USDA-APHIS 2012), as described in subsection 1.3.2. APHIS uses these processes to authorize the importation, movement, or field testing of those GE organisms that are categorized as "regulated articles" under 7 CFR part 340.

3.3.2 Petition and Determination of Non-regulated Status Under 7 CFR part 340

Under 7 CFR part 340.6 in the current regulations, APHIS may determine a currently regulated GE organism should no longer be subject to 7 CFR part 340 in accordance with the petition procedure. A determination of non-regulated status means that APHIS has determined that the GE organism is unlikely to pose plant pest risks, and should therefore no longer be regulated. Once APHIS has made this determination, the GE organism will no longer be subject to 7 CFR part 340. However, use of the GE organism remains subject to all other laws and regulations relative to its use, including those laws and regulations administered by the EPA, U.S. Fish and Wildlife Service (USFWS), and FDA.

3.3.3 Authorization of Interstate Movement and Import of GE Organisms

Import and movement of regulated articles into the United States under 7 CFR part 340 requires an import permit or an import notification issued by APHIS (USDA-APHIS 2011, USDA-APHIS 2012), as described in section 2.1.3. To date, APHIS has issued more than 12,000 authorizations for the importation of GE organisms, and nearly 12,000 authorizations for the interstate movement of GE organisms. The purpose of the permit and notification procedures is to prevent the accidental release of a GE organism into the environment during interstate movement or importation. For these activities, applicants must disclose the origin and destination, the means of movement, and procedures to safeguard against the escape of the GE organism. The introduction into the United States of such regulated articles may also be subject to other regulations promulgated under the Plant Protection Act (7 U.S.C. 7701–7772; PPA) [41] and found in 7 CFR parts 319, 330, and 360.

Any unintended release of a regulated GE organism during importation or movement due to spillage, improper disposal, transportation accidents, theft, or vandalism, could pose an

[41] Under the PPA, " no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and is in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States."

unintended plant pest risk. These types of events would constitute an unauthorized release and a compliance infraction and are subject to APHIS enforcement actions.

Movement/Shipment: APHIS oversees the movement of the following groups of GE organisms if they pose plant pest risks:

- insect
- nematode
- mite
- slug
- snail
- protozoan, or other invertebrate animal
- bacteria
- fungi
- parasitic plant
- virus
- any organism similar to or allied with the foregoing

The current regulations (§ 340.7 and § 340.8) and permit/notification requirements include provisions and prescribed standards for containers, marking, and identity that apply to shipments of regulated GE organisms (USDA-APHIS 2011, USDA-APHIS 2012).

Among the GE organisms APHIS regulates, some microorganisms are exempt from permit for interstate movement.[42] These include research organisms such as *Escherichia coli k- 12,* sterile strains of *Saccharomyces cerevisiae,* and non-sporulating strains of *Bacillus subtilis*. While APHIS exempts these GE organisms from permitting and notification procedures, these exempt GE organisms must still follow the container requirements for the shipment of microorganisms.

Importation: To be authorized for importation, the GE organism and its movement must meet APHIS notification and permit requirements (USDA-APHIS 2011, USDA-APHIS 2012). To date, APHIS has received only a small number of requests to import GE organisms for non-propagative uses (human or animal food, or food processing, often abbreviated "FFP"), and these have been addressed on a case-by-case basis based on familiarity with the crop, the inserted gene or new trait, and the import conditions and intended use. Currently, few nations are exporting GE agricultural products to the United States, and the United States remains a primary exporter of these products. However, as research and development of new GE organisms increases worldwide, and other countries approve agricultural biotechnology products for domestic use or for export, the United States will likely see an increase in requests to import GE organisms for research or commercial purposes.

In addition to APHIS requirements for the importation of GE organisms under 7 CFR part 340, APHIS regulations at 7 CFR parts 319–37 (covering importation of plants and seeds for planting) and 7 CFR parts 319–56 (covering fruits and vegetables imported for non-propagative use), govern the importation of non-GE organisms. Hence, importation of GE organisms from other countries must comply with both sets of regulations.

If a foreign company or government wants to import a currently regulated GE organism into the United States, it must either have a U.S. agent obtain a permit or notification acknowledgement to authorize the import, or it must work through a domestic agent to obtain a determination of non-regulated status pursuant to the petition process described in 7 CFR part 340.6. The GE

[42] For a description of exemptions see 7 CRF 340.2 (b).

organism is subjected to the same case-by-case assessment required for domestic GE organisms. If APHIS determines that the GE organism is unlikely to pose a plant pest risk, and determines the organism is not subject to 7 CFR part 340, its progeny, and products derived from it can be imported into the United States subject to phytosanitary or other requirements imposed by U.S. regulatory agencies such as the FDA or the EPA. In most cases, the developer of a new GE organism with commercial value will seek deregulation in the United States, allowing for cultivation and use for human or animal food.

As new GE agricultural products are developed (including small grains, fruits, and vegetables) and commercialized overseas, APHIS may be required to ensure these products have undergone appropriate risk assessment before entering the United States, where the GE organism is subject to the PPA and 7 CFR part 340. Hence, as revisions to regulations are considered, APHIS needs to ensure that it has appropriate oversight over imported products in order to evaluate any risk they may present to U.S. agriculture. APHIS would address issues related to the unintentional or unauthorized importation of GE organisms into the United States that have not completed APHIS regulatory review on a case-by-case basis. Under the current regulations, authority for applying remedial measures or safeguards to prevent the introduction of regulated GE organisms, including those that may be inadvertently mixed with U.S. commodities, is found in 7 CFR part 340.0 (b). APHIS may take action under 7 CFR part 340.4 (f) to remove or destroy the commodity containing unapproved material.

3.3.4 Environmental Releases of GE Organisms in the United States and U.S. Territories

Environmental releases authorized via APHIS permit or notification procedure, which have been conducted by industry, academia, and government, have taken place throughout the United States and its territories. To date, APHIS has issued more than 18,000 authorizations for the environmental release of GE organisms at multiple sites, primarily for research and development of improved crop varieties (ISB 2015). APHIS has, to date, denied slightly more than 1,500 requests for permits or notifications, many of which were denied because APHIS ultimately decided the requests lacked sufficient information on which to base an Agency decision. Authorized environmental releases have encompassed over 100 different types of GE organisms, and include row crops, trees, turf grasses, and ornamental plants.[43] Less than 1% of the total number of authorized field releases involved non-plant species. A summary of the GE organisms field tested under APHIS authorization is provided in Table 3-9.

Table 3-9. GE Organisms Authorized for Environmental Release: APHIS Permit and Notifications

Pest, Disease, and Research Related	Crop and Pasture Plants	Ornamental Plants
Agrobacterium tumefaciens	Alfalfa	Anthurium
Arabidopsis thaliana	Barley	Begonia semperflorens
Aspergillus flavus	Barrel clover	Chrysanthemum
Bacterial spot of tomato	Beet	Cypress Vine
Belladonna	Blueberry	Dendrobium Orchid
Black nightshade	Mustard green	Easter Lily
Cephalosporium stripe	Kale	Gladiolus
Citrus tristeza virus	Turnip	Iris
Citrus viroid iii	Bunchberry	Marigold

[43] Ornamental plants are those that are grown for decorative purposes, such as cut flowers, houseplants, and those for use in gardens and landscaping.

Table 3-9. GE Organisms Authorized for Environmental Release: APHIS Permit and Notifications

Clavibacter xyli
Cryphonectria parasitica (chestnut blight)
Erwinia amylovora
Erwinia carotovora
Fusarium graminearum
Heterorhabditis bacteriophora (beneficial nematodes)
Neotyphodium Spp. (fungal endophyte)
Pectobacterium carotovorum (plant pathogen)
Pink bollworm (cotton pest)
Pseudomonas (basic research)
Rhizobium etli / R. leguminosarum (nitrogen fixation)
Tobacco mosaic virus (Tmv)
Western orchard predatory mite
Xanthomonas campestris (plant disease)

Trees
Allegheny serviceberry (*Amelanchier laevis*)
American chestnut
American elm
Aspen
Black cottonwood
Eastern cottonwood
Eucalyptus *(E. camaldulensis, E. grandis, E. urophylla)*
Loblolly pine
Pitch x loblolly pine
Poplar (*Populus* x *euramerica*)
Poplar (grey, hybrid black, hybrid Nm6)
Radiata pine
Walnut

Pharmaceutical and Industrial Plants
Guayule
Switchgrass
Rice
Tobacco
Mouse-Ear thale cress (*A. thaliana*)
Corn

Camelina / false flax
Carrot
Cassava
Chickpea
Chicory
Corn
Cotton
Cow pea / black eyed pea
Cranberry
Cucumber
Dry bean / pinto bean
Eggplant
Ethiopian mustard
Field pea
Lettuce
Melon
Oat
Oilseed rape
Onion
Pea
Peanut
Pepper
Peppermint
Potato
Rice
Romaine lettuce
Raspberry
Russian wildrye
Safflower
Sorghum
Soybean
Squash
Strawberry
Sugarbeet
Sugarcane
Sunflower
Sweet potato
Sweetgum
Switchgrass
Tobacco
Tomato
Watermelon
Wheat

Geranium
Petunia
Rhododendron
Rose (*Rosa hybrida*)

Orchard/Plantation Trees & Vines
Apple
Avocado
Banana
Carrizo citrange (sweet orange)
Banana (cavendish)
Citrus sinensis x *poncirus trifoliata*
Coffee
European plum
Galaxy apple
Grape
Grape rootstocks
Grapefruit
Grapefruit, Orange, C-22
Mexican lime
Muscadine grapevine
Papaya
Pear
Persimmon
Pineapple
Plum
Thompson seedless grapevine

Grasses
Bahiagrass
Bermudagrass
Creeping bentgrass
Dwarf Bahiagrass
Tall fescue (*Festuca arundinacea*)
Italian ryegrass
Kentucky bluegrass
Miscanthus
Perennial ryegrass
St. Augustine grass
Velvet bentgrass

Source: (ISB 2015)

Authorized field releases for testing of GE organisms (primarily plant varieties) expanded from 4 in 1985, to 1,194 in 2002, and have gradually declined since then (Figure 3-9). APHIS authorized field releases occur at discrete locations for specified periods of time, generally from 1 to 3 years. Approval of the location of field test sites involves consideration of potential environmental effects associated with the particular GE organism being evaluated. Notification performance standards and permit conditions apply specific restrictions to field tests to limit the environmental release of authorized GE organisms to the area authorized for field testing.

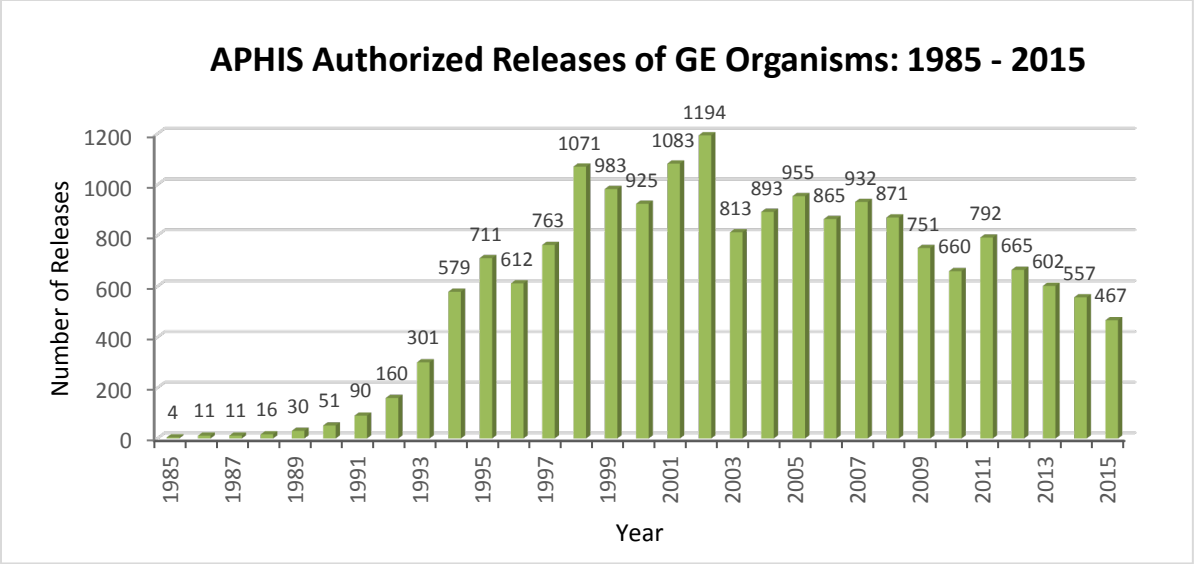

Figure 3-9. Authorized Field Releases of GE Organisms: Permits and Notifications
Source: (ISB 2015)

While the number of APHIS authorized releases has declined since 2002, the total annual acreage authorized for field tests has increased. Where a little over 139,000 acres were authorized for environmental releases in 2000, around 447,631 acres were authorized for environmental release in 2015 (Figure 3-10). The largest authorized acreage for any single permit or notification has been for field testing of GE corn, soybean, potato, and cotton; these ranging from around 10,000 to 50,000 acres.

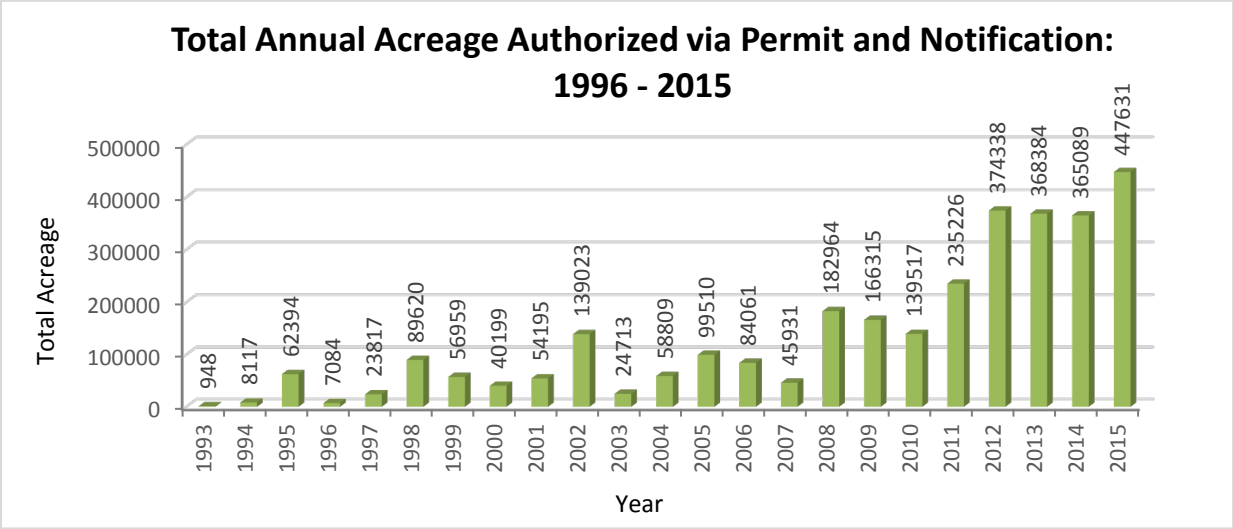

Figure 3-10. Total Acreage for Authorized Environmental Releases: 1996 – 2015
Source: (ISB 2015)
*Note: 1993 is the earliest year for which acreage data is available. Records of the release sites and authorized planting acreages prior to 1993 are not complete and are not included here. Data reflects only permits and notifications that were authorized by APHIS. Some permit requests and notifications are denied, others are

withdrawn after submission. Denied and withdrawn permit applications and notifications are not included. Data provided are estimates, there can be slight variance in the numbers due to differences in the date of issuance of a permit or acknowledgement of a notification, and the effective date of the permit or notification. Also note that not all acres authorized are actually planted.

An authorized permit or notification can comprise multiple release sites. Authorization can also include testing of more than one variety of GE organism-trait combination (phenotypic categories),[44] each of which may be tested at the authorized sites. Hence, while the number of APHIS authorized field releases peaked in 2002, a more accurate indication of the amount of research and development activity that occurs under permit or notification includes the number of authorized sites, acres, and variety of GE organism-trait combinations field tested. For instance, while the number of field releases authorized in 2015 was only about half the number in 2006, the number of sites authorized in FY 2015 was about double the number authorized in 2006, the number of acres was almost 5.5 times larger, and the number of authorized phenotypic categories was 21.5 times larger.

Field trial data for 2015 is provided in Figure 3-11 and Figure 3-12. For example, APHIS authorized, via permit or notification, a total of 91 field trials in Iowa in 2015; these were conducted across 1,059 individual sites. Data on all current and prior field trials authorized by APHIS is publicly available at the USDA funded Information Systems for Biotechnology website (ISB 2015).

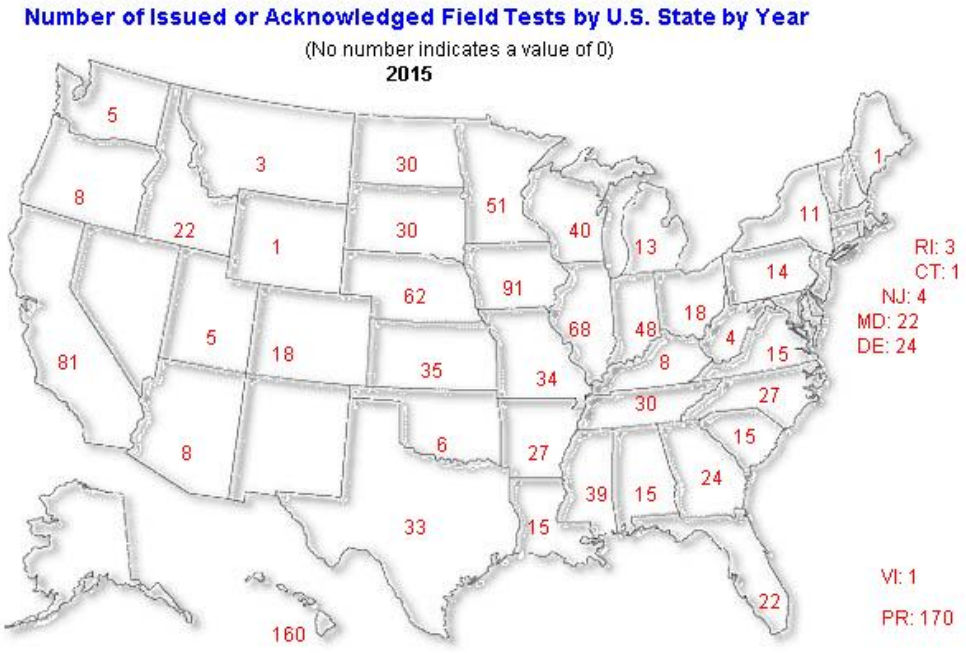

Figure 3-11. Total Number of Field Tests Authorized by APHIS in 2015
Source: (ISB 2015)

[44] Phenotype is the collective expression of genes in an organisms DNA (genotype) that determine characteristics such as morphology, physiology, biochemistry, etc. Phenotype can be determined by both genes alone, and the interaction of the genotype with environmental factors. APHIS currently categorizes the traits that are expressed in GE organisms into 10 phenotypic categories.

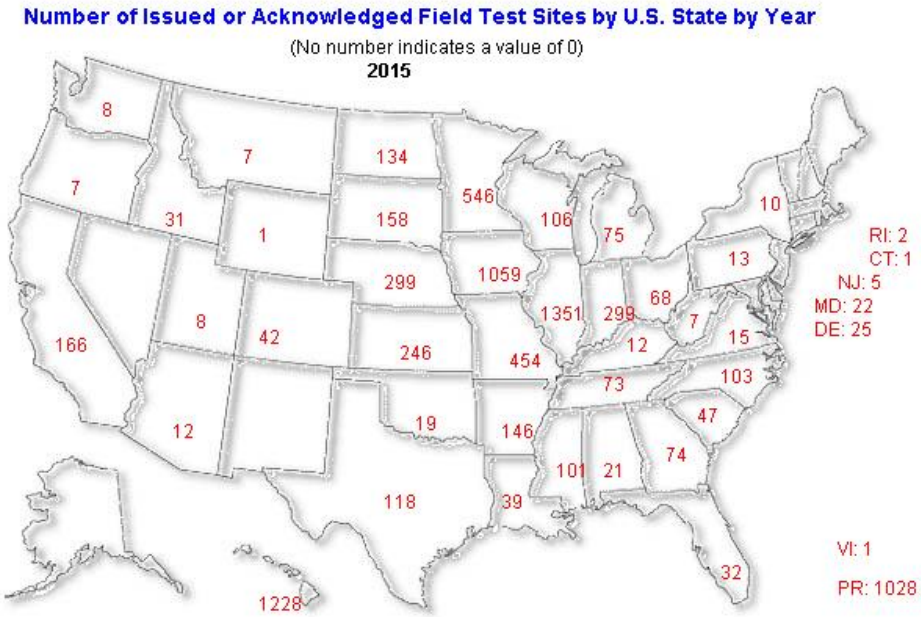

Figure 3-12. Total Number of Field Sites Authorized by APHIS in 2015
Source: (ISB 2015)

Because the vast majority of field trials involved GE plants (as summarized in Table 3-9), this has resulted in a greater number of requests and approvals for locations with climate and field conditions conducive to plant growth, as is evident with the large numbers of field tests conducted in Hawaii, Puerto Rico, Illinois, Iowa, and California. Figure 3-13 summarizes the distribution of field trials authorized throughout the United States and its territories.

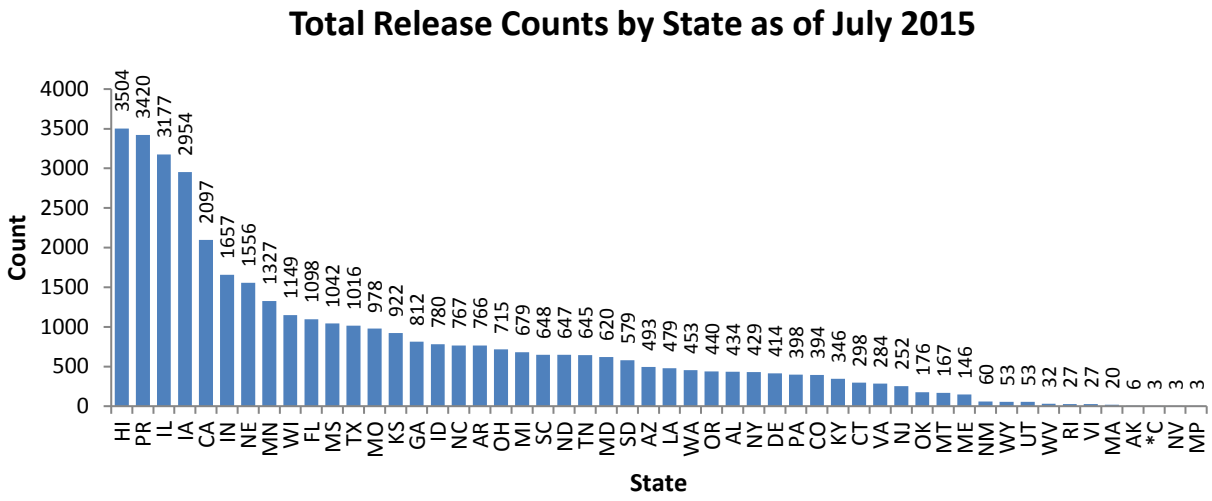

Figure 3-13. GE Organism Field Trials by State
Source: (ISB 2015)

3.3.4.1 GE Plants

Most authorized field trials have involved major crop plants. For example, between the years 1997 and 2016, GE corn has been approved for 8,428 field releases; GE soybeans for 2,496 field releases; GE cotton for 1,177 field releases; and GE potatoes for 955 releases (Figure 3-14).

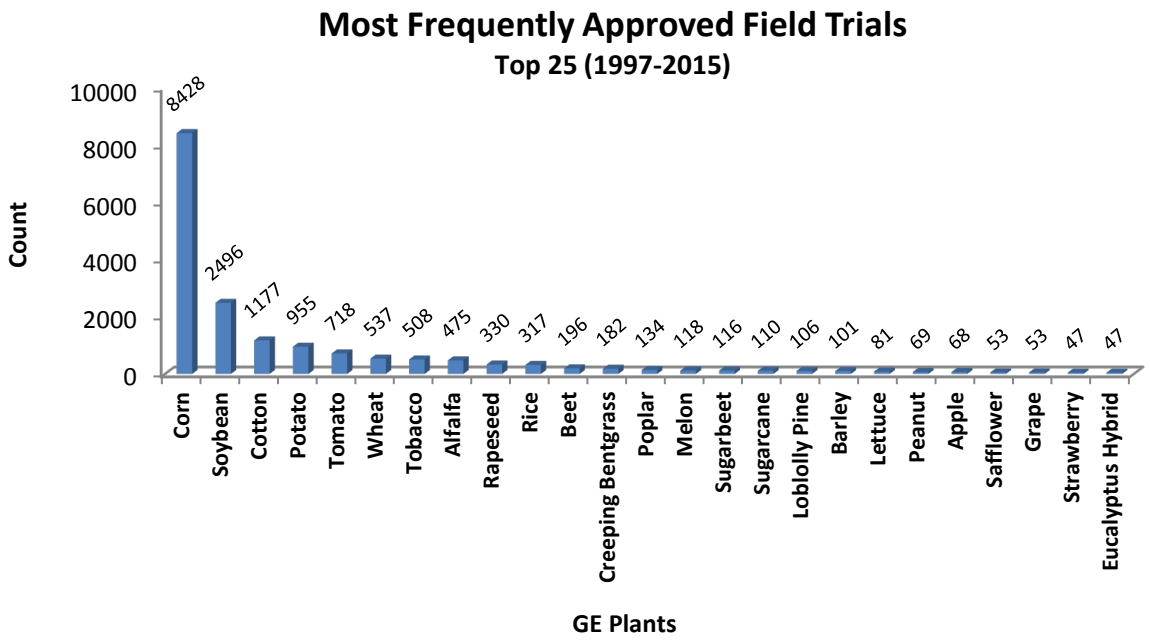

Figure 3-14. GE Plant Varieties Approved for Field Trials
Source: (ISB 2015)

Table 3-10 summarizes the distribution of APHIS authorized field trials for the top 25 GE plants by percentage of total field trials conducted. GE corn varieties comprise ~44.9% of field trials, soybean 13.3%, cotton ~6.3%, and potato ~5.1% of all field trials. Field releases for all other GE plant varieties have each comprised less than 4% of total field releases (as of July 2016).

Table 3-10. Total and Percentage of Field Trial Counts: 25 Most Frequently Approved GE Plants as of July 2016

Regulated GE Plants	Total Releases	% of Total Releases
Corn	8428	44.9%
Soybean	2496	13.3%
Cotton	1177	6.3%
Potato	955	5.1%
Tomato	718	3.8%
Wheat	537	2.9%
Tobacco	508	2.7%
Alfalfa	475	2.5%
Rapeseed	330	1.8%
Rice	317	1.7%

Table 3-10. Total and Percentage of Field Trial Counts: 25 Most Frequently Approved GE Plants as of July 2016		
Beet	196	1.0%
Creeping Bentgrass	182	1.0%
Poplar	134	0.7%
Melon	118	0.6%
Sugarbeet	116	0.6%
Sugarcane	110	0.6%
Loblolly Pine	106	0.6%
Barley	101	0.5%
Lettuce	81	0.4%
Peanut	69	0.4%
Apple	68	0.4%
Safflower	53	0.3%
Grape	53	0.3%
Strawberry	47	0.3%
Eucalyptus Hybrid	47	0.3%

Source: (ISB 2015)

Authorizations of field trials for GE plants, via permits and notification acknowledgements, has included total acreage ranging from .001 up to 100,000 acres. An authorized field trial could include either one site, or multiple sites across an authorized area. Hence, the size of a field trial site is relative to the total acres authorized for the field trial, the number of individual sites authorized for field testing, and acreage actually planted for field testing. While APHIS authorizes a specific amount of acreage, and the number of sites for field testing of GE organisms, not all field tests are actually conducted. For example, in fiscal year 2012 (latest year for which compiled data is available), APHIS authorized via notification 8,870 sites for field testing of GE organisms. Of these, only 1,967 sites were actually planted (22.2%). Similarly, APHIS authorized 2,732 sites via permit in FY 2012, of which 1,160 were planted (42.5%). Hence, the acreage actually utilized for field tests is commonly less than that authorized under the notification or permit.

The median size of an authorized field trial site is approximately 5 acres, and average size about 20 acres, although some field trials, particularly for corn, soybean, cotton, rice, and potato, can range from several hundred to a few thousand acres in size. Summary data on the size of field trials for 25 most frequently tested GE plants are provide in Table 3-11. Field trials are typically smaller during the research and development phases and increase in size when seed production is expanded in anticipation of commercialization of seed. Authorization requests are typically submitted months in advance of planting in anticipation of research and development needs, and often entail requests for much more acreage than is actually planted. Data in Table 3-11 provides general figures on the size of field trials. The actual size of individual field trials will vary, although will largely be within the scope of the acreage data provided below.

Table 3-11. Size of APHIS Authorized Environmental Releases: 25 Most Frequently Field Tested GE Plants

Regulated GE Plants	Total Acreage per Authorized Permit and Notification		Total Acreage per Authorized Site	
	Average	Median	Average	Median
Corn	255	12	16	4
Soybean	505	15	27	5
Cotton	271	12	30	5
Potato	167	2	20	1.5
Tomato	3	1	2	1
Wheat	15	3	5	2
Tobacco	33	1	9	0.5
Alfalfa	65	8	19	5
Rapeseed	76	10	27	4
Rice	34	2	16	1
Beet	16	5	5	1
Creeping Bentgrass	34	3	18	1
Poplar	3	1	2	1
Melon	4	1	2	0.5
Sugarbeet	97	10	13	5
Sugarcane	3	1	2	1
Loblolly Pine	6	1	2	0.5
Barley	1.5	1	1	1
Lettuce	3	1.5	1	1
Peanut	1	1	1	1
Apple	2	1	1	1
Safflower	185	7	54	5
Grape	5	2	3	1
Strawberry	1	0.5	0.5	0.5
Eucalyptus Hybrid	14	1	3	1

Source: (ISB 2015)

3.3.4.2 GE Microorganisms

GE microorganisms are developed for a variety of purposes (Amarger 2002, Vidaver, Tolin and Post 2012). Current research is investigating their use in the bioremediation of pollutants in contaminated soils and water; as biocontrol agents; to serve as nitrogen fixing bacteria; and for production of pharmaceutical and industrial compounds. GE microorganisms are also developed to investigate plant pests and disease. For instance, GE *Erwinia amylovora*, which causes fire blight, a contagious disease affecting apples and pears, and GE *Fusarium graminearum*, which causes head blight, a disease affecting wheat and barley, have been developed to investigate mechanisms of disease and disease prevention.

In accordance with the Coordinated Framework, APHIS regulates GE microorganisms that are plant pests under the PPA; the EPA regulates microorganisms and other GE constructs intended for pesticidal purposes and subject to the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA). The EPA also regulates certain GE microorganisms used as biofertilizers, bioremediation agents, and for the production of various industrial compounds including biofuels under the Toxic Substances Control Act

(TSCA). In addition, under the FFDCA, FDA regulates microorganisms, including GE microbes, and their products that are used in human and animal food.

GE insects, nematodes, bacteria, viruses, and other regulated microorganisms subject to 7 CFR part 340 do not qualify for notification; a permit application must be submitted for introductions of these types of GE organisms. Examples of APHIS regulated environmental releases for GE bacteria include:

- *Clavibacter xyli* for insect control
- *Pseudomonas* species for modified growth characteristics (ability to survive epiphytic stress), virulence reduction (removing or inactivating virulence genes), and expression of marker genes
- *Erwinia amylovora* and *E. carotovora* conferring marker genes and avirulence (inactivation of virulence genes)

Since 2007, APHIS has issued an average of 68 GE microorganism interstate movement permits per year, and a total of 617 from 2007 through 2015. During the same time frame, APHIS authorized an average of 3 environmental release permits per year for GE microorganisms, and a total of 26 from 2007 through 2015.

The few examples of GE microorganisms that are currently used in agriculture include GE A*grobacterium radiobacter* K1026 and *Bacillus thuringiensis kurstaki* strain EG7841, which are used as biocontrol agents. The use of these GE microorganisms is regulated by the EPA under FIFRA. GE *Agrobacterium radiobacter* K1026 is a derivative of *A. radiobacter* K84, a naturally occurring soil bacterium effective in protecting against crown gall disease in nut trees, ornamentals, and stone fruit such as cherries and plums (Vidaver, Tolin et al. 2012). *Bacillus thuringiensis kurstaki* strain EG7841, known by the trade name Crymax, has been engineered to guard against lepidopteran larvae that defoliate and damage plant tissue (Vidaver, Tolin et al. 2012).

Over the years, APHIS has reviewed various GE microorganisms for their potential to adversely affect agricultural health, and determined that some GE bacteria and fungi are not subject to regulation because they are not plant pests (e,g, GE *Agrobacterium. radiobacter* K1026, described above). Examples are provided in Table 3-12.

Table 3-12. GE Bacteria and Fungi Not Considered Plant Pests

Microorganism	Phenotype	Description
Trichoderma hamatum/ T. koningii	Marker Gene	Naturally occurring soil fungus that is used for the control of plant diseases. Not a plant pest and thus not subject to regulation under 7 CFR part 340.
Aureobasidium pullulans	Marker Gene	Naturally occurring and ubiquitous fungus found throughout the environment. Not a plant pest and thus not subject to regulation under 7 CFR part 340.
***Agrobacterium radiobacter* K1026**	Bacterial Resistance	EPA regulated microbial pesticide used to control crown gall disease in woody plants. It is a non-pathogenic strain of Agrobacterium.

3.3.4.3 GE Nematodes

Pathogenic nematodes have been frequently used to manage agricultural pests, namely insects and arthropods, for many years. Nematodes are a phylum of roundworms found in soil or water, and some species are naturally parasitic in plants or animals. To date, APHIS has only authorized one GE nematode, *Heterorhabditis bacteriophora*, for field release. This species was genetically engineered for enhanced thermotolerance (Hashmi, Hashmi, Glazer et al. 1998).[45] Unmodified *H. bacteriophora* is commonly used for the biological control of grubs, moths, beetles, and other pests; the GE *H. bacteriophora* was developed to allow use of the nematode in a wider range of environments. It is expected there will be further development of beneficial GE nematodes, and that APHIS may be regulating more GE nematode environmental releases. Nematode biotechnology research largely involves development of traits that would enhance pest and disease control.

3.3.4.4 GE Organisms Developed for Pharmaceutical and Industrial Purposes

Development of GE plants and microorganisms to produce pharmaceutical or industrial products is an emerging interest due to the potential social and economic benefits, as well as production efficiencies, that could derive from this technology. These are discussed as a specific category of GE organisms given their purpose is not for the production of food or fiber products. To date, it is largely GE plants producing pharmaceutical or industrial products that APHIS has regulated, and emphasis will be given to these. However, GE microorganisms are also a potential source.

A variety of plants such as corn, rice, tobacco, and potato are being investigated for the production of drugs or biologics that can be used to treat or prevent disease in humans and animals. Interests in plant made industrials include enzymes for use in detergents, and polymers for use in manufacturing. For example, APHIS currently regulates the field testing of GE switchgrass designed to produce proteins for decontamination of soil pollutants, and GE rice, corn, and potato to produce pharmaceutical proteins.[46] Due to the concerns about the inadvertent mixing of GE P/I-producing plants that are also cultivated for human or animal food (i.e., corn), these are handled very differently from those GE crop plants developed for use as food and fiber. Under current regulations, GE P/I-producing plants are field tested under highly stringent conditions in areas of low agricultural production, and required to be field tested only under permits, which are issued on a case-by-case basis after scientific review.[47] GE P/I-producing plants field tested under APHIS authority are also inspected much more frequently than regulated food and fiber GE crop plants.

In 2003, APHIS modified its permit confinement measures and procedures to verify compliance and to enhance the transparency for permits intended for pharmaceutical and industrial use to include: a larger perimeter fallow zone (50 ft); cleaning of field equipment and storage facilities

[45] Thermotolerance is the ability of an organism to withstand heat.

[46] Release Permits for Pharmaceuticals, Industrials, Value Added Proteins for Human Consumption, or for Phytoremediation: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/reports/pharma-table

[47] See USDA-APHIS Biotechnology Regulatory Services, Permit User's Guide With Special Guidance for ePermits [v. 3/7/2012]: https://www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf

using APHIS-approved procedures; dedicated planting and harvesting equipment and storage facilities; planting restrictions in the subsequent growing season; APHIS approved training; and additional compliance and inspection oversight by APHIS.[48] Field trials of GE P/I-producing plants are currently somewhat limited. For example, in 2015 APHIS issued only 3 permits for the field testing of GE P/I-producing plants; in 2014, 6 permits; and in 2013, 3 permits.[49] Much of the work has moved to non-food crop platforms (e.g., tobacco) where expression levels have been increased through technological breakthroughs making indoor production feasible. To date, no GE organisms that produce pharmaceutical or industrial compounds have been deregulated by APHIS.

3.3.5 Compliance and Enforcement Actions

Current 7 CFR part 340 describes APHIS' compliance, enforcement, and remediation activities that may be taken under PPA authority. When APHIS authorizes the import, movement, or environmental release of GE organisms by issuing permits and acknowledging notifications, APHIS requires compliance with 7 CFR part 340, including those conditional requirements that may be prescribed in the permit or notification (USDA-APHIS 2011, USDA-APHIS 2012). APHIS conducts targeted and random inspections of field tests and evaluates potential noncompliance incidents. The Agency also inspects facilities, and may inspect and review equipment, records of developers, and potential incidents reported by permittees. Authorizations under the permitting and notification procedures require that noncompliance incidents be reported to APHIS by the person authorized within designated time frames described in the notification or permit.

If an incident occurs, APHIS requires that compliance with regulations quickly be restored by the permittee or notifier to protect U.S. agriculture, the food supply, and the environment. Incidents with low potential impacts may require simple remedial actions, such as correcting clerical errors or improving monitoring procedures. Serious incidents, such as unauthorized or accidental releases, may require destruction of research plots, quarantine of harvested crops, formal corrective action plans, or other long-term measures. When the permittee or responsible person self-reports an incident, they will typically have already begun to implement corrective actions. APHIS strives for long-term compliance by having permittees reassess and modify their existing procedures to prevent recurrence of incidents. A serious incident, or a history of lesser incidents, could prompt involvement of APHIS' Investigative and Enforcement Services for further investigation. APHIS also works closely with state departments of agriculture and other federal agencies, including the FDA, the EPA, and the Department of Justice, to ensure compliance with APHIS regulations.

Since 1995, there have been thousands of authorized field releases under permit and notification (as described throughout this section). Between 1995 and 2015, there were 23 instances of noncompliance with APHIS regulatory requirements resulting in civil penalties (USDA-APHIS 2016b). Hence, permit and notification holders have largely had a successful history of compliance with APHIS current regulations. When the responsible person has not adhered to

[48] 68 Federal Register, No. 46 (Monday, March 10, 2003), pp. 11337 - 11340, Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds

[49] USDA-APHIS Release Permits for Pharmaceuticals, Industrials, Value Added Proteins for Human Consumption, or for Phytoremediation: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/reports/pharma-table

regulations and permit/notification requirements, the result has been a noncompliance incident. Some incidents have been serious and resulted in an APHIS investigation. Other APHIS inspection and enforcement actions have resulted in remediation (USDA-APHIS 2016b). Major incidents of noncompliance with APHIS biotechnology regulations have included failure to comply with notification performance standards for field trials; failure to notify APHIS of an accidental/unauthorized release within the required time period; failure to contain or devitalize regulated seed as required; failure to maintain appropriate isolation distances between regulated organism and non-regulated organisms; and failure to monitor for volunteers GE plants in the year following a field test on an insect resistant corn variety. In all instances APHIS required remediation actions, and in many instances, civil penalties issued.

3.3.6 Determination of Non-regulated Status and Adoption of GE Crops

As of January 2017, APHIS has made determinations of non-regulated status for 125 GE organisms (ISB 2015). These span across 18 different types of commercial crop plants (Table 3-13). Once APHIS determines it has no regulatory authority over a GE plant, it can be cultivated for commercial purposes and bred into other commercially available lines of that crop plant for the development of plant varieties with new traits. This would include traditional breeding with other GE plants that APHIS determined are not subject to regulation. Domestic and international markets influence which GE crop plants and traits are adopted by growers and sold commercially. Several crops that have been determined to have non-regulated status have either never been commercialized, or have not been widely adopted in the market (i.e., plum, rose).

Table 3-13. APHIS Determinations of Non-regulated Status as of May 2016

GE Organism	Petitions
Alfalfa (HR, PQ)*	2
Apple (PQ)*	1
Beet/ Sugar Beet (HR)*	3
Canola (HR, AP, PQ)*	2
Chicory (AP)	1
Corn (HR, IR, AP, PQ)*	38
Cotton (HR, IR)*	17
Flax (HR)	1
Papaya (VR)*	2
Plum (VR)	1
Potato (IR, VR, PQ, FR)*	8
Rapeseed (HR, AP, PQ)	7
Rice (HR)	2
Rose (PQ)	1
Soybean (HR, IR, PQ, AP)*	20
Squash (VR)*	2
Tobacco (PQ)	1
Tomato (PQ)	11

Source: (ISB 2015)

*Produced in the United States. Items with no asterisk were not commercially produced in the United States as of 2016. HR = herbicide resistance; IR = insect resistance; VR = virus resistance; AP = agronomic properties; PQ = product quality; FR = fungal resistance

GE crop varieties currently comprise around 90% of U.S. acres planted with commercial corn, soybeans, and cotton (Figure 3-15). Adoption of stacked varieties in particular has accelerated in recent years. Stacked-trait cotton reached 79% of cotton plantings in 2015, and plantings of stacked-trait corn made up 77% of corn acres in 2015. All GE cotton, taking into account the acreage with either or both HR and Bt traits, reached 94% of cotton acreage in 2015. Adoption of all GE corn accounted for 92% of corn acreage, and GE soybean adoption rates reached 94% (USDA-ERS 2015a). GE HR canola and HR sugarbeets are also above 90% adoption. The rate at which U.S. farmers adopt GE crop varieties appears to have reached a plateau for corn, soybeans, and cotton at high adoption rates of around 92-94% of planted acres. Other GE crops adopted and commercially grown in the United States are HR alfalfa, virus-resistant papaya, and virus-resistant squash.

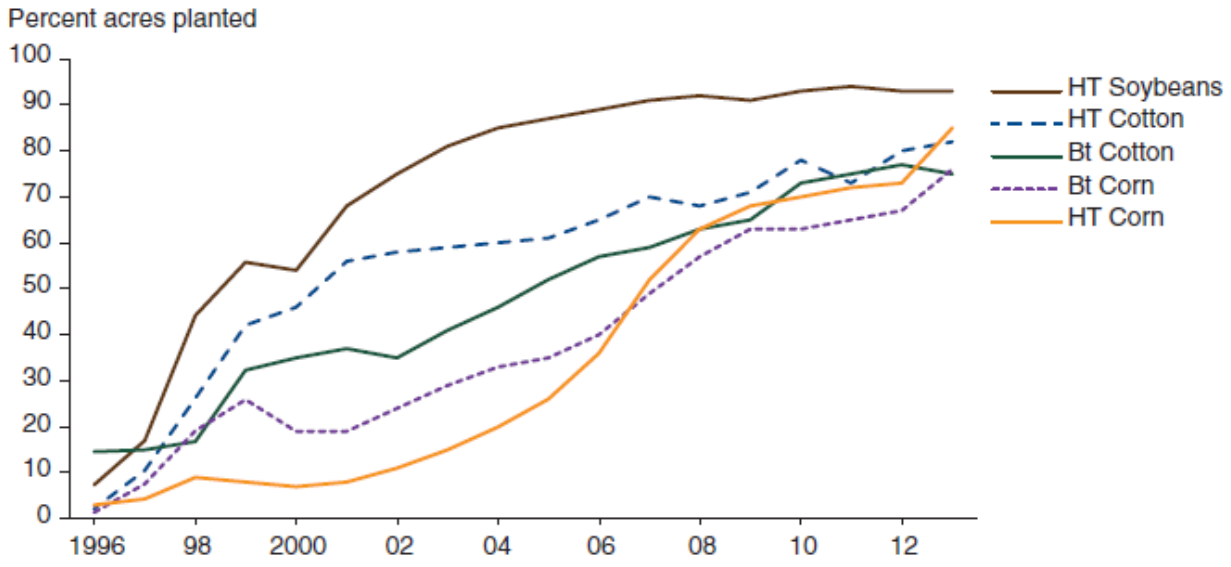

Figure 3-15. Adoption of GE Crops in the United States, 1996 through 2014
Source: (USDA-ERS 2015a)

Farmers generally adopt a GE crop relative to the benefits they can derive from it, such as increased crop yields per acre, increased farm net returns, time savings, and/or reduced exposure to pesticides (Fernandez-Cornejo, Wechsler et al. 2014a, Livingston, Fernandez-Cornejo, Unger et al. 2015). Potential net benefits are a function of the particular crop farmed and geographic location; agronomic input and market commodity prices; existing on-farm crop production systems; and farmer abilities and preferences (Fernandez-Cornejo, Wechsler et al. 2014a, Livingston, Fernandez-Cornejo et al. 2015).

While U.S. farmers have widely adopted GE varieties for corn, soybeans, cotton, and several other major U.S. crops, conventional non-GE crop varieties currently comprise more than half of U.S. cropland. The market for organic crop commodities in particular has seen significant growth over the last decade. Hence, modern agriculture is comprised of GE, conventional, and organic cropping systems, which collectively provide domestic and global needs and customer preferences for human and animal food, and fiber (Table 3-14). As for GE crops, these are generally used to produce processed foods and food ingredients, such as corn chips, breakfast

cereals, soybean protein bars, cornstarch, corn oil, soybean oil, canola oil, flaked corn, soybean meal, and canola meal.

Table 3-14. GE, Conventional, and Organic Cropping Systems in the United States: 2014

Crop	U.S. Crop Acreage, 2012-2014	GE Varieties: GE Trait	GE Varieties: Estimates for 2009-2014	Non-Ge Varieties: Conventional Systems	Non-Ge Varieties: Organic Systems
			Percent U.S. Crop Acreage		
Total U.S. Cropland	387,598,860		47	52	0.8
Field, Hay and Forage Crops					
Field corn	90,597,000	HR and/or Bt	93	7	0.3
Soybeans	84,100,000	HR	94	6	0.2
Alfalfa	18,300,000	HR	29	70	1.4
Cotton	11,400,000	HR and/or Bt	96	4	0.1
Canola	1,700,000	HR	94	6	(d)
Sugar beets	1,200,000	HR	98	2	--
Total	380,019,881		48	51	0.8
Vegetables					
Sweet corn	554,970	HR and/or Bt	8	90	2
Squash	40,050	Virus Resistance	12	71	17
Total	4,492,086		0.6	96	4
Fruits					
Papaya	2,272	Virus Resistance	68	32	--
Total	3,086,893		0.03	95.7	4

Source: (Greene, Wechsler et al. 2016)

Notes: (d) Not disclosed to protect producer confidentiality; -- = no acres reported.

As a result of the benefits provided by GE crops, they have been widely adopted in many other countries, both developed and developing. As of 2014, GE crops were planted in 28 countries, with acreage expanding more than 100-fold since the introduction of GE crop varieties in the mid-1990s. Specifically, GE crop acreage grew from approximately 4.2 million acres in 1996 to 448 million acres in 2014 (Table 3-15) (ISAAA 2014a). Net global economic benefits from GE crops at the farm level have been estimated to amount to approximately $20.5 billion in 2013 and $133.4 billion for the 18 year period between 1996 and 2013 (Brookes and Barfoot 2015).

Table 3-15. Global Area of Biotech Crops in 2014: by Country

Rank	Country	Area (million acres)	Biotech Crops
1	**USA**	180.6	Corn), soybean, cotton, canola, sugarbeet, alfalfa, papaya, squash
2	**Brazil**	104.3	Soybean, corn, cotton
3	**Argentina**	60.0	Soybean, corn, cotton
4	**India**	28.7	Cotton
5	**Canada**	28.7	Canola, corn, soybean, sugar beet
6	**China**	9.6	Cotton, papaya, poplar, tomato, sweet pepper
7	**Paraguay**	9.6	Soybean, corn, cotton

Table 3-15. Global Area of Biotech Crops in 2014: by Country			
8	**Pakistan**	7.1	Cotton
9	**South Africa**	6.7	Corn, soybean, cotton
10	**Uruguay**	4.0	Soybean, corn
11	**Bolivia**	2.5	Soybean
12	**Philippines**	2.0	Corn
13	**Australia**	1.2	Cotton, canola
14	**Burkina Faso**	1.2	Cotton
15	**Myanmar**	0.7	Cotton
16	**Mexico**	0.5	Cotton, soybean
17	**Spain**	0.2	Corn
18	**Colombia**	0.2	Cotton, corn
19	**Sudan**	0.2	Cotton
20	**Honduras**	<0.1	Corn
21	**Chile**	<0.1	Corn, soybean, canola
22	**Portugal**	<0.1	Corn
23	**Cuba**	<0.1	Corn
24	**Czech Republic**	<0.1	Corn
25	**Romania**	<0.1	Corn
26	**Slovakia**	<0.1	Corn
27	**Costa Rica**	<0.1	Cotton, soybean
28	**Bangladesh**	<0.1	Brinjal/Eggplant
	Total	448.5	

Source: (James 2014)

3.3.7 GE Traits of Regulated and Non-regulated GE Organisms

APHIS authority in determination of whether a GE organism is subject to regulation, and regulation of that organism, can involve assessment of various introduced traits. Examples of such traits include insect resistance, viral/fungal resistance, thermo-tolerance, drought resistance, modified fiber properties, modified gluten content, added nutrients, and pharmaceutical production properties. APHIS currently categorizes the traits that are expressed in GE organisms into 10 phenotypic[50] categories (Table 3-16).

Table 3-16. APHIS GE Trait Phenotypic Categories and Some Examples	
Agronomic Properties (AP)	Cold tolerance, flower development altered, growth rate altered
Bacterial Resistance (BR)	Crown Gall Resistant, Xylella fastidiosa Resistant, Xanthomonas campestris, Diffenbachia Resistant
Fungal Resistance (FR)	Stalk Rot Resistance, Powdery Mildew Resistant, Fusarium Resistance
Herbicide Resistance (HR)	Phosphinothricin, Glyphosate, and Dicamba Resistance
Insect Resistance (IR)	Lepidopteron Resistant, Coleopteran Resistant, Aphid Resistant

[50] Phenotype is the collective expression of genes in an organisms DNA (genotype) that determine characteristics such as morphology, physiology, biochemistry, etc. Phenotype can be determined by both genes alone, and the interaction of the genotype with environmental factors.

Marker Gene (MG)	Green Fluorescent Protein, Red Fluorescent Protein, Beta-glucuronidase
Nematode Resistance (NR)	Root-Knot Nematode Resistant, Soybean Cyst Nematode Resistant
Other (OO)	Transgene Excision, Transformation Frequency Increased, Novel Protein Produced
Product Quality (PQ)	Fatty Acid Level Altered, Altered Amino Acid Composition, Modified Seed Composition
Virus Resistance (VR)	Sorghum Mosaic Potyvirus Resistant, Potato Y Potyvirus Resistant, Grapevine Fanleaf Nepovirus Resistant

Most regulated field trials and U.S. acres planted with commercial GE crops are those with traits that provide HR and/or insect resistance (IR) (Figure 3-16). HR crops are able to tolerate certain herbicides, such as glyphosate or glufosinate, allowing growers the opportunity to control pervasive weeds in an efficient and cost effective manner (Fernandez-Cornejo, Wechsler et al. 2014a, Livingston, Fernandez-Cornejo et al. 2015). Commercially available HR crops include soybeans, corn, cotton, canola, sugarbeets, and alfalfa. Commercially available IR crops in the United States include corn, cotton, and soybean. Most IR crops contain a trait derived from the naturally occurring soil bacterium Bt, which produces an insecticidal protein that protects the GE plant from insect damage.

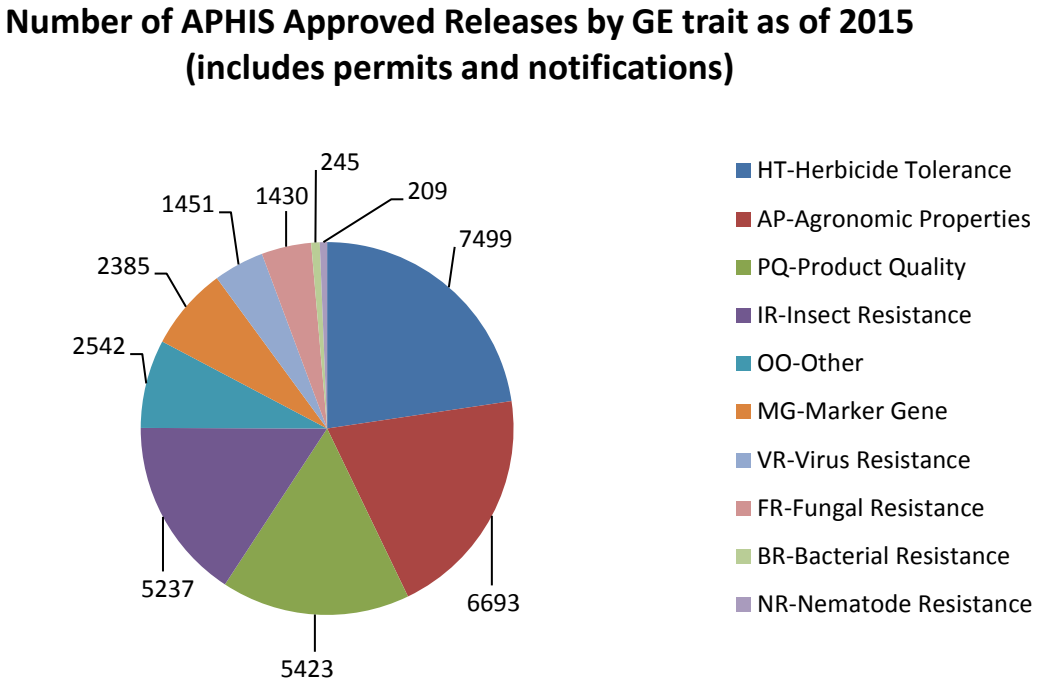

Figure 3-16. Distribution of GE Traits in Field Testing
Source: (ISB 2015)

Historically, HR and IR have been the most commonly developed, field tested, and commercially produced phenotypes. However, over the last decade, traits for improved product quality and agronomic properties have been engineered into corn and other plants. More recently, product quality, agronomic properties, herbicide resistance, and insect resistance have been combined into what are termed "stacked-trait" GE plant varieties (e.g., see (Fernandez-Cornejo, Wechsler et al. 2014a)).

As GE plants continue to be developed, APHIS expects to see more traits for resistance to plant diseases caused by bacteria, fungi, nematodes, and viruses. In the past 5 years, there have been approximately 50 field trials involving plants genetically engineered for resistance to bacterial pathogens. These types of GE crop plants could, to some degree, alter agronomic practices much in the same way as the currently available IR traits do. That is, some crop disease management practices (e.g., spraying with crop protectants) may diminish or be eliminated, and some new practices may be added, depending on the disease resistant trait and plant combination, and the prevalence and nature of plant disease in a given area.

For example, the availability of GE plants that can resist bacterial and fungal pathogens may lead to a reduction in antimicrobial pesticide use for the control of these pathogens, and allay development of antibiotic resistance. Currently, the antibiotic streptomycin is used to control fire blight on apples (73 FR 44157, July 30, 2008). However, as a result of streptomycin use in management of fire blight disease, streptomycin resistant bacteria populations have become more prevalent (73 FR 44157, July 30, 2008). Recently, and as a consequence of streptomycin resistance, the antibiotic gentamicin, used in the treatment of disease in humans, has been approved by the EPA for use on apples to control fire blight (73 FR 44157, July 30, 2008). Hence, disease resistant GE crop plants could reduce the amount of antibiotics and other pesticides that are applied to control certain microbial diseases in plants. However, as with current GE IR crop plants, these types of GE crop plants would also raise questions about potential impacts on non-target organisms, as well as the development of resistance within target pest populations.

The GE crops and traits discussed above, as well other traits in development, may be field tested in the United States or its territories under APHIS authorization. The traits currently available and in development are summarized in Table 3-17.

Table 3-17. Biotech Crops Currently Available and in Development

	Input traits				Output traits	
Crop	**Herbicide Resistance**	**Insect Resistance**	**Virus/Fungi Resistance**	**Agronomic Properties**	**Product Quality**	**Pharmaceuticals/ Nutraceuticals**
Corn	C	C	D	C, D	D	C, D
Soybeans	C	D		D	C, D	
Cotton	C	C		D	D	
Potatoes			D	D	D	D
Wheat	C		D			
Other field crops	C, D	D	D	D	D	D
Tomato, squash, melon, sweet corn		C	C, D	D	C,D	D
Other vegetables	D				D	

Papaya	C		
Fruit trees	D		D
Other trees		D	D
Flowers			D

Notes: C – Commercially available; D – In development
Source: (Fernandez-Cornejo, Wechsler et al. 2014a)

3.4 Genetically Engineered Organisms and the Environment

As described in Chapter 2, APHIS regulates the importation, interstate movement, and environmental release of GE organisms if (1) the recipient, genetic donor, or vector organisms are plant pests or of unknown classification or (2) the Administrator has determined or has reason to believe the GE organism is a plant pest. Title 7 CFR part 340 applies to any living GE organisms that are parasitic plants, microorganisms, insects, fungi, viruses, as well as those created using any plant pest organisms (bacterial and viral plant pathogens) as the donor organisms and vector agents.

The vast majority of potential environmental interactions that may derive from APHIS regulation of GE organisms are through authorized field trials of GE organisms, and the majority of these are for plants developed for food, fiber, pharmaceutical, industrial, and forestry purposes. To a lesser extent, APHIS has regulated GE ornamental plants, although this area of research and development is of increasing interest, namely in development of desired traits such as abiotic stress resistance, pest and disease resistance, and flower color. The only GE ornamental products that have thus far been introduced to the market are flower color modified varieties of carnation (*Dianthus caryophyllus*) and rose (*Rosa · hybrida*). GE microorganisms developed for agricultural purposes are primarily those used for disease control, which are regulated by the EPA (Wozniak, McClung, Gagliardi et al. 2012). GE microorganisms are also explored for antibiotic and vaccine production, such as through processes of microbial fermentation. The potential environmental interactions that may derive from the importation, interstate movement, and environmental release of regulated GE organisms are reviewed below.

3.4.1 GE Crop Plants

GE crop plants currently comprise the majority of GE organisms that APHIS regulates and reviews in petitions for determinations of non-regulated status. APHIS expects that GE crop plants will continue to comprise the larger portion of GE organisms developed for commercial purposes, and that will be subject to APHIS review and regulation under 7 CFR part 340. Stakeholder concerns regarding the environmental impacts of GE crop plants, which are recognized by APHIS, are largely those related to potential gene flow and effects of the trait gene and/or gene product on other plant species and non-target organisms, the potential "weediness" of a GE plant, and the evolution of pest or weed resistance as a result of the presence of the transgene. Indeed, gene flow is a frequently expressed public concern in regard to the field testing and deregulation of GE plants.

3.4.2 Gene Flow and Weediness of GE Crop Plants

Gene flow among GE crops and conventional and organic cropping systems is topic of great interest to commercial farmers, and international, federal, and state regulators, as such gene flow

can adversely affect farmers' net returns on crops, and domestic and international trade. Gene flow from GE plants to wild relative species is also a topic of interest among ecologists and environmentalists, federal and state regulators, as well as commercial farmers, due to concerns that a transgene may confer weediness traits to wild relatives.

Of particular interest to APHIS is the possible occurrence of gene flow from a GE plant to sexually compatible wild relative species that could lead to introgression of the trait gene in a wild population, and development of a phenotype that could adversely affect agricultural interests and/or the environment. The risk of such gene flow exists primarily when APHIS authorizes the field testing of certain regulated GE plants, and to a much lesser extent APHIS authorizations for importation and interstate movement. APHIS mitigates the risk for gene flow by imposing confinement and inspection requirements, via notification performance standards and permit conditions, on the importation, movement, and field testing of regulated GE plants (USDA-APHIS 2011, USDA-APHIS 2012).

Once APHIS has determined that a GE crop plant is not subject to 7 CFR part 340 it may be used for commercial crop production, subject to voluntary consultation with FDA, and EPA reviews and approvals, as appropriate. In this case, the potential may exist for gene flow from a GE crop plant to wild relative plants, or gene flow from a GE crop plant to a non-GE crop plant. Where these risks may exist, under current regulations APHIS has no regulatory oversight of GE crop plants that are not subject to 7 CFR part 340, nor the potential impacts that may derive from gene flow among GE and non-GE crops, or GE crops and wild relatives species. Hence, APHIS' primary interest has been gene flow during the environmental release, interstate movement, and importation of GE plants; those activities that APHIS regulates under current 7 CFR part 340.

3.4.2.1 Definition and Types of Gene Flow

Gene flow refers to the movement of genes from one genetically distinct population to another. The term "gene flow" can be synonymous with "outcrossing"[51] and the terms are used here interchangeably. Neither term implies the long-term persistence or introgression[52] of gene(s) into a recipient population. Gene flow occurs between organisms of the same species, or among closely related species. A hybrid is the offspring of two genetically dissimilar but sexually compatible species, generally within the same genus, although hybrids between different genera are possible.

Speciation is commonly defined as the origin of reproductive barriers among populations that permit the maintenance of genetic and phenotypic distinction among populations in geographical proximity (Seehausen, Butlin, Keller et al. 2014). These reproductive barriers derive from sexual/natural selection that creates extrinsic reproductive isolation, or by the evolution of genetic incompatibilities (as an indirect consequence of selection, genetic drift, and genomic conflict) that cause intrinsic reproductive isolation. Where there is genomic conflict, speciation is

[51] Outcrossing refers to the natural occurrence of gene flow among sexually compatible plants, or intentional introduction of genetic material into a breeding line with pollen from a different plant of the same species, often one that is a different variety.
[52] Introgression is the permanent incorporation of a gene(s) from one species into the genome of another. Introgression typically follows hybridization and the repeated backcrossing of interspecific hybrids. A prerequisite for introgression from a crop plant gene to a wild relative population is the occurrence of hybrids sufficiently fit to produce progeny, and for such hybrids to repeatedly reproduce in the wild. In order for introgression to occur first generation hybrids have to backcross with wild parental plants and produce fertile progeny.

much less likely to be initiated in the presence of gene flow. In general, speciation is driven by factors involving extrinsic reproductive isolation, and genome-environment interactions (Seehausen, Butlin et al. 2014).

While various factors serve to maintain the genetic and phenotypic distinction among populations, and drive speciation, these factors do not always preclude gene flow between species and hybridization among species can occur (see review by (Seehausen, Butlin et al. 2014)). In specific reference to GE plants: Gene flow between sexually compatible GE crop plants and non-GE crop plants, as well as wild plants, is possible, and an important consideration in the design of field trials and cultivation of GE food and fiber crops, as well as those crop plants developed to produce pharmaceutical and industrial compounds (PMPIs).

The study of gene flow from domesticated crop plants to wild relatives and potential ecological impacts on wild plant populations is not new; however, the advent of GE crop plants has resulted in an increased interest in such gene flow. The occurrence of gene flow from wild plants, or other crop plants, *into* commercial crops has historically been more important as breeders and seed-producers were (and still are) concerned with preserving the genetic purity of their breed-stock and seed, and consequently preventing genetic contamination by accidental pollen- and seed-based gene flow from wild plants or other crop plants (Ellstrand 2014).

Gene flow as a mechanism for the unintended movement of GE plant transgenes to non-GE crops and wild or feral plants has generated considerable discussion and research since the advent of GE crops in the 1990s. The primary environmental concerns with GE crops have been the potential for gene flow to weedy or wild relatives, and the conferring of a trait that could increase the fitness of the wild population and exacerbate any potential weediness characteristics in the wild plant. Factors such as the particular type of GE plant being grown, occurrence of wild relative(s) with which the GE plant may crossbreed, and GE trait all require consideration when evaluating the potential environmental impacts that could result from gene flow (Warwick, Beckie and Hall 2009, Ellstrand 2014).

Gene flow can occur via pollen, seeds, or vegetative propagules. The physical and biological processes and mechanisms by which pollen mediated gene flow occurs is not unique or different for GE or non-GE crops. Hence, the likelihood of occurrence of pollen mediated gene flow among all crop types (conventional, GE, and organic) and among crop plants and wild relative species is the same. As a group, GE plants are no more or less likely to hybridize with wild relatives than their non-GE counterparts (Ellstrand 2014). The rate and success of pollen mediated flow is dependent on numerous factors such as the:

- presence, abundance, and distance of sexually-compatible plant species;
- overlap of flowering times among populations;
- method of pollination;
- biology and amount of pollen produced; and,
- weather conditions, including temperature, wind, and humidity.

Gene flow can also occur as a result of seed inadvertently entering the environment during transport or being incorporated into a crop field's soil as a result of crop plant residue (e.g.,

volunteer GE plants, discussed below). Seed-mediated gene flow depends on many factors, including the absence, presence, and extent of seed dormancy; various dispersal pathways (animals, humans, water, wind); and environmental conditions, all of which facilitate or deter seed germination. Seed mediated gene flow from the occurrence of unintended volunteer GE plant populations is an important consideration, as volunteer plants occur where seed is spilled, or from volunteer plants occurring in subsequent crops planted in the same field. Such volunteer GE plant populations can serve as reservoirs from which a transgene could be passed into the genome of a wild relative or subsequent crop if the volunteer population is not detected and eliminated.

Vegetative propagation occurs naturally and is used by growers to purposely propagate certain species of crop plants (e.g., ornamentals). Vegetative propagules (e.g., rhizomes, roots, or bulbs) could allow a GE plant to reproduce in isolation and become a source of gene flow (Mallory-Smith and Zapiola 2008). Transport of propagules could also occur between fields via natural means or through the movement of equipment across or between fields (Mallory-Smith and Zapiola 2008). Vegetative propagation of field crops is limited to root crops, such as potato, yams, pineapple, and cassava. Some of the biofuel crops, such as miscanthus (*Miscanthus x giganteus*) and giant reed (*Arundo donax* L.) also reproduce via vegetative propagation. Most fruit and nut trees are vegetatively propagated by grafting.

3.4.2.2 Gene Flow to Wild Relative Species

Hybridization between conventional crops and wild relative species is known to occur and has occurred over time. Twenty-two of the world's major crops show some evidence of past hybridization with at least one wild relative (Chapman and Burke 2006, Ellstrand 2014). Gene flow from non-GE crop species to a wild or weedy relative has also resulted in the evolution of at least 8 weedy and invasive lineages (Ellstrand 2014). Most non-GE crops that are cultivated, worldwide, mate with wild relatives, and hybridization and subsequent introgression has, in some instances, created problems in terms of the evolution of increased weediness in some species, as well as economic damage (Ellstrand 2003, Ellstrand 2012). Non-GE crop to wild relative hybridization and introgression has also resulted in an increased extinction risk for wild relatives that were deemed to be rare (Ellstrand, Heredia et al. 2010, Ellstrand 2012). Consequently, given that GE crops differ little from their conventional counterparts other than the introduced trait, GE crops would pose no less risk of hybridization with wild relatives, as well as introgression of the trait into wild populations (Ellstrand, Heredia et al. 2010, Ellstrand 2012).

Because pollen-mediated gene flow naturally occurs among crops, as well as between crops and wild relatives, the introduction of GE crops and trees has raised concerns about gene transfer between sexually compatible GE and wild plants, and potential impacts on agricultural production and the environment. Currently, commercially grown GE HR crops in the United States include soybeans, corn, cotton, oilseed rape/canola, sugarbeets, alfalfa, and rice.

Commercially grown Bt crops in the United States include corn and cotton. Commercially grown GE virus resistant crops are papaya and squash. Soybean, cotton, and corn, do not have compatible wild relatives in the United States; hence, the risk of gene flow to wild relatives is not a significant concern. Gene flow to feral or wild relatives of papaya is not considered an issue

because no wild relatives occur where the crop is grown (Hawaii, Puerto Rico, Florida) and the crop itself is not weedy.

Rice and oilseed rape/canola do have compatible relatives in the United States (e.g., red rice and Brassica species, respectively) and outcrossing with wild relative species may occur. The issue of bolting of and possible gene flow from GE sugarbeets to wild compatible species is primarily a concern in California where the common beet (*Beta macrocarpa*) can be found. While of some concern, sugarbeet (*Beta vulgaris*) rarely bolts and is not freely compatible with *B. macrocarpa.* Cultivated squash (*Cucurbita pepo*) is another species that will hybridize with its wild relative, *C. pepo*.

Cultivated alfalfa (*Medicago sativa* L.) is sexually compatible with feral alfalfa (*Medicago sativa* L.)[53], found along roadsides and in natural and semi-natural habitats. With the exception of introduced naturalized populations of yellow flowered alfalfa (*Medicago sativa subsp. falcata* L.), close relatives of alfalfa do not occur in North America. There are no sexually compatible wild relatives of *Medicaga sativa* in North America. Hence, the risk for cross pollination and subsequent transgene introgression is limited to cultivated and feral alfalfa populations growing in North America.

GE crops will vary in their propensity to outcross depending on several factors, including whether they are self-pollinated or cross-pollinated, the proximity or absence of sexually compatible wild relatives, and the physical and spatial barriers separating GE crops from sexually compatible wild relatives. The conditions that are conducive to gene flow will be unique to each GE crop-wild relative and environmental factors in the area where the GE crop is cultivated (i.e., physical and spatial barriers, weather).

To date, there have been no documented cases of introgression of GE trait genes into wild populations (Ellstrand 2012), although there have been instances of GE plants occurring outside areas of cultivation, and in some cases hybridization with wild relatives. A little over 20 such incidents have occurred since the first field release of a GE crop in 1987 (Ellstrand 2012, Ellstrand 2014). Some of these events most likely occurred by unintended pollen exchange, others by inadvertent seed mixing (by humans or otherwise), and others by seed dispersal.

As an example, GE canola (*Brassica napus*) populations have been documented growing outside of areas of cultivation in the United States. This has been attributed to seed spills along transport routes (Schafer, Ross, Londo et al. 2011), with some GE canola populations showing evidence of hybridization with other GE canola plants. In Canada, GE HR canola (*Brassica napus* L.) has also presented as a volunteer plant in cultivated fields, and an increasing management problem (Knispel and McLachlan 2010). Similar instances with wild populations of GE canola have occurred where feral GE plants were identified growing along railway lines and in port areas at four sites in Switzerland (Schulze, Frauenknecht, Brodmann et al. 2014). GE canola plants originating from seed spills were also found along roadsides leading from Japanese ports that unload canola (Katsuta, Matsuo, Yoshimura et al. 2015). While such populations of GE *Brassica napus* have been identified in the wild, evidence of adverse environmental impacts has

[53] Cultivated alfalfa occurring outside of cultivated lands.

not yet been associated with wild populations of GE *Brassica napus* (e.g., see (Warwick, Beckie et al. 2009, Devos, Hails, Messean et al. 2012, Luijten, Schidlo, Meirmans et al. 2015)).

Other instances of GE plant-wild relative hybridization include glyphosate-resistant creeping bentgrass (GRCB; *Agrostis stolonifera* L.), which occurred in central Oregon (Reichman, Watrud, Lee et al. 2006). During field testing of GRCB in August 2003, there was a documented strong wind event in the production control area that moved seed and panicles from windrows[54] of the Northernmost GRCB production field (Zapiola, Campbell, Butler et al. 2008). As result of both pollen and seed dispersal, hybridization with wild populations of *Agrostis* spp. occurred (Zapiola, Campbell et al. 2008). Reichman, et al. suggest that pollen-mediated hybridization and seed dispersal contributed to the spread of GRCB transgenes into wild populations (Reichman, Watrud et al. 2006).

GE cotton-wild type hybrids (*Gossypium hirsutum*) have also been reported in Mexico (Wegier, Pineyro-Nelson, Alarcon et al. 2011). In this instance gene flow likely occurred via seed dispersal and cross-pollination. This assumption is supported by the fact that GE cotton seeds are transported over long distances as livestock feed in this region (Ryffel 2014).

The salient environmental concern is whether the flow of a GE trait gene (i.e., herbicide resistance, insect resistance) to a wild relative will have adverse ecological consequences. For a significant environmental impact to occur, gene flow would have to lead to the production of a fertile hybrid plant that produces viable offspring, and the resulting GE-wild plant hybrid having some type of competitive advantage that can lead, ultimately, to introgression of the GE trait gene into a wild plant population. Gene flow itself does not necessitate the increased fitness of a hybrid. The GE trait gene in a wild relative or other crop plant may very well prove detrimental to the hybrid, or have no effect (Ellstrand, Garner, Hegde et al. 2007, Ellstrand 2014, Goldstein 2014). The ecological consequences of a GE trait gene in a wild species depends on the type of trait, the stability of the gene in the genome, the fitness conferred to the hybrid through expression of the trait gene, and ecological factors in the area of the hybrid (Felber, Kozlowski, Arrigo et al. 2007, Ellstrand 2014).

It is generally assumed traits that impart increased fitness will persist in populations and those that impart negative effects on plant fitness will not. If a resulting GE-wild type hybrid had a competitive advantage over wild populations, it could persist in the environment and potentially disrupt the local ecology. Where the transgenic trait does not provide fitness, and is not deleterious to survival of the hybrid, the transgene may still persist in wild populations with no effects on the local ecology. This could be the case for a number of introduced traits.

Where a GE-wild type hybrid population does develop, and the transgene does impart fitness to the wild population, there will be significant concerns regarding the potential invasiveness or weediness of GE-wild type hybrids, and the potential for hybrids to modify ecosystem dynamics. Whether the otherwise benign hybridization with sexually compatible wild relatives would itself constitute an environmental harm (e.g., the transgene did not enhance fitness), it would require

[54] A row of hay or grass raked together to dry before being raked into heaps.

evaluation on a case-by-case basis relative to the species' involved, and the ecosystem where the hybrid(s) occurred (e.g., the presence of sensitive species or habitats).

In respect to the occurrence of a GE-wild type hybrid, gene flow from a GE crop plant to wild or weedy relative species does not necessarily constitute an environmental harm in and of itself, nor does it inherently imply environmental damage (Ellstrand 2014). The salient issue is what the resultant ecological consequences of such gene flow to a wild population may be (Ellstrand 2014). Current understanding suggests that the presence of a GE trait outside the area of cultivation will likely have little or no adverse consequences unless:

(1) the GE trait confers novel or enhanced fitness or weediness to the GE-wild relative hybrid, resulting in the evolution of increased weediness or invasiveness in wild type hybrids, or

(2) the GE trait confers to GE-wild relative hybrid progeny reduced fitness, resulting in a selective disadvantage in wild relative populations (Kwit, Moon, Warwick et al. 2011, Ellstrand 2014).

Hence, in evaluating potential environmental impacts it is not the risk of gene flow itself that is the chief concern, but rather the environmental consequences that could occur as the result of such an event; whether the transgene will persist in a wild population, and whether hybrid or introgressed populations will have adverse effects on ecosystem dynamics.

As previously discussed, corn, soybean, and cotton do not have wild relatives in the United States. One exception is the possibility of gene flow from GE cotton to wild or feral cotton relatives in Hawaii, Florida, Puerto Rico, and the U.S. Virgin Islands (Mendelsohn, Kough, Vaituzis et al. 2003). Consequently, the EPA restricts the sale or distribution of Bt cotton in these areas.

Cultivated GE rapeseed/canola, squash, and sugarbeet do have wild relatives in the United States and outcrossing with wild relative species may occur. Generally, the potential for gene flow from crops to wild relatives in the United States is limited to species of wheat, rice, sorghum, rapeseed/canola, sunflower, sugarbeet, and squash (CAST 2007). If the wild relatives grow in proximity to these types of GE cultivars, or GE seed of these species is inadvertently introduced in the area of their wild relatives, gene flow from GE crop to wild relative species could potentially occur. Such an outcrossing to wild relative populations could result in adverse, or no effects on the fitness of the hybrid plants. Adverse effects would be an increase in the fitness and weediness of a hybrid plant, as such characteristics could impact other plant and animal populations. Introgression of a transgene into wild relative populations, which implies at least no detrimental effects on fitness, could have various effects on ecosystem dynamics, ranging from significantly adverse to negligible. Where no effects on fitness were conferred, GE-wild type hybrids could persist as feral populations, as in the case of GE-wild type rapeseed.

The other concern with transgene flow to wild relatives would be the increased risk of extinction. This is really more of an academic discussion given there are no current GE organisms with known relative species at risk of extinction, and development of future GE organisms that have relative at-risk species is highly improbable (unless the GE plant is developed to conserve an at-

risk species). However, this topic is given mention to round out the conceptual framework in which gene flow to wild relatives is considered among the scientific community. Because populations at risk for extinction are often small in number, any substantial increase in gene flow from another population could increase their risk of extinction; this could occur by genetic swamping, outbreeding depression, or both (Ellstrand 2014). The transgene itself may not necessarily affect an at-risk population; any substantial increase of foreign alleles, transgenic or not, that decrease fitness or otherwise affect an at-risk population will challenge the sustainability of that population, and could lead to extinction (Ellstrand 2014). Lastly, a GE-wild type hybrid population could putatively overwhelm the habitat of an at-risk species, leading to its demise.

As for GE plants, data providing instances where GE plant-wild relative hybrids had an increase in fitness is rather limited (Reichman, Watrud et al. 2006, Warwick, Beckie et al. 2009, Zapiola and Mallory-Smith 2012). APHIS is not aware of any instances of transgene introgression, or where a transgene conferred a selective advantage to a GE-wild type hybrid population. A fairly recent review on this topic concluded that new populations of invasive GE plants that originate from transgene introgression have not been observed (Kwit, Moon et al. 2011), and hybrids of GE crop-wild relative species that have disrupted ecosystems (altered population structures, ecosystem goods and services) have not been described in the scientific literature (Lu and Snow 2005, CAST 2007, Chandler and Dunwell 2008, Mallory-Smith and Zapiola 2008, Mercer and Wainwright 2008, Warwick, Beckie et al. 2009, Kwit, Moon et al. 2011, Mallory-Smith and Sanchez Olguin 2011, Schafer, Ross et al. 2011, Van Deynze 2011, Ellstrand 2012, Yang, Wang, Su et al. 2012, Ellstrand 2014, Ryffel 2014). These observations may in part be due to the fact that the highly domesticated nature of crop plants derived from centuries of breeding has generally reduced the weedy and invasive characteristics of most crop species. This would include GE crop varieties, as most GE crop varieties are developed using domesticated crop plants (Warwick, Beckie et al. 2009). Although the degree of domestication varies among crop species, current GE crop varieties, being derived from domesticated crops, share similar or identical domesticated traits. Or rather, they are comprised of the same domesticated genome, the introduced trait gene(s) and associated genetic material such as promoter and terminator gene sequences being the exception.[55]

In summary, ecosystem level impacts, to date, have not been identified as a result of gene flow from regulated GE plants, or non-regulated commercial GE crop plants. However, the potential for gene flow and development of GE-wild type hybrids will remain a primary consideration in the field testing and commercial production of GE plants, to varying degrees, depending on the particular plant species and local ecology. Fundamentally, gene flow is not considered a harm in and of itself; rather, it is the environmental and economic consequences of gene flow that are of concern. In terms of risk assessment; risk = hazard x exposure. In this sense, gene flow is the exposure pathway, and hazard is the potential weedy or invasive characteristics that may be conferred to wild relative species by the GE trait gene (or the potential economic harm that can derive from the unintended presence of a GE trait gene or its gene product in a non-GE crop or crop commodity – discussed in section 3.10). Risk is the environmental consequences of gene

[55] For example, the genome of domesticated corn (Zea mays) contains around 2.3-billion base-pairs and 32,000 protein-coding genes, spread across 10 chromosomes. Modern methods of genetic engineering modify a small subset of the 2.3-billion base-pair sequence, with negligible effect on domesticated traits.

flow. Hence, in evaluating the risk of gene flow, one of the key components is assessment of the likelihood or probability of exposure.

Generally, field testing presents a very low risk of environmental harm as APHIS takes precautions to limit the likelihood of gene flow to wild relative species via notification and permitting requirements.[56] For some GE organisms that are field tested, however, the potential for gene flow to wild relative species, or rather, gene flow related to the particular GE organism-trait combination, has not been well characterized, and specific permitting conditions assigned to confine the GE organisms to the field site (i.e., GE plants developed to produce pharmaceutical or industrial products). In these instances APHIS may require data collection on the possible occurrence of gene flow. In either case, monitoring and mitigation measures will continue to be basic practices in the field testing of GE organisms, when the possibility of gene flow to sexually compatible wild relative species exists.

Gene flow from commercial GE crops to sexually compatible wild relative species will remain a concern. As described, a little over 20 such incidents have occurred since the first field release of a GE crop in 1987; the result of unintended pollen exchange, inadvertent seed mixing (by humans or otherwise), and by seed dispersal. For this reason there may be restrictions on the commercial use of certain GE crop plants. For example, the EPA restricts the sale or distribution of Bt cotton in areas where gene flow from GE cotton to wild or feral cotton relatives could occur.

3.4.2.3 Gene Flow to Non-GE Crops

Gene flow from regulated and non-regulated GE plants to non-GE cropping systems could potentially occur as a result of cross-pollination and seed dispersal, as described above. Based on historical precedent, it is the potential economic impacts that are expected to be the greater concern for both GE and non-GE cropping systems, as opposed to the potential environmental impacts. This is particularly important for the identity-preserved and organic markets, which are required to maintain low levels of GE material in their production systems, or none at all. Unintended presence of GE plant material can occur not only from gene flow, but also due to failed crop segregation during harvesting, shipping, and processing. Hence, the maintenance of crop product identity is fundamental to ensuring the sustainability of these crop production systems, maintenance of price premiums in the market, and avoidance of trade barriers for identity-preserved and organic crops.

As a consequence of the importance of meeting industry standards for identity-preserved and product integrity, the concept of coexistence among conventional, organic, and GE cropping systems has emerged as a central theme in modern agriculture (Van Deynze 2011). Coexistence, and gene flow among GE and non-GE cropping systems is fundamentally an economic issue, not an environmental issue, nor unique to GE crops. As such, coexistence and gene flow among conventional, organic, and GE cropping systems are addressed in further detail in the section on socioeconomics.

[56] Such as required by APHIS-BRS notification and permitting procedures, and APHIS-BRS compliance and inspection activities.

3.4.2.4 Volunteer and Weedy Plants

The term "weed" commonly refers to any plant growing where it is not wanted; particularly plants that tend to overgrow or outcompete more desirable plants. Weeds can characterized as native or non-native, invasive or noninvasive, and noxious or non-noxious. A robust plant could be desirable in some locations (i.e., for stabilization of erosional soils or as ornamentals), be regarded indifferently in other locations, and yet be a weed in some places, or an invasive species in other locations. With weeds, there is a direct effort to suppress or eliminate the plant from a regularly managed area. If invasive and ecologically encroaching on a natural area, the plant may be aggressively targeted for suppression or eradication unless it has established to the extent that attempts to control are not feasible.

Control of agricultural weeds is a key concern and weed management practices may be based on GE HR crops. GE crop plants can also be considered a "weed" if they occur where they are not wanted, commonly referred to as "unintended presence". Evaluating the risk of a GE plant occurring outside the area where it is intended to be grown, and where it may present as a weed, requires consideration of the relationships among species of plants, land management practices, and environmental factors.

In assessing the potential impacts of a GE plant on its environment, the plant species, its genome and traits, [57] the environment in which it is planted or introduced, land management practices (or lack of), and the interactions of each of these must necessarily be considered and weighed. To assess whether a crop plant will be "weedy", or cause an impact on the environment requires an understanding of the plant itself. The place that the plant occupies in its environment, its ecological niche, is highly relevant in that the plant responds to its environment and function in that niche in characteristic ways, dependent upon the genetic architecture typical of its species, and, if possessing a transgene, then the trait(s) conferred by that gene (or genes) as well. Because the colonization of a plant species in any given environment is dependent on a suite of environmental and human selective pressures, evaluation of a single protein or function alone without taking account of the context and complexity in which weeds are selected and propagate provides little meaningful information to evaluation of the risk a GE plant may present as a weed.

Volunteer plants, whether GE or non-GE, are those that have emerged in or around a cropping system unintentionally, usually as a result of dropped seed or plants reemerging from a prior crop. Volunteer plants, while a source of gene flow (discussed above), generally serve as weeds in a subsequent crop not of the same variety, and appropriate stewardship practices are required to mitigate their occurrence. Volunteer plants could also, putatively, spread to wild unmanaged areas and present problems to ecosystem integrity. The relative weediness of a crop volunteer, to include GE crop plants, depends in part on the particular crop plant species (e.g., corn and canola are common volunteers), seed disbursement and germination characteristics, land management practices, and environmental factors (Beckie and Owen 2007, Jeschke and Doerge 2010).

As an example: non-GE cereal rye (*Secale cereale* L.) is a primary grain crop and volunteer feral rye (*Secale cereale*), which closely resembles cultivated cereal rye (*Secale cereale* L.), has been

[57] For the purposes of this discussion "trait" refers to the genotype, and "characteristics" refers to the expression of the genotype, or phenotype. For example, the resulting characteristics expressed from selection pressures.

a serious agricultural weed problem in the Western United States (Burger, Lee and Ellstrand 2006). Around the 1960s, feral weedy rye populations were emerging as increasingly problematic on farmed lands, and as an invasive species on uncultivated lands as well. As a weed of cultivated rye, the feral rye populations were such a problem that farmers had to abandon efforts to grow cultivated rye for human consumption (NRC 1989, Ellstrand, Heredia et al. 2010). Subsequently, weedy feral rye (non-GE) spread elsewhere in the Western United States and the Canadian province of British Columbia (Ellstrand, Heredia et al. 2010).

Feral rye was originally thought to be a hybrid of cultivated rye and the wild mountain rye *S. strictum* (C. Presl). However, subsequent genetic analysis of feral weedy rye found they were no more closely related to mountain rye than cultivated cereal rye (Burger, Lee et al. 2006). It was ultimately determined that the feral weedy rye populations are of a single lineage, which apparently evolved directly from one or more cultivars of cereal rye (Burger, Lee et al. 2006, Ellstrand, Heredia et al. 2010).

While not a volunteer crop plant, wild red rice (*O. sativa f. spontanea*) provides an example of the relationship between a crop plant and wild weedy relative species. Wild red rice has been a significant weed of cultivated rice (*Oryza sativa japonica* and *O. sativa indica*) for well over a century. When red rice co-occurs with cultivated rice, rice crops suffer depressed yields, and when co-harvested, the presence of the red rice weed degrades the quality of harvested rice crops. Because it is the same species as cultivated rice, with similar morphology and physiology, it is very difficult to control by both weeding and chemical means (Ellstrand, Heredia et al. 2010).

Fundamentally, the potential for a crop plant to become weedy or invasive derives primarily from the particular plant species being cultivated, and to a lesser extent, albeit important, the management practices employed in crop production. Nearly all major crop species are highly domesticated and possess numerous selected (bred) traits that facilitate the production of desired human and animal foods, and fibers. However, crops vary in their degree of domestication, or the proportion of domestication traits vs. wild traits. As examples, the current crop cultivars of corn and bread wheat did not naturally occur prior to human intervention. Current rice and oilseed rape cultivars were derived from significant breeding, and are not found in their so-called natural state (Warwick and Stewart 2005). On the other hand, cranberry remains essentially undomesticated.[58]

Domesticated crop plants and weeds can be considered ecologically similar in that both adapted to growth and development in managed habitats (e.g., farmlands), and are often grown or grow in dense monocultures (Warwick and Stewart 2005). However, crop plants and wild weeds differ from each other in that crops are highly dependent on humans for propagation as a result of their domestication, the intentional human-mediated selection for desired traits, where weeds are independent of direct human intervention for propagation. While most crop plants require cultivation to thrive, weeds have a genetic architecture that enable them to thrive independent of human propagation. This distinction aside, both crop plants and weeds have a dependency on

[58] Cultivated cranberry is little changed from wild cranberry; there has been limited breeding of cranberry for commercial crop purposes.

managed habitats to grow (Warwick and Stewart 2005). For example, weeds in particular can thrive in managed habitats such as crop fields, yards, and urban areas.

Within the context of the scenarios described above, the primary concerns with volunteer GE plants are that they can (1) reduce crop yield, (2) require time and money to manage as weeds, and (3) lead to instances of unintended presence of GE volunteer plant material in harvested crops.[59] For example, GE canola (*Brassica napus*), discussed above, is a common volunteer plant and an increasing management problem in cultivated fields in Canada (Knispel and McLachlan 2010). Volunteer GE corn, as well, can be problematic in corn-to-corn, and corn-to-soybean rotational cropping systems (Marquardt , Terry and Johnson 2013). Volunteer plants, including volunteer GE plants, are generally controlled with herbicides, crop rotation, and tillage, although hand weeding is also used (Beckie and Owen 2007). Control of volunteer GE HR crop varieties can be somewhat more complicated than control of naturally occurring herbicide-resistant crop plants and conventional non-HR volunteer plants, given most GE HR varieties contain at least one HR trait, if not more (Beckie and Owen 2007).

While all plants that have been domesticated for crop use have the capacity to occur as feral populations and present problems as weeds or invasive species, this has rarely occurred (rye being one of the rare cases) (Warwick and Stewart 2005, Ellstrand, Heredia et al. 2010). In general, there are few verified examples of crops where volunteer plants have directly evolved into competitive weeds, and data showing that a weed arose directly from a crop plant have not been produced. In a study examining well-domesticated plants (those that have been intentionally cultivated and thus under intentional or unintentional selection) for at least 1,000 years, there were found to be 13 examples of plant lineages descended from crop progenitors that are considered nuisance weeds (Table 3-18) (Ellstrand, Heredia et al. 2010). Six of these are directly descended from a crop; six are descended from hybrids between a domesticated species and a wild relative, and one is descended from hybrids between two cultivated taxa (Ellstrand, Heredia et al. 2010). Ten are primarily noxious weeds of agriculture, one is an invader of non-managed ecosystems, and the remaining two are both weedy and invasive.

Table 3-18. Weeds evolved from domesticated plants

Crop and Species	Location	Key evolved traits relative to crop ancestor
Endoferal (descended directly from cultivated crop species)		
Artichoke (*Cynara cardunculus* var. *scolymus*)*	U.S.: CA	Spininess, smaller more numerous heads, leaves deeply dissected, delayed and extended flowering period
Bread wheat (*Triticum aestivum*)*	China	Easily broken shaft or main stem - facilitates shattering ++
Radish (*Raphanus sativus*)*	Brazil	Resistance to ALS-inhibiting herbicides
Rice (*Oryza sativa japonica*)*	China	Seed shattering
Rice (*Oryza sativa indica*)*	Southeastern U.S.	Seed dormancy and shattering

[59]The mixing of genes and gene products from unintended plant sources can occur with both conventionally bred plants as well as biotechnology-derived plants. These occurrences can result from natural processes such as the movement of seeds or pollen, mixing of seed, or human-mediated processes associated with field testing, plant breeding, or seed production. The APHIS policy on low level presence covers the unintended low-level mixing with commercial seeds and grain of genes and gene products from GE plants that are still subject to regulation by APHIS. USDA-APHIS (2007). *Low-Level Presence. APHIS Factsheet: Biotechnology Regulatory Services.* U.S. Department of Agriculture, Animal and Plant Health Inspection Service. Available at https://www.aphis.usda.gov/publications/biotechnology/content/printable_version/fs_llppolicy3-2007.pdf..

Table 3-18. Weeds evolved from domesticated plants		
Rye (*Secale cereale*)*	U.S:CA, WA	Shattering, smaller seed, delayed flowering
Exoferal (descended from hybrids between a cultivated crop and another, usually wild, species)		
Finger millet (*Eleusine coracana* subsp. *coracana*)* × wild finger millet (*Eleusine coracana* subsp. *africana*)	Africa	Change in structure of spikelets (short stem with attached flowers)
Grain sorghum (*Sorghum bicolor*)* × Johnsongrass (*S. halepense*) Exoferal	U.S: NE, TX	Perennial, shattering, rhizome
Grain sorghum (*Sorghum bicolor*)* × *S. propinquum*	Diverse geographic origins	Perennial, shattering, rhizome
Radish (*Raphanus sativus*)* × Jointed charlock (*R. raphanistrum*)	U.S: CA	Earlier bolting, earlier flowering, increased flower number, increased fruit number, increased seed number
Rice (*Oryza sativa indica*)* × Brownbeard rice (*O. rufipogon*)	U.S: Southeastern U.S	Seed dormancy and shattering
Sugarbeet (*Beta vulgaris* subsp. *vulgaris*)* × Sea beet (*B. v. maritima*)	France, Germany, Italy	Shift to annual from biennial habit, woody root
Exo-endoferal (feral lineage descended from hybrids between two crops)		
Rice (*Oryza sativa japonica*)* × Rice (*O. s. indica*)*	Bhutan	Seed dormancy and shattering

Notes:
* Domesticated crop plant
++ Separation of seed from the plant. In the history of crop domestication breeding has involved a mutation in a crop plant that reduces shattering in order to retain the seed/grain (e.g., wheat).
Source: (Ellstrand, Heredia et al. 2010)

Hence, the domesticated nature of most crop plants rather limits the likelihood of successful colonization outside areas of cultivation. In addition to the usual challenges for propagation, such as reproduction and competition, crop plants may face additional challenges due to their inherent domesticated traits that render them dependent on human cultivation, and less fit to propagate when not managed. However, some GE crop plants, dependent on the species and trait, may present issues in regard to potential environmental impacts, thus requiring efforts to prevent entry into semi-natural areas (e.g., rangeland, production forests) or areas that are essentially natural and unmanaged (e.g., nature reserves) during field testing of the GE plant.

If current domesticated crop plants were to become established outside of their area of cultivation, they would more likely be casually feral rather than fully naturalized or even invasive due to their domesticated characteristics (Warwick and Stewart 2005). Although related wild relative weeds could contribute weediness traits to crop-wild relative hybrids, it appears that weeds generally do not arise from crop-wild weed hybridization, but by other factors described herein: it is more of the exception than the rule that crop plants develop as feral weeds (Warwick and Stewart 2005). In general, the multiple factors required for weed evolution, whether as crop-turned-weed on its own or development of weediness via hybridization with related weeds or wild species, render the risk of occurrence of crops as weeds rare in nature; most domesticated crop plants stay domesticated (Warwick and Stewart 2005).

With respect to transgenes that confer herbicide resistant traits; volunteer GE HR crop plants possessing these traits would have an increased potential for weediness and adaptiveness in

agricultural settings, but only when those herbicides to which the GE plant is resistant are used for control of weeds (Warwick and Stewart 2005). Consequently, in considering the risk for weediness, this would necessitate the need for use of diverse herbicides, a greater diversity in available herbicide resistance traits, and more dependency on crop and herbicide rotations as part of crop management (Warwick and Stewart 2005).

The potential receiving environments for a particular GE crop plant would need more attention if there were evidence for important interactions between the GE plant trait and the unmanaged environment. As an example, for GE crops developed for stress-tolerance, volunteers from these varieties may have a fitness advantage over plants less tolerant to environmental stressors, not only in agricultural fields, but in natural habitats as well (Beckie and Owen 2007). Consequently, these types of traits would require greater attention in regard to their risks as potential weeds. Volunteer GE plants that present issues as weeds are generally controlled with herbicides, tillage, and crop rotation, although hand weeding is also used (Beckie and Owen 2007). Control of volunteer HR crop varieties can be somewhat more complicated than control of conventional volunteer plants, given most GE HR varieties contain at least one HR trait, if not more (Beckie and Owen 2007). Management of current and future GE crop volunteers is and will be required as an integrated practice in the production of GE crops (Beckie and Owen 2007).

3.4.3 Agronomic Practices and Inputs

GE crop production may somewhat differ in potential environmental impacts relative to non-GE crops as a result of the agronomic practices growers may use in production of a particular GE crop. In general, use of GE crop varieties can result in changes to the types and quantity of pesticides used, as well as the types of tillage and crop residue management practices employed. The environmental impacts may be beneficial, benign, or adverse depending on the nature of the agronomic practices involved. This section summarizes the associations among GE crops and the particular agronomic practices that might be employed in their production.

3.4.3.1 Tillage

Tillage is a fundamental method by which growers control weeds, and the various tillage practices used differ in their environmental impacts. Conventional tillage, involving extensive incorporation of crop residue into the soil typically leaving less than 15% of crop residue on the field, has historically been the most common practice in agriculture. Conservation tillage, including no-till practices, in contrast, is associated with leaving at least 30% of crop residue on fields and can result in substantially less soil erosion than other tillage practices.

One of the advantages of GE HR crop plants is their ability to handle broad-spectrum herbicides in the post emergent stage of crop production. In general, GE HR cropping systems are associated with conservation tillage; a tillage method that can reduce the adverse effects of tillage on soil and water quality, as well as soil erosion (Horowitz, Ebel and Ueda 2010, NRC 2010b, Fernandez-Cornejo, Hallahan, Nehring et al. 2012). Although trends in adoption of conservation tillage practices were evident before the introduction of GE HR crops, the trend appears to have accelerated after introduction of GE crops (Fernandez-Cornejo, Hallahan et al. 2012). This is attributed to the fact that effective weed control using herbicides greatly facilitates conservation and no-till farming, and this was simplified by the introduction of GE HR cropping systems. While a clear cause and effect relationship between GE HR cropping systems and

conservation tillage has not been established (NAS 2016), both GE crops and the percentage of cropping area farmed with no-till and reduced-till practices have increased over the last two decades(Fernandez-Cornejo, Hallahan et al. 2012). In 2009, 44% of cropland devoted to major crops (corn, soybean, wheat, cotton, and rice) was farmed using conservation tillage (Horowitz, Ebel et al. 2010). No-till farming, in particular, has recently been employed on around 35% of U.S. cropland (Horowitz, Ebel et al. 2010).

However, the development of herbicide resistant weeds have forced growers in some areas to include or intensify tillage to control weeds in order to sustain maximum yields and net returns on crop production. For example, in Southern states conventional tillage is becoming a more common practice in glyphosate resistant cotton due to the evolution of glyphosate resistant weeds (CAST 2012). Hence, the development and management of herbicide resistant weeds has emerged as a determining factor in the type of tillage growers of GE crops can employ.

3.4.3.2 Pesticide Use

3.4.3.2.1 Background

Pesticide use in relation to GE crops, in particular, is of interest as some pesticides can be harmful to wildlife and humans, and insects and weeds can become resistant to insecticides and herbicides, respectively.

However, in regard to potential harms to humans and wildlife, pesticide use data commonly referred to in the lay and peer review literature citing the weight or volume of pesticide used conveys little meaningful information without understanding pesticide toxicity, or the potential harmfulness of a pesticide, which varies widely among the pesticides used. Pesticide toxicity is dependent on the dose, duration, and frequency of exposure; dose being relative to the inherent toxicity of the active ingredient in a pesticide. Pesticide use on all crops, GE and non-GE alike, is regulated by the EPA.[60] The EPA evaluates the toxicity of pesticides via human health and environmental risks assessments, which are conducted for a pesticide prior to its registration and authorization for use.

Pesticides are classified into four categories based on toxicity: pesticides that are considered highly toxic are classified as Toxicity Category I, moderately toxic as Category II, and slightly toxic or relatively nontoxic as Categories III and IV. While some pesticides products are considered only slightly toxic or relatively nontoxic, all pesticides can be hazardous to humans and wildlife if the instructions on the label are not followed. In other words, pesticides can be hazardous if the recommended safe dose, duration, and frequency of exposure is exceeded. Hence, adherence to EPA pesticide label requirements is fundamental to safe use of pesticides.

Toxicity data on pesticides is available online from the following resources: (1) the EPA's ecotoxicology knowledgebase (ECOTOX), which provides single chemical environmental toxicity data on aquatic life, terrestrial plants, and wildlife (US-EPA 2016b); (2) the Pesticide

[60] EPA – Pesticides: http://www.epa.gov/pesticides

Action Network;[61] the Integrated Risk Information System;[62] Toxicology Data Network;[63] and, Agency for Toxic Substances and Disease Registry.[64]

In regard to the development of insect and weed resistance, pesticide use data can provide some basic information on the relationship between use and development of resistance. However, it is not a direct correlation; development of resistance depends on various factors, such as insect and weed characteristics, pesticide chemical properties, and cultural practices. For example, cultural practices would include crop rotation, tillage practices, continuous or repeated use of a single herbicide, or several herbicides that have differing modes of action, and use of an herbicide at a rate in excess of the amount needed for weed control. Bearing these factors in mind, insecticide and herbicide use relative to GE IR and HR crops are summarized below.

3.4.3.2.2 Overview

The types and quantities of pesticides applied by U.S. farmers have changed considerably over the last several decades (Fernandez-Cornejo, Nehring, Osteen et al. 2014). This is in part a reflection of the wide adoption of certain GE crop varieties after their introduction the late 1990s. For example, a recent meta-analysis of 147 studies, including GE HR soybean, corn, and cotton, as well as GE IR corn and cotton, found that, on average, adoption of GE crops has reduced chemical pesticide use by 37%, increased crop yields by 22%, and increased farmer profits by 68%. The reported yield gains and pesticide reductions were larger for GE IR crops than for GE HR crops (Klümper and Qaim 2014). Reviews of pesticide use in U.S. agriculture have been conducted by the USDA and National Academy of Sciences, and that data is included here by reference (Fernandez-Cornejo, Osteen, Nehring et al. 2014, Fernandez-Cornejo, Wechsler and Milkove 2016, NAS 2016b).

3.4.3.2.3 Insecticide Use

Insecticide use fluctuates relative to crop acreage, pest pressure, pesticide regulation, technology, and other factors. A recent report by the National Academy of Sciences found that in all cases examined, the use of Bt crop varieties reduced the application of synthetic insecticides in Bt based cropping systems. In some cases, the use of Bt crop varieties has also been associated with reduced use of insecticides in adjacent cropping systems cultivating non-Bt varieties, due to the area wide suppression of insect pests (NAS 2016b). The NAS findings are consistent with USDA data that indicate the adoption of Bt corn and cotton is positively correlated with a reduction in insecticide use (Figure 3-17). In general, research by USDA-ERS and others suggests that, controlling for other factors, insecticide use has declined with the adoption of Bt corn and Bt cotton (Coupe and Capel 2015). For example, insecticide use for corn production, which peaked in the late 1970s and 1980s at 0.35-0.45 pound per acre, declined throughout the 1990s and 2000s to under 0.05 pound per planted acre (Figure 3-17). Insecticide use for cotton, which peaked at 9.5 pounds per planted acre in 1967, has declined to less than 1 pound per planted acre (Figure 3-17) (NRC 2010b, Fernandez-Cornejo, Nehring et al. 2014).

[61] Pesticide Action Network (PAN) Database: http://www.pesticideinfo.org/

[62] EPA – Integrated Risk Information System: http://www.epa.gov/iris

[63] National Institutes of Health, Health & Human Services – Toxicology Date Network: http://toxnet.nlm.nih.gov/

[64] Agency for Toxic Substances and Disease Registry: http://www.atsdr.cdc.gov/

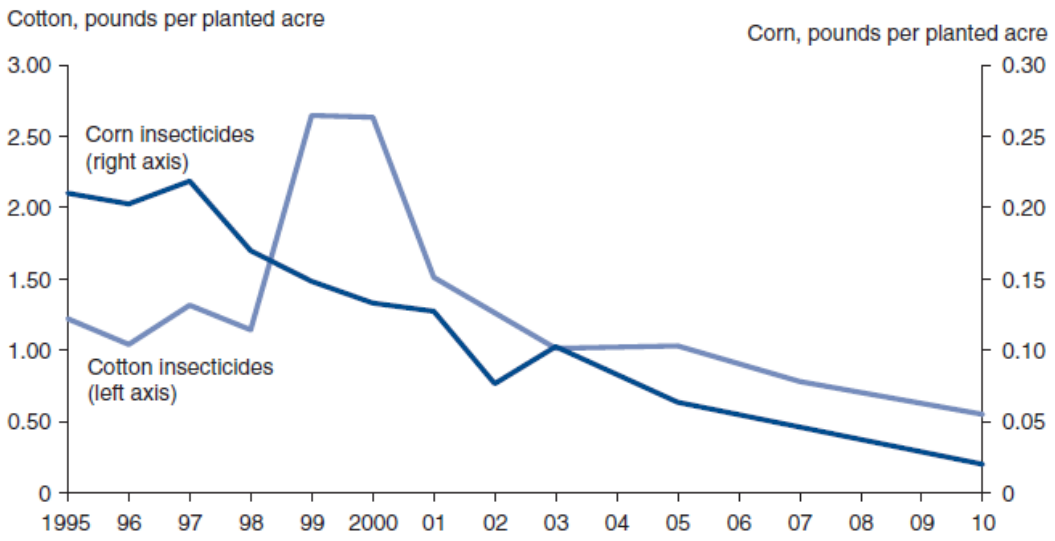

Figure 3-17. Insecticide Use in Corn and Cotton Production, 1995-2010
Source: (Fernandez-Cornejo, Wechsler et al. 2014a)

Apart from direct reduction of insecticide use, several studies have found that area-wide suppression of insects such as the European corn borer and pink bollworm are associated with the use of Bt corn and Bt cotton, respectively (e.g., see review by (Fernandez-Cornejo, Wechsler et al. 2014a)). Hence, cultivation of Bt crops may provide tangential benefits to adjacent farms through controlling the area-wide prevalence of certain insect pests, and reduced the need for insecticide use in nearby cropping systems (NAS 2016b).

3.4.3.2.4 Herbicide Use

The effect of HR crops on herbicide use is mixed. Adoption of HR crops likely reduced herbicide use initially (Brookes and Barfoot 2010, Fernandez-Cornejo, Wechsler et al. 2014a); however, development of glyphosate resistance among certain weed populations may have encouraged farmers to increase application rates, increase the frequency of applications, as well as encourage the use of less environmentally benign herbicides, offsetting the potential environmental advantages of HR crops (Fernandez-Cornejo, Wechsler et al. 2014a).

Herbicide use on GE corn, cotton, and soybean declined slightly in the first years of use of these HR crops, but increased modestly in later years (Figure 3-18). Despite the relatively minor effect HR crop adoption has had on overall herbicide usage, HR crop adoption has enabled farmers to substitute glyphosate for more toxic herbicides, which can present greater risks to humans and wildlife. Because glyphosate is less toxic and less persistent than some of the more traditional herbicides, the net impact of HR crop adoption is considered to have been an improvement in environmental quality and a reduction in health risks (Fernandez-Cornejo, Nehring et al. 2014).

In general, most studies agree that, overall, there has been a shift away from more toxic herbicides to those that are more environmentally benign (Brookes and Barfoot 2010, NRC

2010a, Fernandez-Cornejo, Nehring et al. 2014), although total herbicide use has not significantly decreased in the United States since the adoption of GE HR crops in the late 1990s.

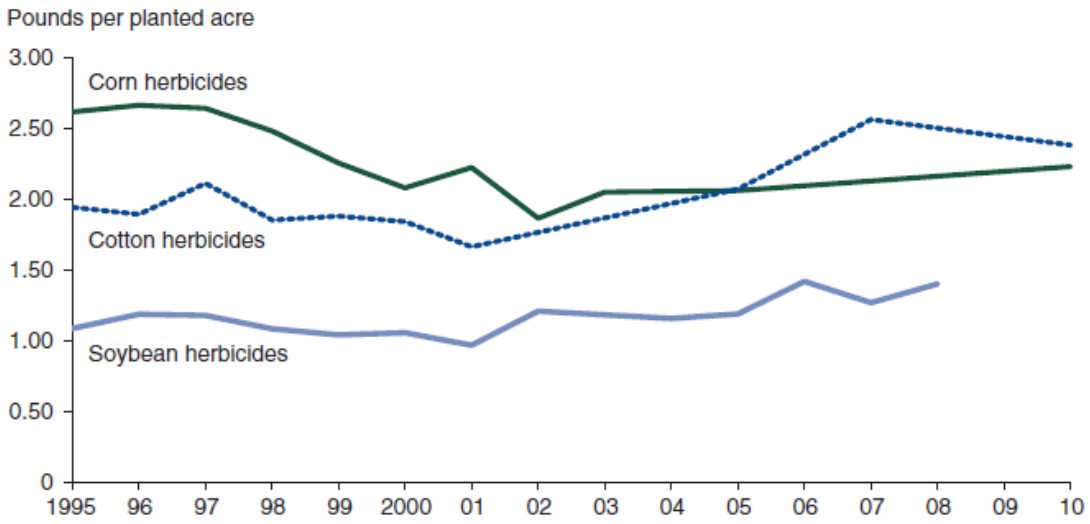

Figure 3-18. Herbicide Use: Corn, Cotton, Soybean, 1995-2010
Source: (Fernandez-Cornejo, Wechsler et al. 2014a)

This information on herbicide use in the United States is largely in agreement with analyses by Coupe and Capel, who concluded that there has been a reduction in the annual herbicide application rate to corn since the advent of GE crops, that the herbicide application rate is largely unchanged for cotton, and that herbicide use on soybean has increased (Coupe and Capel 2015). Similarly, Brookes and Barfoot concluded that global aggregate reductions in both the volume of herbicides used (by weight of active ingredient) and their associated potential toxicity indicate net improvements to the environment (Brookes and Barfoot 2013b).

However, in some countries, there has been a net increase in the average amount of herbicide active ingredient applied to GE HR crops relative to usage on conventional crops (Brookes and Barfoot 2010). As in the United States, this is attributed to the singular use of glyphosate and development of glyphosate resistance in some regions. This problem has influenced the general mix, total amount, and overall profile of herbicides applied to GE HR crops in areas where glyphosate resistance has occurred (Brookes and Barfoot 2010). As a result of glyphosate resistance, the amount of herbicide active ingredient applied and number of herbicides used with GE HR crops in several regions of the world has increased (Brookes and Barfoot 2010).

More recently, GE 2,4-D (2,4-dichlorophenoxyacetic acid) resistant corn and soybean crops have entered the commercial market, which were controversial as commercial production of these crops will increase the amount the 2,4-D used in the United States. Pesticides used on 2,4-D resistant crops are regulated by the EPA. The final regulatory decision document for Enlist Duo, a recently registered 2,4-D based herbicide, is available in EPA docket EPA-HQ-OPP-2014-0195 at www.regulations.gov. When used according to EPA label directions, the EPA states that Enlist Duo does not pose adverse risk to the environment or human health. Any future use of

pesticides on GE crops that enter commercial production would be determined by the EPA, as further described in subsection 2.7- Human Health.

Evaluation of pesticide use based on weight can be misleading. Benbrook and many others use weight as a basis for increase or reduction in usage. However, pesticides are formulations of active ingredients and carriers/solvent such as water or oils, and the toxicity of pesticide active ingredients varies widely.

3.4.4 Pest and Weed Resistance

3.4.4.1 Pest Resistance

If used properly GE IR based crops can reduce the need for chemical pesticides and the risks they may pose to human health and the environment. Consequently, they are considered one of the safest methods of insect pest control. However, one concern with GE IR crops is that their long-term use could promote the development of insect resistance.

It has long been recognized that continued exposure of crop pests to pesticides through aerial or ground applications can result in the development of resistance (adaptation) to pesticides. This is, likewise, an important issue for GE plants, and other organisms, with pest resistant traits. A recent review of 77 studies from 5 continents reporting field monitoring data for resistance to Bt crops finds that most pest populations remain susceptible. However, reduced efficacy of Bt crops due to developed resistance to Bt derived PIPs has been reported for 5 of 13 major pest species examined, compared with resistant populations of only one pest species in 2005 (Tabashnik, Brevault and Carriere 2013). The review by Tabashnik et al. concluded that pests can evolve resistance to Bt crops in as few as 2 years, although efficacy can be sustained for 15 years or more where proper integrated resistance management practices are implemented (Tabashnik, Brevault et al. 2013).

Hence, while the use of Bt based crops has been effective as part of integrated pest management programs used in commercial crop production, their efficacy may wane if a pest adapts to the mechanism of action of the particular Bt Cry protein,[65] and becomes less susceptible. Thus, where not judiciously used, GE IR crops may see a decline in efficacy over time, while also contributing to increasingly limited pest management options. For instance, Bt insecticide is used in organic farming, either as a spray or ground application to help control pests in these crops, and is one of the few pesticides permitted by USDA organic standards.

As with Bt traits, GE plants developed for resistance to viruses, fungi, bacteria, and nematodes may not remain effective in the long-term if used as the only means of control, and the use of, and potential environmental effects of, such GE applications requires salient consideration. For GE IR crops to continue as viable methods of insect control, it is essential that strategies are employed to minimize the selection of resistant insect populations.

[65] Bacillus thuringiensis (Bt) strains synthesize crystal (Cry) and cytolytic (Cyt) proteins that are toxic to certain orders of insects.

Many of the insect and disease-resistant GE crop plants contain PIPs, which are genes (and any gene products) that have been introduced into GE plants to confer pest and disease resistant traits; namely resistance to insects, or pathogenic bacteria, fungi, or viruses. PIPs are regulated as pesticides by the EPA under FIFRA because they meet the FIFRA definition of a pesticide - they are intended for preventing, destroying, repelling, or mitigating a pest. [66] Current GE IR crops that contain EPA regulated PIPs include Bt potato, corn, cotton, and soybean (US-EPA 2015b). GE plum also contains an EPA regulated PIP conferring resistance to the plum pox virus.

Due to concerns regarding the development of IR for GE plants expressing PIPs, the EPA has established mandatory insect resistant management (IRM) practices for specific crop types, which include the incorporation of structured or natural refuges [67] to reduce the likelihood of development pest resistance (US-EPA 2015d). As part of this program, in January of 2015 the EPA proposed a framework to reduce corn rootworm resistance (US-EPA 2015c). The proposed framework includes requirements that include:

- crop rotation in areas at risk of corn rootworm resistance and use of corn varieties containing more than one Bt toxin;
- development and implementation of strategies to better detect and address areas of resistance as they emerge; and
- use of different and improved scientific tests and sampling requirements to study the problem and more reliably ensure that resistance to the Bt corn toxin is identified.

The proposed framework is currently under public review, and EPA's docket for general information on insect resistance management can be found under docket number, EPA-HQ-OPP-2011-0922 (http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2011-0922).

In general, the emergence of insect resistance to Bt crops has been of relatively low agronomic or environmental consequence to date. Only two pest species are known to have evolved resistance to Bt crops in the United States (NRC 2010a), and 5 species globally. However, insect resistance management remains a key concern and will continue to be an essential aspect of both GE and non-GE crop production systems (Tabashnik, Brevault et al. 2013).

3.4.4.2 Weed Resistance

Weeds are a significant problem in the efficient production of agricultural crops and difficult to control. Weeds can result in reduced crop yields, reduced product quality, and increased harvest costs. While exact figures are difficult to come by given there are no large scale commercial crops produced without weed management, it has been estimated that yield losses due to weeds could increase in the United States by $15.5 billion/year without the use of herbicides (Gianessi and Reigner 2007). Management of weeds often requires significant resource inputs to produce maximum yields and net returns on crop production.

[66] NOTE: EPA does not regulate the GE plant itself, only the inserted PIP gene(s)/protein(s).

[67] Growers who plant crops with insect-resistant Bt trait(s) must also plant a non-insect-resistant crop refuge area, which is a block or strip of crops without the Bt gene. The purpose of the refuge areas is to prevent pest populations from developing resistance to the Bt trait. A structured refuge sets aside some percentage of the crop land for non-Bt varieties of that crop.

Prior to the development of synthetic pesticides following World War II, farmers controlled weeds by tillage, mowing, site selection, crop rotation, use of crop seed free of weed seeds, and hoeing or pulling by hand. U.S. farmers began shifting to synthetic pesticides after commercial introduction in the 1940's because they were inexpensive, effective, and easy to apply. Synthetic pesticides made crop production more efficient by providing effective control of weeds and reducing the need for tillage. Currently, herbicides are a fundamental input for the control of weeds. They have allowed growers to reduce the time, effort, and cost of managing weeds. However, their use can be controversial as a result of the development of HR weeds.

It is well recognized that the singular, long-term use of an herbicide can promote the development of resistant weeds. This is not unique to GE crop varieties themselves; herbicide resistance has routinely occurred with conventional crops and herbicides since their introduction in the1950s (Figure 3-19). To be clear, the development of HR weeds discussed in this section does not involve gene transfer. This discussion is on herbicide use and the selection pressures that result in the evolution of HR weeds. Gene flow is discussed in section 3.4.2.

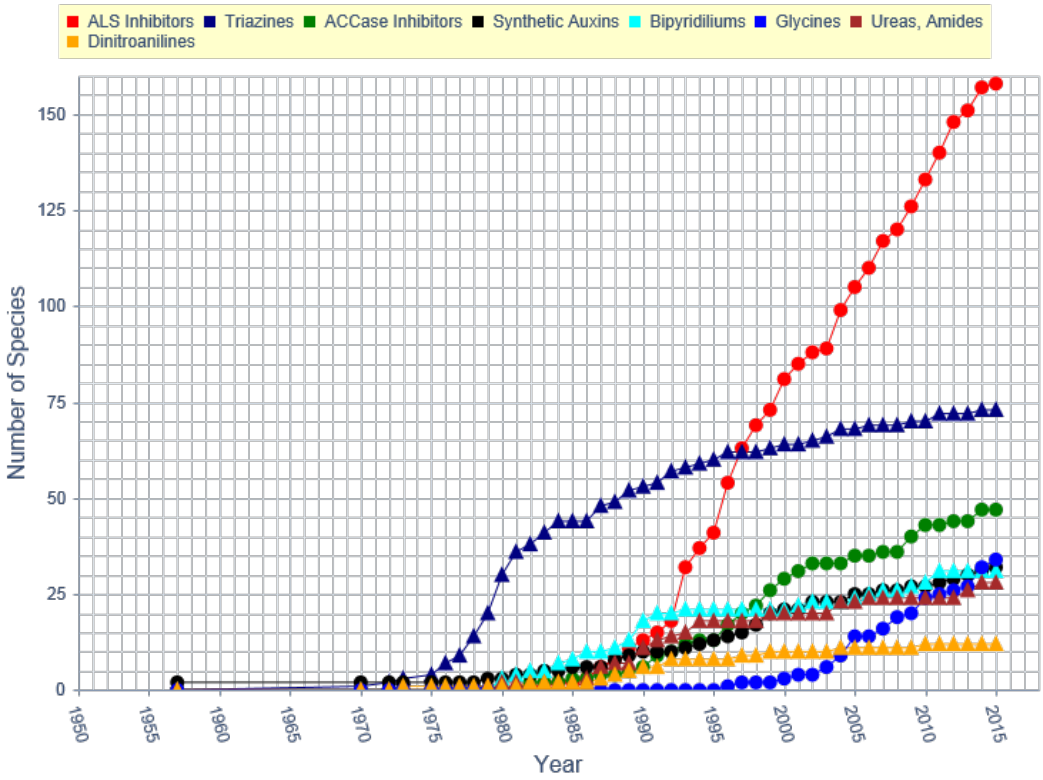

Figure 3-19. Increase in the Development of Herbicide Resistance: Herbicide Modes of Action

The herbicide groups with the most herbicide resistant weeds are acetolactate synthase (ALS) inhibitors (i.e., imidazolinone and imazethapyr); ACCase inhibitors (i.e., phenylpyrazoline); triazine based photosynthesis II inhibitors (i.e., atrazine); synthetic auxins (i.e, dicamaba, 2,4-D); bipyridilium based photosynthesis I inhibitors such as paraquat; glycines, which include the EPSP synthase inhibitor glyphosate; various ureas and amides that inhibit the photosynthesis II process; and dinitroaniline based microtubule inhibitors such as trifluralin.

Source: (Heap 2015)

Whether among GE or non-GE crops, the tendency for the development of herbicide resistance is dependent on the type, quantity, and modes of action of herbicides used in crop production, and the plant/weed species present in the area where the herbicides are applied. In regard to the development of herbicide resistance, over reliance on any one herbicide, and the lack of crop rotation will increase selection pressure and the potential development of weed resistance to the herbicide (Owen 2011, Vencill, Nichols, Webster et al. 2012).

The top 15 herbicides with weed resistance are summarized in Figure 3-20. Among these, development of resistance has occurred most frequently with the triazine atrazine, and the acetolactate synthase (ALS) inhibitors imazethapyr, tribenuron-methyl, imazamox, chlorsulfouron, and mesosulfuron-methyl. Glyphosate has seen development of 36 resistant weed species. Glufosinate and dicamba, which are used in combination with GE HR crops, have seen development of 10 and 2 weed species, respectively.

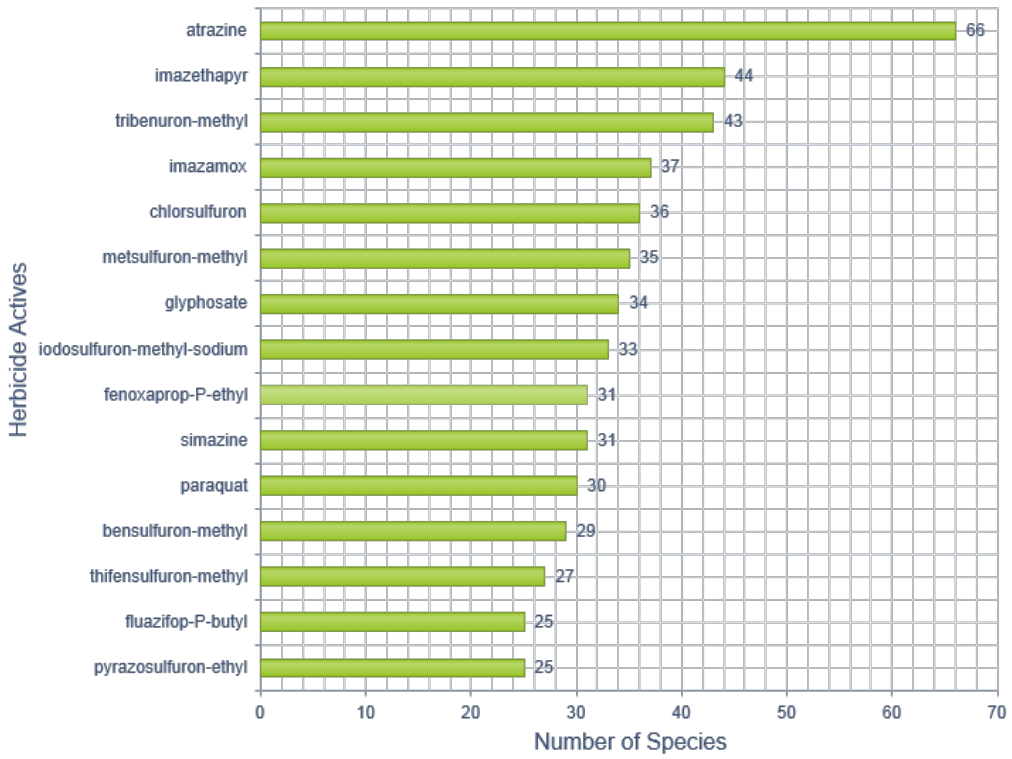

Figure 3-20. Top 15 Herbicides and the Number of Herbicide Resistant Weed Species - Globally
Source: (Heap 2015)

The problem with development of herbicide resistance has been addressed in part by the adoption of stacked-trait varieties of GE crops, which allow use of multiple herbicides with varying modes of action. For example, while stacked-trait varieties comprised less than 1% of planted acres in 2000, they comprised 76% of planted acres in 2014 (USDA-ERS 2015a). GE varieties incorporating three or four traits are now common.

Specialists in weed science recommend the use of an integrated weed management (IWM) approach, which includes science-based crop improvement and tools developed over the last 60 years, to provide producers practicable and effective means by which to manage weeds (Weller, Owen and Johnson 2010, Owen 2011, Owen 2012, Vencill, Nichols et al. 2012). IWM includes timely herbicide applications, use of herbicides with multiple modes of action, crop rotation, various tillage practices, and weed surveillance (Owen 2011, Garrison, Miller, Ryan et al. 2014, CLI 2015). To assist growers in managing weeds, individual states track the prevalent weeds in crops in their area and the most effective means for their management, typically through state agricultural extension services, which work with USDA (IPM 2015).

There is some evidence that herbicide resistant weed populations can be controlled or effectively eliminated over time. For instance, it has been shown that weed population densities can be decreased in continuous glyphosate resistant corn cropping systems incorporating IWM strategies, although reductions in the density of high-risk weed species may take from 2 to 6 years (Gibson, Young, Owen et al. 2015). While IWM can generally be successful in deterring glyphosate resistance in the short term while reducing weed infestations and maintaining crop yield potential, it may take many years to affect the weed seedbank. This is particularly relevant for those weed species with a greater propensity for herbicide resistance and cropping systems using crop varieties comprised of a single herbicide resistant trait (Gibson, Young et al. 2015).

3.4.5 GE Forest and Orchard Trees

GE fruit trees have been and are developed for commercial food markets. GE trees are also being explored for use in commercial forestry and for ecological restoration purposes. APHIS has authority to regulate a GE tree when such a tree is plant pest, or believed to be a plant pest, under current 7 CFR part 340. APHIS authorized field tests of regulated GE forest and fruit trees have been conducted since 1989 (ISB 2015).

The environmental concerns surrounding GE trees are similar to those with GE crop plants, namely the potential for introgression of GE traits into sexually compatible wild, feral, or commercially grown species via pollen or seed mediated gene flow. For example, traits that confer increased fitness to the tree may, conceptually, increase its propensity to establish outside areas of cultivation, become invasive, and alter the ecology of an area. As with certain GE crop plants, potential impacts on non-target species can also be a concern. While these environmental concerns are present, they have not been observed as a result of field trials, or commercial production of GE orchard trees. Other than introgression of transgenes into wild or feral populations, potential adverse effects on the surrounding ecology as a result of cultivation of GE orchard trees would be no different than their non-GE counterparts. In some instances, such as for disease resistant GE varieties, these may benefit surrounding plants by suppressing the incidence and prevalence of disease.

3.4.5.1 Orchard Trees

Various GE orchard and plantation trees have been developed and field tested, to include apple, avocado, banana, European plum, papaya, lime, and grapefruit. As of 2015, the GE orchard trees of apple (non-browning trait), plum (plum pox virus resistant), and papaya (papaya ringspot virus) have been deregulated under 7 CFR part 340. Papaya is in commercial production in Hawaii, and plum and apple may see commercial scale production over the coming years. Gene

flow and introgression between GE and wild apples, papaya, and plum is possible and depends upon complex genetic and ecological interactions. GE apple can naturally outcross or hybridize with other cultivated or wild apple varieties where there is overlapping flowering time. Hybridization with other commercially grown or feral papayas may occur, depending on the distance to such plants. GE plum (*Prunus. domestica*) is a hexaploid species and does not naturally cross-fertilize with most other *Prunus* species such as apricot, almond, peach, and cherry, or diploid plum. Cross-compatibility with the Damson plum species (*P. spinosa*) has been reported with hybrid progeny displaying various levels of fertility.

Producers of GE fruit and nut trees would have to segregate production of GE and non-GE trees, or take other measures, such as covering flowers during the time of pollen production to prevent cross-pollination. Gene flow is relatively low among papaya as most of the papaya was hermaphrodite in Hawaii.

For orchard trees, isolation distances between the GE orchard tree and sexually compatible wild or feral relatives, as well as other commercial trees, are required to preclude gene flow. For example, pollen distribution for apple trees is generally limited to less than ~ 980 ft/300 m with a precipitous decline beyond ~190 ft/58 m (Larsen and Kjær 2008, Tyson, Wilson and Lane 2011). For plum and papaya, gene flow dramatically decreases at distances over ~1300 ft/400 m (Mendoza, Laurena and Botella 2008, Scorza, Kriss, Callahan et al. 2013).

3.4.5.2 Commercial Forestry

Several varieties of GE trees have been field tested under APHIS authorization; these being American elm, loblolly pine, pitch X loblolly pine, poplar, and eucalyptus. To date, GE trees for commercial forestry purposes have not been issued determinations of non-regulated status by APHIS. APHIS received its first petition for deregulation of a GE freeze-tolerant eucalyptus tree, which is currently under review. If deregulated, GE freeze-tolerant eucalyptus could potentially be used for commercial purposes.

In terms of commercial forestry, research and development of GE trees is done for the purposes of introducing desired traits that can increase the productivity of trees stands, improve fiber/wood product quality, expand the range of climate conditions under in which a commercial tree species can be cultivated, and modify wood fibers to make the wood more amenable to paper and paperboard processing. For example, the paper industry is interested in reducing the processing costs and use of potentially harmful chemicals in the removal of lignin from wood (Kraft process).

3.4.5.3 Ecological Restoration

In terms of ecological restoration, an example would be the current efforts to develop a GE blight resistant American chestnut for reintroduction into forest ecosystems. The American chestnut, once one of the most dominant trees in the Eastern United States, is effectively extinct as a result of a pathogenic fungus (*Cryphonectria parasitica*) that destroyed most of the U.S. population.[68] The American Chestnut Research and Restoration Project (SUNY-ESF 2016) is

[68] Chestnut blight was accidentally introduced into the United States in the early 1900s via imported chestnut trees from Asia. There were an estimated 4 billion American chestnut trees in the U.S. in the 1800s, accounting for around one quarter of all U.S. hardwood trees.

developing a GE American chestnut tree that is resistant to the fungus, with the aim of reintroducing GE resistant trees back into forest ecosystems of the Eastern United States (reforestation). GE trees may also be developed to remove environmental contaminants from soils and wetlands where other forms of cleanup may be prohibitively expensive.

3.4.5.4 Environmental Risk Analyses

Evaluation of the potential environmental impacts of GE trees differs from GE crop plants in several ways. For example, tree pollen can travel long distances; pine pollen up to 25 miles from its source (Williams 2010). Trees are also long lived perennials, whereas most crop plants are annuals, and many tree species reproduce for years before being harvested. Lastly, because trees are far less domesticated than row crops, there may exist substantial populations of sexually compatible relatives in the wild, and the GE tree itself would likely be viable outside areas of commercial cultivation. Hence, the long life span of trees, combined with the fact that many species can cross-pollinate with closely related species, are salient concerns in regard to potential gene flow (Strauss, Kershen, Bouton et al. 2010).

Environmental risk analyses conducted as part of GE tree field trials largely seek to determine the effectiveness of risk mitigation measures used in the confinement of gene flow. In such analyses a number of factors have to be considered, which include (1) the reproductive biology of the GE tree species and sexually compatible wild relative species; (2) the potential for long-distance dispersal of pollen, seed, or propagules; and (3) ecological interactions, particularly where protected species are concerned (Häggman, Raybould, Borem et al. 2013). With specific regard to ecological interactions, environmental risk analyses may include, as applicable: (1) the potential invasiveness of the GE tree or GE-wild relative hybrids; (2) effects of one plant on another through the release of biochemicals (known as allelopathy);[69] and (3) effects on hydrology, biodiversity, and soil nutrient use. In the United States, risk assessments have been conducted for APHIS authorized field testing of eucalyptus, poplar, white spruce, and sweetgum, as well as non-forest trees including papaya, apple, walnut, and plum (see (ISB 2015)).

In issuing a field trial permit for regulated GE trees, APHIS imposes permit conditions that are designed to prevent the movement of the GE trait outside of the field test site (USDA-APHIS 2011, USDA-APHIS 2012). Such conditions also require trials to be conducted in areas isolated from sexually compatible relatives, and removed from potentially affected threatened and endangered (T&E) species, and critical habitat. Permit applicants must indicate how the GE trees will be devitalized on completion of field testing, and how they will ensure that any underground plant parts capable of reproduction are removed and likewise devitalized. APHIS requires monitoring for and reporting of any sign of potentially invasive characteristics, pollen dispersal, and occurrence of volunteers. APHIS compliance and the site inspection processes provide further environmental protection measures. Any future field testing of regulated GE

[69] Allelopathy refers to the beneficial or harmful effects of one plant on another plant through the release of biochemicals, known as allelochemicals. Such allelochemicals are released from plant parts by leaching, root exudation, volatilization, residue decomposition, and other processes in both natural and agricultural systems Ferguson, J., Rathinasabapathi, B. and Chase, C. (2016). *Allelopathy: How Plants Suppress Other Plants [HS944]*. Retrieved January 19, 2016, from ftp://ftp.aphis.usda.gov/foia/FOLDER_10/AR00036513%20Ferguson%20and%20Rathinasbapathi.pdf..

trees under the current regulatory regime would continue to be done so under APHIS permitting and 7 CFR part 340 requirements.

While there are no known environmental harms that have resulted from field testing of GE forest and orchard trees, there are concerns among some stakeholders regarding the potential environmental impacts of GE trees, particularly those developed for commercial forestry purposes.

3.4.6 GE Ornamentals

Development of GE ornamental plants is of increasing interest, namely in development of desired traits such as abiotic stress resistance, pest and disease resistance, and flower color. APHIS has authorized the field testing of various GE ornamental plants, which include anthurium, marigold, geranium, petunia, dendrobium orchid, Easter lily, gladiolus, iris, petunia, and chrysanthemum. GE ornamentals have not seen wide scale commercialization due to international regulatory requirements and restrictions, such as those limiting approval only to GE ornamentals with modified flow color, and the high cost of regulatory approval, both in the United States and abroad, which makes the development of GE ornamentals unattractive from a business perspective (Chandler and Sanchez 2012). The only GE ornamental products that have so far been deregulated and released to the market in the United States are flower color modified varieties of carnation (*Dianthus caryophyllus*) and rose (*Rosa hybrida*).

For GE ornamental plants, environmental concerns are largely similar to those for GE crop plants. Namely, whether there is any difference in the invasive potential of the GE variety compared to non-GE varieties of the same species, or there is the potential for gene flow to sexually compatible wild relatives (Chandler and Sanchez 2012). For instance, ornamental species in North America where gene flow from non-native species has occurred include the genera *Rosa*, *Quercus*, and *Rhododendron* (Chandler and Sanchez 2012). *Rosa hybrida* is an important cut-flower, shrub, and pot plant and its cross-compatibility with naturally occurring wild *Rosa* populations can be of particular concern in some parts of the world (Chandler and Sanchez 2012). Hence, for ornamentals, post-release monitoring may be required as part of commercial production to provide information on potential unintended effects, such as the establishment of volunteer populations, introgression with sexually compatible wild or cultivated species, or changes to agricultural practices relating to chemical use (Chandler and Sanchez 2012). For field testing of GE ornamentals, the same confinement requirements as prescribed for crop plants apply.

3.4.7 GE Microorganisms

As summarized in subsection 3.3.4.2, GE microorganisms are developed for use in the bioremediation of pollutants in contaminated soils and water; as biocontrol agents; to serve as nitrogen fixing bacteria; and for production of food substances, and pharmaceutical and industrial compounds. APHIS regulates GE microbes that are plant pests under the PPA; hence, APHIS evaluates the plant pest risks of GE microorganisms. The EPA regulates microorganisms and other GE constructs intended for pesticidal purposes and subject to FIFRA and the FFDCA. The EPA also regulates certain GE microorganisms used as biofertilizers, bioremediation agents, and for the production of various industrial compounds including biofuels under TSCA. In addition, under the FFDCA, the FDA regulates microorganisms, including GE microbes, and

their products that are used in human and animal food. At present, GE microorganisms have seen limited use in agriculture and largely remain in the domain of research and development as matters of containment and potential ecological impacts are still being refined.

Under FIFRA, microbial biopesticide products, as with all other pesticides, are evaluated for their risks and benefits to society. The environmental risk and benefits of GE bacteria, viruses, protozoa, algae, and fungi intended for use as pesticides are regulated by the EPA under 40 CFR part 158.2100. Additionally, the EPA evaluates the potential for effects upon T&E species under the Endangered Species Act (ESA). The EPA evaluates potential toxicity of GE microorganisms to non-target organisms and dietary risks to infants and children under FIFRA and the FFDCA.

Stakeholders can be reluctant to the use of microorganisms for agricultural purposes, as compared with chemicals, largely due to familiarity with the causal relationship between certain bacteria/viruses and human disease, and less awareness of the beneficial role of microbes in the environment (Vidaver, Tolin et al. 2012). The use of taxa that include human and/or animal pathogens can also be of concern for some stakeholders, even when there is no evidence of the ability of microorganisms to cause harm (Wozniak, McClung et al. 2012). Concerns of horizontal gene transfer among naturally occurring microbiota (prokaryotes), or from prokaryotes to eukaryotes has also been of concern.

While ecological concerns and regulatory constraints (compliance with applicable laws administered by USDA, EPA and FDA) remain obstacles for testing of GE microorganisms in the field, and commercial application, bioconfinement of microorganisms is possible, both through genetic and physical means, and there are substantial environmental benefits that may be derived from GE microorganisms. These include (US-EPA 2015i):

- biomass conversion for chemical production
- microbial fuel cells
- mining and resource extraction
- building materials
- waste remediation and pollution control
- non-pesticidal agriculture

Consequently, APHIS expects to see increasing use of GE microorganisms in the coming years for the applications described above.

3.4.8 Summary of GE Organisms and the Environment

APHIS has authorized more than 18,000 environmental releases of GE organisms (ISB 2015, USDA-APHIS 2016a). These releases have encompassed more than 100 different types of GE organisms, and include row crops, trees, turf grasses, and ornamental crops. The vast majority of GE organisms regulated by APHIS have been GE crop plants. Less than 1% of the total number of authorized field releases involved non-plant species. When conducted according to permit and notification requirements, field trials of GE organisms present minimal environmental risk. None of the non-plant GE organisms regulated by APHIS has had any identifiable impacts on the environment.

Unique concerns regarding the environmental impacts of GE plants are those related to potential gene flow and the effects of GE traits on other plant species, the effect of a transgene on non-target organisms, the potential "weediness" of a GE plant, and evolution of pest or weed resistance as a result of the presence of the transgene. Isolated instances of non-compliance with regulations have resulted in the unauthorized release of GE plants, and in the case of bentgrass, gene flow to sexually compatible resident species. To date, field trial data providing instances where regulated GE plant-wild relative hybrids had an increase in fitness is limited (Warwick, Beckie et al. 2009). APHIS is not aware of any documented introgression of a transgene that confers a selective advantage to a wild population, and new populations of invasive GE plants that originate from transgene introgression have not been found (Kwit, Moon et al. 2011).

For those GE crop plants APHIS has determined are not subject to 7 CFR part 340: The available science provides little evidence that the cultivation of the presently commercialized GE crops have resulted in adverse environmental impacts that are unique or differ from conventional cropping systems (i.e., (Sanvido, Romeis and Bigler 2007, Brookes and Barfoot 2013b, Klümper and Qaim 2014) and others). Hybrids of GE crop-wild relative species that have disrupted ecosystems (altered population structures, ecosystem goods and services) have not been described in the scientific literature.

Generally, to date, GE crops have been found to have no more or fewer adverse effects on the environment than non-GE crops produced conventionally (NRC 2010a, NAS 2016b). The use of insecticides with toxicity to non-target organisms or greater persistence in soil and waterways has typically been lower in GE cropping systems than in non-GE, non-organic fields (NRC 2010a). For example, a recent study by Yi and Sangwon found that the impact per hectare of corn and cotton crops on the ecological health of freshwater systems decreased by about 50% in the last decade (Yi and Sangwon 2015). This change was mainly attributed to the use of GE crops, which reduced the application of insecticides and use of less environmentally friendly herbicides such as atrazine.

Commercial crop production of any type, whether a conventional, organic, or GE cropping system always has some degree of impact on the environment. Air pollutants, introduction of pesticides and fertilizers (organic or synthetic) to surface water and groundwater, soil erosion, land use, and loss of biodiversity and habitats are all potential impacts that can derive from commercial crop production (e.g., (Bahlai, Xue, McCreary et al. 2010, Brookes and Barfoot 2010, Tuomisto, Hodge, Riordan et al. 2012, Klümper and Qaim 2014) and others). These are issues that all farmers, not just those growing GE crops, work with in providing sufficient human food, animal food, and fiber to meet market demands. The degree of environmental impacts can be minor or noticeably adverse, depending on a variety of factors that include the type and quantity of agronomic inputs and practices employed, geographic locale, local biota, weather, inherent soil characteristics, and crop type being produced.

In agriculture, resource utilization efficiencies can be improved in different ways and requires continuous research and innovation (FAO 2014b). Modern agriculture strives to balance these potential environmental impacts with societal needs for human and animal food, fiber, and biofuels. Accordingly, the main challenges for all agricultural systems are to improve nutrient and pest management while sustaining maximal crop yields on minimal areas of land. These challenges are location-specific and encompass valuation of environmental, economic, and

societal needs and concerns. Such efficiencies are directly affected by the choice of plant cultivars that exist for various types of crops, and the agronomic practices used in the management of crop production (e.g., tillage; timing and quantity of agronomic inputs such as insecticides, herbicides, fertilizers; irrigation inputs).

In commercial crop production, both in the United States and abroad, sustaining maximal crop yields is a primary concern in efficiently meeting demands for food, fiber, and fuel, particularly in the context of increasing population, limited lands, persistence of pests, disease, and weeds, and an increasingly constrained resource base (FAO 2014b). To the extent agricultural biotechnologies facilitate achieving maximal crop yields with minimal inputs, and reduce environmental impacts, they provide valuable options for commercial crop producers (FAO 2014b). This is particularly important when considering the well-recognized impacts of agriculture on environmental quality; increasing demands on water resources; increasing global demand for food, fiber, and fuel; and relatively uncertain effects of global warming and regional climate change on crop production (e.g., drought, pest infestations) (Backlund, Janetos et al. 2008, Brevik 2013, Hatfield, Takle et al. 2014, IPCC 2014).

Although GE cropping systems have been found to have no more, or in some instances fewer impacts, on the environment than conventional cropping systems (Brookes and Barfoot 2013b, Klümper and Qaim 2014, Brookes and Barfoot 2015), all agricultural production, GE and non-GE alike, can result in well understood environmental impacts as described throughout this dPEIS. Fundamentally, sustainable agricultural productivity encompasses not only the transformation of resources into agricultural products that benefit human welfare, but also the extent to which environmental benefits or costs are coproduced with the agricultural system (FAO 2014b). The stewardship of such environmental benefits or costs, collectively using conventional, GE, and organic cropping systems is and will remain an ongoing effort shared by industry, growers, and state and federal agencies. The potential environmental impacts of a GE cropping system will vary according to the specific crop species being cultivated, the pests and weed problems present in a given area for that specific crop, the particular phenotype conferred by the introduced trait gene and gene product(s), the naturally occurring biota in the area, and abiotic environmental factors.

3.5 Physical Environment

3.5.1 Soils

Maintaining soil fertility is a principal component of sustainable agriculture and major determinant of crop yield and product quality. Fertilizer and pesticide inputs, tillage, and irrigation practices can potentially affect soil quality, and in turn air and water quality. Tillage practices in particular, along with crop rotation and cover crop practices, can affect the erosional capacity of soils. Beneficial soil microorganisms, which are major determinants of soil fertility, can also be affected by agronomic practices. Soil microorganisms are discussed in Subsection 3.6.6–Soil Biota.

GE crops are field tested, and commercially cultivated, on a wide variety of soils in the United States (e.g., (IPM 2015)). In an agricultural setting, concerns regarding soil quality are the same for all cropping systems, GE and non-GE alike. Such concerns include the potential for tillage

practices and agronomic inputs to affect soil fertility, erosion, off-site transport of sediments into aquatic ecosystems, and disturbance of soil biodiversity. Tillage systems influence the biological, physical, and chemical properties of soil and consequently have a substantial impact on soil fertility and erosional capacity. Agronomic inputs such as pesticides and fertilizers can potentially affect soil biota, which can in turn, impact the fertility of soil. There has also been some concern expressed regarding the potential effects of GE Bt and HR traits on soil microbiota, and this is discussed in a separate subsection below (3.6.6). The following discussion focuses primarily on the chemical and physical aspects of agricultural soils – namely erosion.

Soil erosion is a significant concern in many areas of the United States (Figure 3-21). While soil erosion can occur through natural processes as determined by soil type, local ecology, and weather, conventional tillage can also result in degradation of soil quality, and contribute to the erosional quality of soils (Berhe and Kleber 2013, Brevik 2013, Gomiero 2013). Conversely, soils under conservation tillage systems have substantially higher soil quality and exhibit less erosion than conventionally tilled soils (Roger-Estrade, Anger, Bertrand et al. 2010, He, Li, Rasaily et al. 2011, Sharma and Abrol 2012, Abdalla, Osborne, Lanigan et al. 2013, Van Eerd, Congreves, Hayes et al. 2014). Consequently, soil management and conservation is a key aspect of current agronomic practices, particularly in the Corn Belt region, and the majority of U.S. farmers are moving away from conventional to conservation tillage practices (USDA-NRCS 2006b, CTIC 2015).

Soil conservation practices aim to reduce field tillage, sustain soil quality, and prevent soil loss. Conservation tillage, which leaves at least 30% of the previous year's crop residue on fields, reduces erosion and runoff, preserves soil organic matter and beneficial biota, maintains nutrients, preserves water-retention capacity, reduces erosion, and requires less time and labor in preparation of the field for planting (Roger-Estrade, Anger et al. 2010, He, Li et al. 2011, Sharma and Abrol 2012, Van Eerd, Congreves et al. 2014). Conservation tillage methods include no-till, strip-till, ridge-till, and mulch-till.

In general, there has been a corresponding overall improvement in the quality of soils in the United States. Over the last three decades as conservation tillage practices increased, total soil loss on erodible croplands in the United States decreased 39% from 462 million tons per year to 281 million tons per year (USDA-NRCS 2006b). This decrease in soil erosion carries with it a corresponding decrease in nonpoint source (NPS) pollution run-off of fertilizer and pesticides. In 2012, farmers applied tillage practices on 278.8 million acres of cropland, which included no-till on 96.5 million acres, conservation tillage on 76.6 million acres, and conventional tillage on 105.7 million acres (USDA-NASS 2012). Use of conservation tillage, to include no-till, has in part been attributed to adoption of GE crops (Fernandez-Cornejo, Hallahan et al. 2012).

While erosion has decreased through adoption of conservation tillage and other practices, it remains a key issue in many areas of the United States. Excessively eroding cropland soils are concentrated in Midwest and Northern Plain States, and in the Southern High Plains of Texas (Figure 3-21). Farmers, including corn growers, producing crops on highly erodible land are required by law to maintain a soil conservation plan approved by the USDA National Resources Conservation Service (USDA-ERS 2012b, USDA-ERS 2012a). These soil conservation plans are prepared by the grower pursuant to the 1985 Food Security Act Conservation Compliance and

Sodbuster programs to minimize soil erosion. Corn farmers also are actively involved in state, local, and national programs that temporarily remove environmentally sensitive land from crop production, including the Conservation Reserve Program, the Conservation Reserve Enhancement Program, and the Farmable Wetlands Program (USDA-FSA 2015).

Soils also play a fundamental role in biochemical processes such as degradation of pesticides and organic matter, and the biogeochemical cycling of carbon and nitrogen. In many cases, crop and soil management practices that increase soil organic matter and plant residues, such as conservation tillage, impart attributes to soil that can hinder pesticide movement, enhance pesticide degradation (Locke and Zablotowicz 2004), and facilitate the natural cycles of soil nutrients.

In summary, land management practices used in crop cultivation can affect soil quality and erosion, both beneficially and adversely. Tillage practices, pesticide application, crop rotation, soil amendment, and other practices can improve soils, but must be applied using sound resource management strategies to avoid degrading soil quality (Montgomery 2007, Berhe and Kleber 2013, Gomiero 2013, USDA-NRCS 2015a). These land management practices are common to, and differ little among GE and non-GE cropping systems, although conservation tillage, to include no-till, are more frequently used in GE than non-GE cropping systems. To the extent certain varieties of GE crops facilitate the adoption of conservation tillage practices, they would be expected to alleviate pressures of soil quality that can derive from crop cultivation.

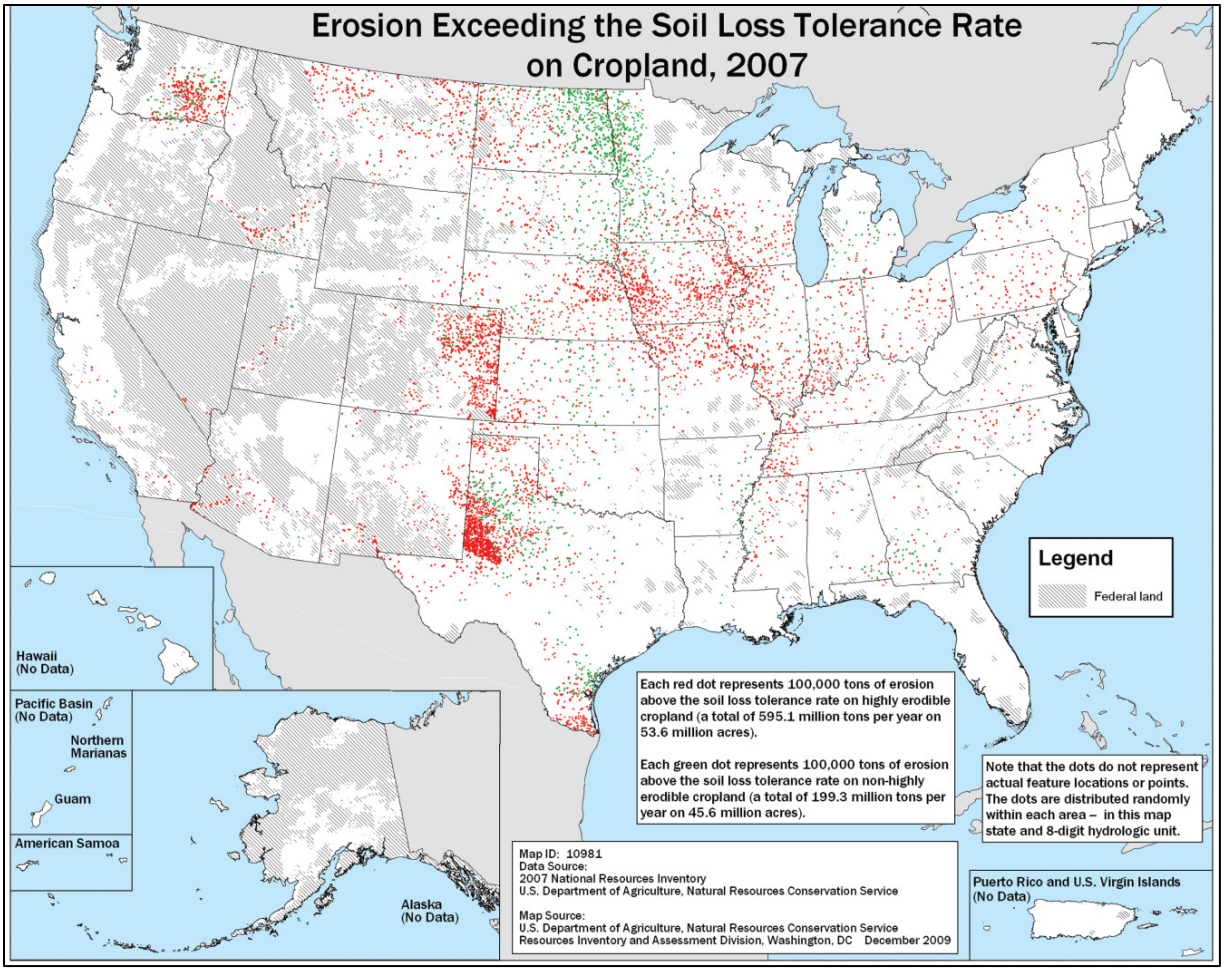

Figure 3-21. Locations and Status of U.S. Croplands Subject to Erosion
Source: (USDA-NRCS 2010)

3.5.2 Water Resources

The salient agricultural issues related to water resources in the United States are use of surface and groundwater for agricultural irrigation, and the potential effects of crop production on water quality. The impacts of crop production on water quality and consumption depend on factors such as the intensity of crop production over time; type of crop; location; type, volume, and toxicity of agronomic inputs applied (i.e., insecticide, herbicide, fertilizer); regional climate and weather patterns; and the agronomic practices employed in management of crop residues. These considerations apply equally to GE and non-GE commercial crop production systems. Unique to GE crop varieties is the possible introduction of GE trait material (proteins, genetic material) into aquatic ecosystems and its potential effect on water resources.

3.5.2.1 Irrigation and Consumptive Uses of Water in Agriculture

Irrigation is a significant aspect of crop production in many areas of the United States. Total water withdrawals for irrigated agriculture were 129 million acre feet in 2010 (latest USGS data), accounting for 32% of the Nation's total water withdrawals. For the 17 contiguous

Western states, which account for approximately 75% of irrigated acres, withdrawals of 106.9 million acre feet comprised nearly 83% of the Nation's irrigation withdrawals (USDA-ERS 2015d).

Irrigated agriculture, while comprising a significant source of water consumption in the United States, also makes a significant contribution to the yield and value of certain crops in the United States. For instance, while just around 6% to 10% of all harvested cropland in the United States is irrigated on an annual basis, this acreage generates nearly half the value of all crops sold (Schaible and Aillery 2012).

Although irrigated agriculture is one of the dominant uses of freshwater in the United States, use of irrigation has been declining since the 1980s (Figure 3-22) (Osteen, Gottlieb and Vasavada 2012). For example, while irrigated cropland area expanded over 40% since 1969, irrigation water application rates have declined about 20%. This is in part due to advancing technologies and increased efficiencies in irrigation systems and on-farm water resources management (Schaible and Aillery 2012).

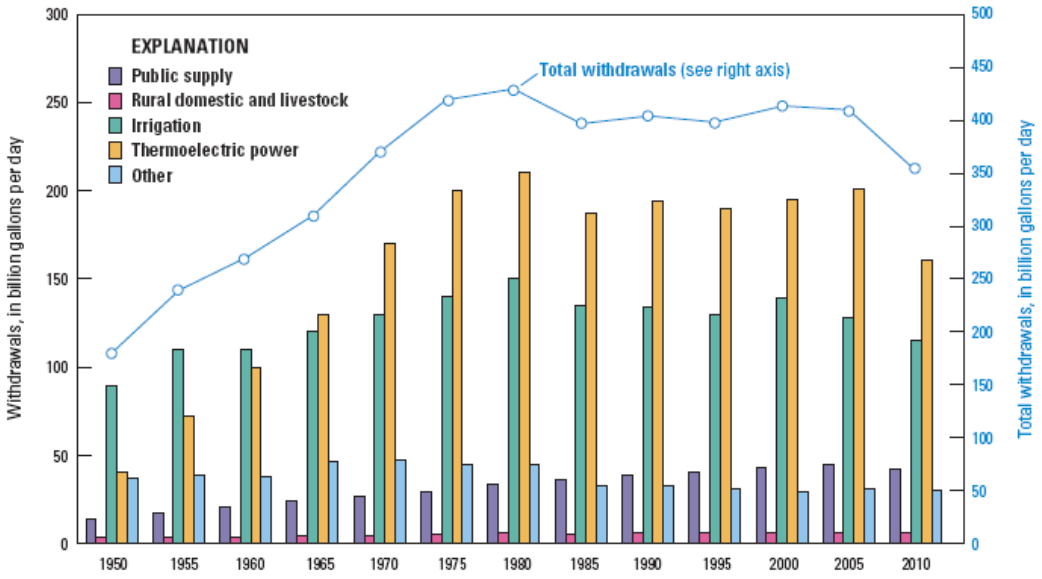

Figure 3-22. Trends in Total Water Withdraws for All Purposes, 1950-2010
Source: (USGS 2015)

Since 1998, irrigated acres have remained relatively steady at around 55-56 million acres annually, averaging around 1.6-1.7 acre-feet/acre (Figure 3-23). In general, irrigated farmland has appeared to have plateaued since the 1990s, and notable increases or decreases in irrigation are not anticipated. However, the need for greater efficiency in agricultural water use, largely due to increasing competing demands for water, is well recognized and conservation measures increasingly implemented on farms across the United States (Schaible and Aillery 2012).

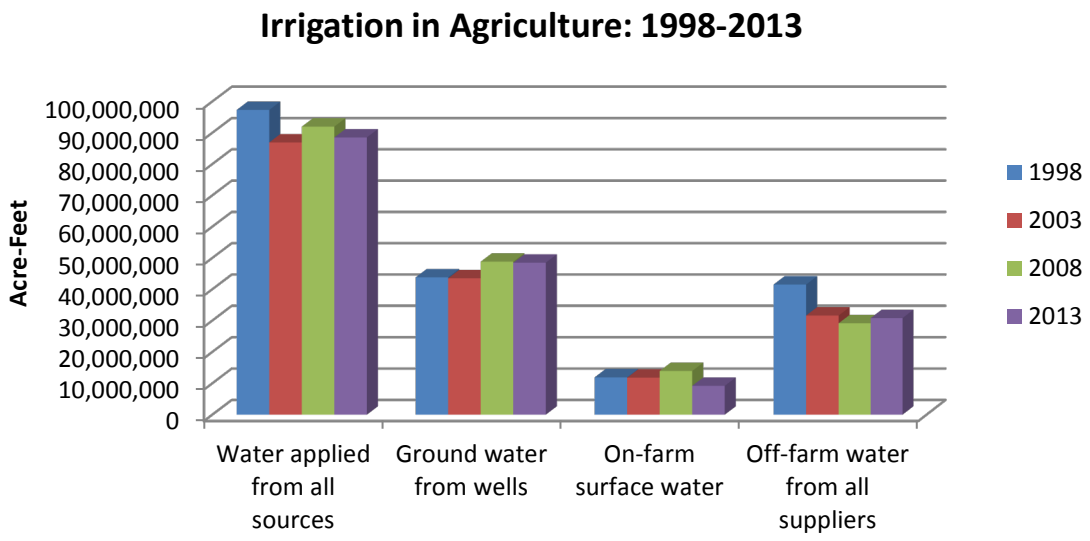

Figure 3-23. Sources and Volume of Irrigated Agriculture, 1998 – 2013
Source: (USGS 2015)

Irrigated farmland is concentrated largely in the Western United States, reflective of regional and local weather patterns and geology (Figure 3-24). Those crops with more than 25% of total acres irrigated in 2012 (most recent data) include rice (100%), cotton (41%), alfalfa hay (35%), peanuts (32%), sugar beets (32%), dry edible beans (29%), and barley (26%). In addition, about 80% of all land in orchards and berries is irrigated (USDA-NASS 2012).

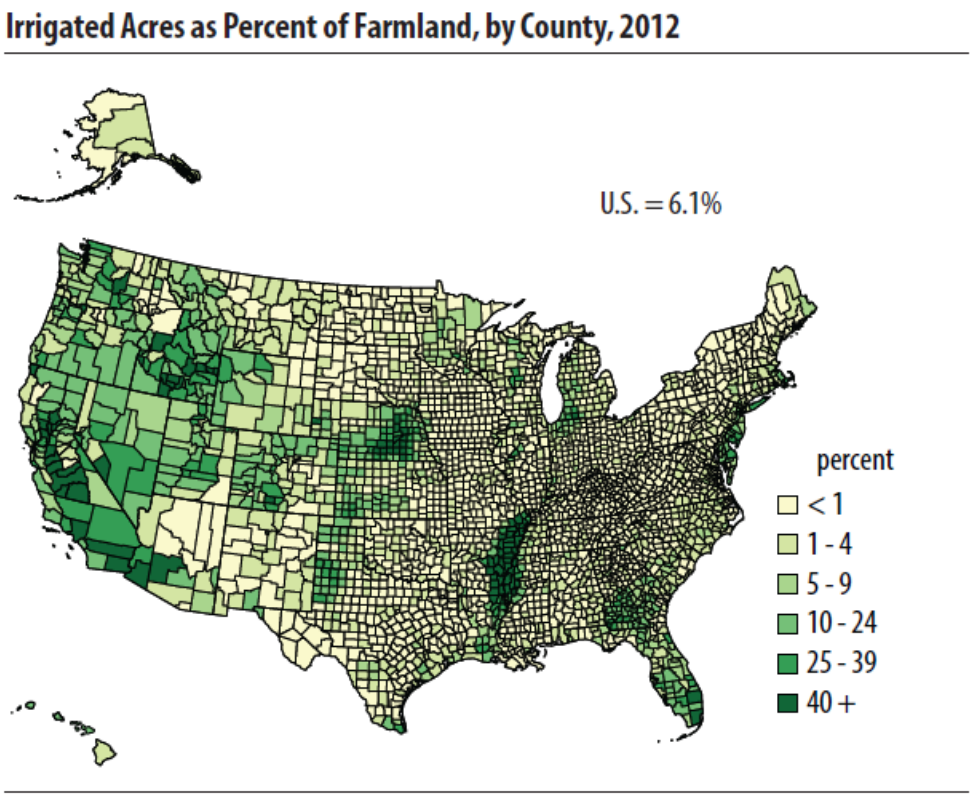

Figure 3-24. Irrigated U.S. Farmland: 2012
Source: (USDA-NASS 2014d)

The geographic distribution of total surface and groundwater withdrawals for irrigation during 2010 (latest data) is shown in Figure 3-25. As illustrated, the majority of irrigation withdrawals were in the 17 Western states (west of solid line). This is typical of areas with average annual precipitation less than 20 inches, which is generally considered the minimal sufficiency to support crops without supplemental water (Maupin, Kenny, Hutson et al. 2014). Surface water was the primary source for irrigation in the arid West, and the 17 Western states cumulatively accounted for 93% of total surface-water irrigation withdrawals and 69% of total groundwater irrigation withdrawals (Figure 3-26) (Maupin, Kenny et al. 2014). This is indicative of both historic and likely future trends in irrigation withdrawals.

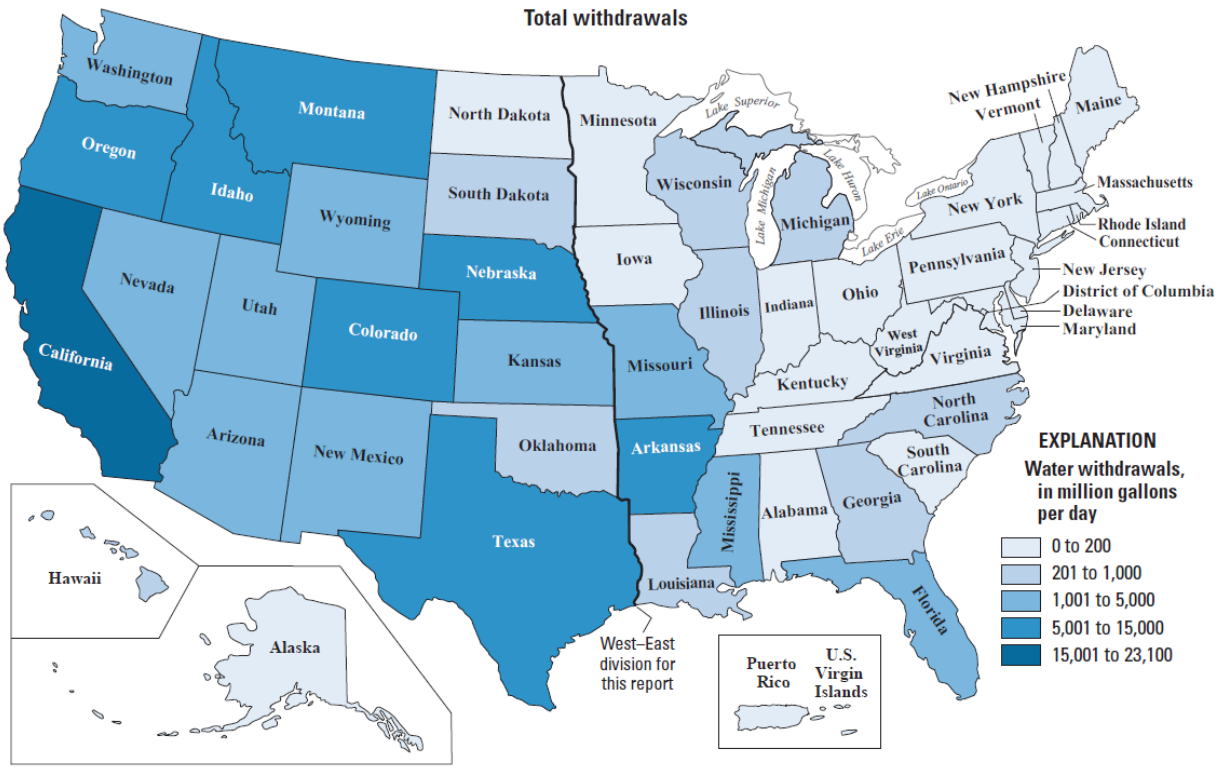

Figure 3-25. Geographic Distribution of Total Surface-Water and Groundwater Withdrawals for Irrigation, 2010
Source: (Maupin, Kenny et al. 2014)

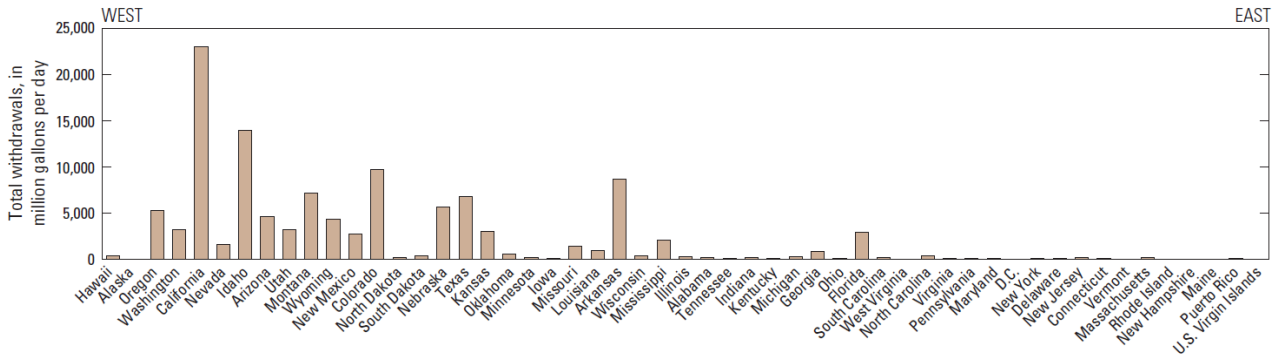

Figure 3-26. Irrigation Withdraws: Regional Distribution in the United States, 2010
Source: (Maupin, Kenny et al. 2014)

Irrigation will remain important to crop production in the United States, with commensurate demands on surface and groundwater resources. This applies equally for all crops, GE and non-GE. Apart from GE drought tolerant plants (currently no commercial varieties), there is no difference in water requirements for GE crop plants. Where agricultural water withdrawals in total are expected to decline over time with the introduction and adoption of improved water

application technologies, demands on agricultural water supplies are expected to increase over time as non-agricultural uses of water continue to expand (Schaible and Aillery 2012).

3.5.2.2 Future Competing Demands and Water Resources Management

3.5.2.2.1 Available Supplies

Historically, increased water demands were met by expanding available water supplies. However, future opportunities for expansion of seasonally reliable water supplies are limited due to lack of suitable water sources, limited funding, and increased public concern for potential environmental impacts (Wiebe and Gollehon 2006, Osteen, Gottlieb et al. 2012). While irrigation has become more water and energy efficient, water scarcity will likely prove a challenge for agriculture in years to come as competing demands for water from other sectors increase. As the demand rises, the price of water will also likely increase, in turn increasing production costs of irrigated agriculture (NRC 2010a).

3.5.2.2.2 Variability in Supply

Climate change is projected to reduce or alter the regularity of water supplies across much of the West due to reduced snowpack, warming temperatures, shifting precipitation patterns, and irregular and unpredictable drought (Schaible and Aillery 2012), consequently increasing demand on water resources in these areas. In the more arid Western states, over half of the renewable water supplies are consumed under normal precipitation conditions. During drought years, water use frequently exceeds renewable supplies by over-drafting water stored in aquifers and reservoirs. While droughts exacerbate supply scarcity, water demands are expected to continue to expand with resulting reallocations among competing users, namely industry, agriculture, and municipalities (Wiebe and Gollehon 2006, Osteen, Gottlieb et al. 2012). The current drought in California, 4 years running in 2015, is an example of these competing forces. It is estimated that global warming has most likely intensified the drought in California by 15 to 20% (Williams, Seager, Abatzoglou et al. 2015). As of 2014, some 500,000 acres of California farmland were fallow due to competing uses for scarce water.

Any reduced water supplies due to changes in patterns of precipitation, and evapotranspiration, will likely further constrain already over-allocated water resources across much of the Western United States. Likewise, increased water demands across industry, municipalities, environmental requirements, and Native American water rights claims, are expected to put additional pressure on water allocations (Schaible and Aillery 2012) in the Eastern states. These trends will contribute to put pressure on water allocations and require water conservation and efficient on-farm management for a sustainable irrigated agriculture sector (Schaible and Aillery 2012). Future water demands will increasingly be met through reallocation of existing resources, improved distribution, and application efficiencies. Because agriculture is the largest freshwater user, reallocation will likely reduce supplies for agriculture in many areas of the United States. (Wiebe and Gollehon 2006, Osteen, Gottlieb et al. 2012).

3.5.2.2.3 Competing Uses

In general, changes in water availability for agricultural uses may have significant impacts on irrigation-dependent crops, with associated implications for local agricultural industries and communities, and commodity prices (Wiebe and Gollehon 2006, Osteen, Gottlieb et al. 2012).

Population growth, Native American water-right claims, water quality improvement initiatives, water related environmental priorities, climate change, food security, and expanding water requirements for energy production are all anticipated to increase demands on water resources, nationally (Schaible and Aillery 2012). Future uses of water by agriculture will be influenced by the ability of growers to improve on-farm efficiencies in water use. This can be achieved through upgrades to physical water application systems, improved on-farm water management and conservation practices, and local and regional policy governing water resources and uses at the farm and watershed levels (Schaible and Aillery 2012).

3.5.2.2.4 GE Plants and Water Resources

GE plant developers are actively working to refine traits for flood or drought tolerance that would enable cultivation in areas with less than optimal water availability. In particular, there is a focus on drought resistance and salt tolerant plants. The development of drought resistant varieties can be difficult because plants with such traits often underperform when not under water stress. To date, APHIS has deregulated one GE crop plant for drought tolerance, which was a corn variety deregulated in 2011. Similar requests may occur in the future. As GE plants are developed with new traits that may more directly impact water resources such as resistance to bacterial and fungal diseases, these would be given individual consideration in future Plant Pest Risk Assessments (PPRA), Weed Risk Assessments (WRA), and environmental analyses, as appropriate.

3.5.2.3 Water Quality

Agricultural activities can impair the quality of surface waters through run-off. EPA water quality assessments indicate agricultural run-off continues to be the leading source of NPS water quality impairments in the United States. Such run off primarily affects rivers and streams, although it is a major source of impairments to estuaries as well (US-EPA 2015j).

The primary NPS pollutants derived from crop production in the United States are sediments, nutrients, and pesticides. The EPA lists sediments as the second most frequent cause of impairment of stream sand rivers, nutrients third, and pesticides sixteenth (Table 3-19) (US-EPA 2015j). Each of these inputs can adversely impact aquatic and terrestrial wildlife, and ecosystem dynamics. Nutrients such as nitrogen and phosphorus discharged from agricultural fields into surface waters also contribute to NPS pollution. Nutrient runoff can cause algal blooms that lead to the development of hypoxic/anoxic conditions,[70] creating an environment that is unable to sustain aquatic life. Excessive sedimentation in runoff can also adversely affect freshwater aquatic ecosystems by covering fish breeding substrates, increasing turbidity, and, in some instances, degrading coastal and marine ecosystems.

[70] Hypoxia means low dissolved oxygen concentrations. Anoxia means a total depletion of dissolved oxygen. Both conditions are harmful to aquatic biota.

Table 3-19. Causes of Impairment in Assessed Rivers and Streams, 2015	
Cause of Impairment Group	**Miles Threatened or Impaired**
Pathogens	177,529
Sediment	119,339
Nutrients	110,100
Mercury	103,617
Organic Enrichment/Oxygen Depletion	89,869
Polychlorinated Biphenyls (PCBs)	80,882
Metals (other than Mercury)	76,583
Temperature	68,807
Habitat Alterations	67,230
Turbidity	46,581
Cause Unknown	46,052
Flow Alteration(s)	42,580
Cause Unknown - Impaired Biota	42,464
Salinity/Total Dissolved Solids/Chlorides/Sulfates	36,700
pH/Acidity/Caustic Conditions	28,645
Pesticides	19,128

Source: (US-EPA 2015j)

3.5.2.3.1 Sediment Run-off

Sediment in surface water is largely the result of soil erosion, which is influenced by both inherent soil properties and crop production practices such as tillage and crop residue management. Sediment can destroy or degrade aquatic wildlife habitat, which reduces biodiversity and impairs commercial and recreational fisheries (Ribaudo and Johansson 2006). Sediment can also clog drainage ditches, irrigation canals, navigation channels, and reduce the useful life of reservoirs. This can result in increased costs associated with dredging and water treatment. By raising streambeds and filling wetlands, sediment also increases the probability and severity of flooding (Ribaudo and Johansson 2006). Regions with the greatest potential to discharge sediment from cropland to surface waters include parts of the Heartland, Mississippi Portal, and Prairie Gateway.

3.5.2.3.2 Nutrient Run-Off

Soils in many areas of the United States where crops are produced are naturally deficient in nitrogen and other nutrients, requiring fertilizer inputs to produce the crop yields necessary to meet market demand and support societal needs. Nitrogen, phosphate, and potash are essential nutrients in crop production, and these are widely applied via chemical fertilizers to crops across the United States on an annual basis. Manure, a source of nitrogen and phosphorus, is also applied as a fertilizer to various crops in the United States, including barley, corn, cotton, sorghum, and soybeans. Nutrients from these fertilizers can enter water bodies through agricultural runoff and leaching.

Nitrogen and phosphorus are the third largest source of impairment of rivers, streams, and estuaries, and a significant problem for Gulf of Mexico ecosystems and fisheries (Wiebe and

Gollehon 2006). Nutrient run-off can impair water quality through the promotion of algal blooms, and result in hypoxia or anoxia, which is harmful to fish and other wildlife. In general, agricultural sources contribute more than 70% of the nitrogen and phosphorus delivered to the Gulf of Mexico, versus only 9% to 12% from urban sources (Alexander, Smith, Schwarz et al. 2008). For example, corn accounts for about 45% of U.S. crop acreage receiving manure, and 65% of the 8.7 million tons of nitrogen fertilizer applied by farmers each year (Ribaudo, Delgado, Hansen et al. 2011). Nitrogen run-off from cornfields, in particular, is the single largest source of nutrient pollution to the Gulf of Mexico's "dead zone" (Ribaudo, Delgado et al. 2011). Agricultural nutrient losses to streams are a primary concern in the Midwest (Ribaudo, Delgado et al. 2011), particularly in relation to the adverse effects of nutrient loads on hypoxia in the Gulf of Mexico (Wiebe and Gollehon 2006).

Agricultural management practices and factors that determine erosion and NPS pollution include the type of crop cultivated; plowing, tillage, and irrigation practices; pesticide and fertilizer application practices (e.g., type, quantity, methods); weather; and regional environment. This applies to both GE and non-GE cropping systems.

When crop production operations are sustainably managed they can help protect watersheds by reducing run-off. For example, conservation tillage practices can reduce the erosional potential of agricultural lands, and consequently, sediment loads and runoff in surface waters (USDA-NRCS 2006b, CEFS 2015).

3.5.2.3.3 Pesticide Run-off

During any given year more than 400 different pesticides are used in agricultural settings, and pesticide levels continue to be a concern for water quality and aquatic life in many of the Nation's rivers and streams in agricultural areas. During 2002–2011 (latest USGS data), 61% of agriculture land-use classification streams exceeded chronic Aquatic Life Benchmark (ALB) criteria for various pesticides. The EPA uses ALB toxicity criteria to evaluate water quality, particularly the potential toxicity of pesticides in streams and rivers. Across these streams, there were 21 pesticides that exceeded chronic ALBs (Stone, Gilliom and Martin 2014).

Where pesticides remain an issue in agricultural production, the impact of crop production on freshwater systems has declined over the last decade. A recent study by Yi and Sangwon (2015) found that the impact per hectare of corn and cotton crops on the ecological health of freshwater systems decreased by about 50% in the last decade (Yi and Sangwon 2015). This change was mainly attributed to the use of GE crops, which reduced the application of insecticides and relatively toxic herbicides such as atrazine. However, the freshwater ecotoxicity impact per hectare of soybean production tripled, largely due to the spread of an invasive species, soybean aphid, that resulted in an increasing use of insecticides.

3.5.2.3.4 GE-trait Material

Some traits, namely insecticidal PIPs such as Bt derived Cry and Cyt proteins,[71] could conceivably enter the aquatic environment via dispersed pollen, crop dust, or plant tissue, and potentially affect non-target aquatic organisms in the same manner as Cry and Cyt proteins may

[71] Bacillus thuringiensis (Bt) strains synthesize crystal (Cry) and cytolytic (Cyt) proteins that are toxic to certain orders of insects.

affect non-target terrestrial arthropods. For a PIP to be registered under FIFRA, the EPA must review ecotoxicity data and reach a determination that the PIP does not pose an unreasonable risk to aquatic organisms.[72] The EPA also requires basic (Tier 1) ecological effects testing on representative non-target terrestrial and aquatic species that includes freshwater fish oral toxicity testing, and freshwater invertebrate testing (i.e., on Daphnia or aquatic insect species). If the results of Tier I testing show adverse non-target species effects at field use rates, then testing of additional species and/or testing at a higher Tier level is required, which would include freshwater and marine or estuarine environmental fate and transport data. If the results from environmental fate studies show a plant protein that is toxic to non-target species persists in the environment at significant levels, then chronic, reproduction, life cycle, and population effects testing is required. Further studies would require data on wildlife population and ecosystem level effects.[73] Hence, it is unlikely that any PIP registered for commercial uses would present a significant risk to aquatic organisms. APHIS would give future GE organisms developed with new PIP traits consideration in PPRAs, WRAs, and environmental analyses as appropriate. These would also require review and approval for use by the EPA.

3.5.2.4 Water Quality Regulation and Improvement

While the Clean Water Act (CWA) governs surface water quality protection in the United States, the CWA does not deal directly with groundwater or with water quantity issues. Under the CWA, it is unlawful to discharge any pollutant from a point source into navigable waters, unless a permit authorized under the CWA was obtained. EPA's National Pollutant Discharge Elimination System (NPDES) permit program controls these point source discharges. NPS pollution, which is the primary type of discharge from agricultural activities, is not regulated under the CWA; rather, it is left largely to voluntary controls implemented by states and local authorities.

Due to the potential impacts of agriculture on water resources, various national and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself (i.e., see (US-EPA 2008, USDA-NRCS 2015a, USDA-NRCS 2015c, USDA 2015a)). At the federal level, the USDA's Environmental Quality Incentives Program is an example of a voluntary program that provides financial and technical assistance to agricultural producers through contracts up to a maximum ten-year term. These contracts provide financial assistance to help plan and implement conservation practices to improve soil, water, plant, animal, air and related resources on agricultural land and non-industrial private forestland. In addition, the Environmental Quality Incentives Program helps producers meet federal, state, tribal, and local environmental regulations.

In addition to USDA initiatives and funding, local and regional policy and regulation governing water resources and uses at the farm and watershed levels will influence future agricultural water consumption. For example, conserved water rights, withdrawal restrictions on groundwater and surface water, drought water banks, and option water markets, can encourage and help producers

[72] EPA - Current & Previously Registered Section 3 Plant-Incorporated Protectant (PIP) Registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

[73] EPA - Introduction to Biotechnology Regulation for Pesticides; https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides#data-requirements

reduce crop consumptive water use while facilitating the reallocation of water to higher valued uses (Schaible and Aillery 2012).

The effectiveness of on-farm and public water conservation programs will depend on how well these programs work together to monitor and track the environmental results of nutrient reduction activities, as well as the extent to which programs complement other watershed conservation and environmental programs and policies (US-EPA 2014a).

3.5.2.5 Summary

All crops, GE and non-GE, can affect water quality through the use of pesticides, fertilizers, and soil management practices, and the associated run-off from fields into adjacent water bodies. However, the use of certain GE crops can influence the quantity and type of insecticides, fungicides, and herbicides used in crop production, largely in beneficial ways. Insect and disease resistant GE crops can reduce insecticide and fungicide use. GE HR crops can reduce, have no effect, or result in increased herbicide use. Development of weed resistance to herbicides may increase herbicide use in some instances (Owen 2011). Such increases in the volumes and varieties of herbicides used could have potentially adverse effects on aquatic ecosystems. To the extent that GE crop varieties facilitate use of conservation tillage practices, and reduce insecticide and fungicide use, commensurate improvements in water quality would be expected (NRC 2010a).

3.5.3 Air Quality

3.5.3.1 National Ambient Air Quality Standards

Because air pollution directly affects human health and can cause adverse environmental impacts, improving air quality in the United States is a significant regulatory goal. The EPA establishes National Ambient Air Quality Standards (NAAQS) pursuant to the Clean Air Act (CAA) that are intended to protect public health and the environment. NAAQS are established for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and particulate matter (PM). In addition to criteria pollutants, the EPA regulates hazardous air pollutants such as ammonia and hydrogen sulfide.

All areas of the nation are classified based on their status with regard to attainment of NAAQS. States enforce the NAAQS through creation of state implementation plans, which are designed to achieve EPA-established NAAQS. The EPA designates a region as being in attainment for a criteria pollutant if atmospheric concentrations of that pollutant are below the NAAQS, or being in nonattainment if criteria pollutant concentrations violate the NAAQS.

Crop production practices can generate air pollutants that can potentially affect the environment and human health, and challenge regional NAAQS. Agricultural emission sources include: smoke from agricultural burning (PM); fossil fuel consumption associated with equipment used in tillage and harvest (CO_2, NO_x, SO_x); soil particulates from tillage (PM); and soil nitrous oxide (N_2O) emissions from the use of fertilizers (Aneja, Schlesinger and Erisman 2009, US-EPA 2013a).

3.5.3.2 Pesticides

Spray drift, and volatilization of pesticides from soil and plant surfaces, can introduce constituent chemicals into the air, which can increase the risk of exposure for both farm workers and the general public. This is a particular concern for agricultural field workers and others in proximity to fields as some pesticides can present human health risks. Drift and volatilization of pesticides can also have unwanted effects on non-target species. Herbicide loss through volatilization can be significant, up to 25 times larger than losses from surface runoff (Gish, Prueger, Daughtry et al. 2011). Pesticide regulation, and requirements for use of EPA registered pesticides, are the same for both GE and non-GE cropping systems.

The EPA's Office of Pesticide Programs has introduced initiatives to help pesticide applicators minimize off-target drift. The EPA's voluntary Drift Reduction Technology Program was developed to encourage the manufacture, marketing, and use of spray technologies scientifically verified to substantially reduce pesticide drift.[74] The EPA is also working with pesticide manufacturers through the registration and registration review programs on improvements to pesticide label instructions to reduce pesticide drift (e.g., (US-EPA 2015g)). In October 2012, the EPA and USDA published guidance that further provides options for improving air quality on agricultural lands (USDA-NRCS 2012a). Where pesticide use will always present an environmental and human health concern, there are ongoing efforts to reduce the run-off, volatilization, and leaching of pesticides into environmental media (US-EPA 2015a, US-EPA 2015g).

3.5.3.3 Emissions Reduction Strategies in Agriculture

Over the past several years, the EPA has developed USDA-approved measures to manage air emissions stemming from cropping systems to help satisfy state implementation plan requirements. In the 2006 PM and 2008 O_3 NAAQS preambles, the EPA recommended that in areas where agricultural activities have been identified as contributing to a violation of NAAQS, USDA-approved conservation systems and activities may be implemented. Specifically, these systems and activities aim to achieve reasonably available control measures and best available control measure levels in these identified areas.

The USDA and EPA provide state, regional, and local regulatory agencies with technical tools and information on how to manage agricultural air emissions. This information gives stakeholders flexibility in choosing which measures are best suited for their specific situations and desired purposes (USDA-EPA 2012).

Current practices used to minimize emissions in crop production include conservation tillage, residue management, wind breaks, burn management, manure management, integrated pest management, nutrient management, fertilizer injection, chemigation and fertigation (inclusion in irrigation systems), and conservation irrigation (USDA-NRCS 2006b, USDA-NRCS 2006a).

[74] EPA - What EPA is Doing to Reduce Pesticide Drift; https://www.epa.gov/reducing-pesticide-drift/what-epa-doing-reduce-pesticide-drift

3.6 Biological Environment

Biological resources such as animal, plant, fungal, and microbial communities in those areas where GE organisms may be released into the environment could potentially be impacted by APHIS decisions under 7 CFR part 340. The regions where such resources are potentially affected are discussed in subsection 2.2 – Major Land Uses in the United States.

3.6.1 Animal, Fungal, and Microbial Communities

The animal, plant, fungal, and microbial (i.e., bacteria) kingdoms are integrally related, and the structure and function of various communities of biota among these are interdependent. Viruses are not classified as biota as they are not considered living organisms; however, for the purposes of the dPEIS they are included as microbiota.

Animal, fungal, and microbial communities provide vital functions for plants that include, but are not limited to, nutrient cycling, fertilization of soils, and controlling plant pests and disease (Ruiz, Lavelle and Jimenez 2008). Arthropods and other animals also serve critical roles in the pollination of crop plants and surrounding vegetation. Invertebrate communities in particular are critical components of plant health and represent the most populous and diverse assemblage of animals in and around areas where APHIS-regulated GE organisms may be field tested, or produced commercially, such as food and ornamental cropping systems, tree plantations, and orchards. Numerous insects and related arthropods perform valuable functions by suppressing both agricultural weed populations and insect pests (Landis, Menalled, Costamagna et al. 2005). Some of these beneficial species include the convergent lady beetle, carabid beetles, parasitoid wasps, and predatory mites (Landis, Menalled et al. 2005, Shelton 2011).

While most animal, fungal, and microbial species are beneficial to plant health, certain insects, bacteria, fungi, and viruses are considered plant pests, as they can harm plants through physical damage, and in severe cases, impede the growth of crop plants where infestations/infections are persistent (discussed below in subsection 3.6.3 - Plant Pests and Disease). This, in turn, can cause significant crop yield and economic losses for crop producers, as well as damage wild plants of cultural value.

GE plants with insect and disease-resistant traits have emerged as an effective method for the targeted control of plant pests and diseases (Birkett and Pickett 2014, Anderson, Gipmans, Hurst et al. 2016, Trapero, Wilson, Stiller et al. 2016). GE plants are developed for resistance to specific pests and diseases to which the plant may be susceptible, termed target organisms. Non-target species would include any species not intended to be affected by the GE plant trait. Non-target species could include insects, other animals, or soil microorganisms that are not a targeted plant pests but may consume or otherwise depend on a GE crop plant as part of its life cycle.

Detailed information on wildlife species in the Major Land Resource Areas discussed above (see Figure 3-8) is provided in the USDA-NRCS Report "Land Resource Regions and Major Land Resource Areas of the United States, the Caribbean, and the Pacific Basin of the United States (USDA-NRCS 2006c). This information is incorporated here by reference. The potential impacts to the animal, fungal, and microbial communities in these ecoregions that may derive from the Alternatives evaluated in this dPEIS are discussed in Chapter 4 - Environmental Consequences.

3.6.2 Plant Communities

Plants, as considered in this section, include all plants other than the GE plant variety being cultivated, field tested, or transported, such as non-GE crops, non-GE ornamentals, and wild plants. Plants, apart from their more obvious contribution to the sustenance of human health, provide a vast array of environmental goods and services. These include food and shelter for wildlife, carbon dioxide removal and carbon sequestration, oxygen production, air and soil temperature modulation, cycling and provision of nutrients for a vast array of biota, maintenance of soil fertility, soil erosion reduction, and aesthetic value.

Use of GE plants and other organisms, currently, is largely localized to agricultural areas. Non-crop vegetation in and around these areas is limited by the extensive cultivation, weed control, and other management practices employed in the cultivation of crop plants, orchard trees, and ornamental plants. Typically, growers encourage the growth of the commercial plant while controlling or limiting the growth of competing plant species that could negatively impact crop yield and plant health. In general, the abundance and variety of plants in intensively managed agricultural settings will be significantly less than that found in an undisturbed ecosystem. Consequently, the potential effects of a GE organism on non-crop vegetation is generally associated with vegetative communities adjacent to fields where GE organisms are used, such as woodlands, rangelands, pasture, and grassland areas. Plants in and around agricultural fields that can adversely affect crop production are generally characterized as weeds, and managed as such. Weed control programs, such as those implementing IWM practices discussed throughout this chapter, are essential to maximizing crop yield and crop commodity quality. Weeds, or rather those plants considered weeds in an agricultural setting, are discussed in subsection 3.6.5 - Agricultural Weeds and Noxious Weeds.

The transport and environmental release of regulated GE organisms may be authorized for any area of the United States or its territories. As such, a list of plant species potentially affected by such transport and release is beyond the scope of this dPEIS. NRCS provides an extensive list of plants in their online PLANTS Database,[75] which provides standardized information about the vascular plants, mosses, liverworts, hornworts, and lichens of the United States and its territories. Rare, threatened, and endangered plant species are discussed in chapter 6.

3.6.3 Plant Pests and Disease

Various species of animals, fungi, and bacteria provide essential services in the sustainable production of agricultural crops (i.e., pollination, soil nutrient quality, soil nutrient assimilation, biological control of pests and disease). However, species that feed on or physically damage crop plants can significantly reduce crop yield and product quality, cause economic losses for crop producers, and affect market pricing of agricultural commodities. Such species are commonly classified as plant pests by the PPA.[76] Estimated losses from pests and disease are

[75] http://plants.usda.gov/java/

[76] The term "plant pest" is defined in the PPA as "any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: a protozoan; nonhuman animal; parasitic plant; bacterium; fungus; virus or viroid; infectious agent or other pathogen; any article similar to or allied with any of the articles specified in the preceding subparagraphs [of the regulations]."

$21 billion from crop pathogens, $13.9 billion from crop pests, and $4.2 billion from forest pests and diseases (Peck 2013).

Approximately 600 species of insects, and numerous species of fungi and nematodes are considered serious pests in agriculture (USDA-ERS 2012a). If these pests were not well managed, commercial crop yields and product quality would decline, likely increasing production costs and food and fiber prices (USDA-ERS 2012a). For example, it has been estimated that approximately 65% of U.S. crop losses are due to non-native introduced pests and disease, at a cost of around $137 billion per year (Fletcher, Bender, Budowle et al. 2006). On a global scale, Oerke (2006) estimated that without pest control, production could decline worldwide by some 54% for corn, 46% for soybeans, 75% for cotton, 58% for potatoes, and 30% for wheat (Oerke 2006). Because there are pests and diseases that can potentially affect all major crops, and there are potential adverse effects of pests and diseases on supplying market demand for human and animal food, and fiber, as well as commodity pricing, the control of pests and disease is a vital aspect of crop management.

Various methods are used to control plant pests and diseases. These include biological controls, such as natural predators, and chemical means, such as insecticides and fungicides. Pests and diseases can also be controlled through the selection of a particular crop variety, crop rotation, adjustment of planting dates, and other cultural practices, although the risk of severe infestations may be greater using cultural methods alone. The development and subsequent adoption of GE PIP based crop plants also provide crop producers effective tools for managing plant pests and disease. GE plants resistant to pests or disease provide growers options in minimizing potential crop losses and crop management costs, and achieving maximal crop yields. Some of the most frequently field tested GE crop plants have been for insect resistant corn, soybean, and cotton, and disease resistant potato. For example, of the field tests authorized by APHIS to date, approximately 45% have been for corn, 13% for soybean, 6% for cotton, and 5% for potato; many of these pest and disease resistant varieties.

Most the pest resistant GE plants field tested have been Bt corn, soybean, and cotton developed for resistance to insects of the orders Lepidoptera, Diptera, Coleoptera, Hymenoptera, Homoptera, Orthoptera and Mallophaga. These include GE corn resistant to the pests black cutworm, armyworm, corn rootworm, southwestern corn borer, and the European corn borer; cotton resistant to bollworm; soybean resistant to pests such as bean shoot moth, soybean looper, fall armyworm, and velvetbean caterpillar; and potato resistant to the Colorado potato beetle.

Disease resistant GE crop plants include potato resistant to blight and the leafroll virus; plum resistant to the plum pox virus; papaya resistant to ringspot virus; and squash resistant to watermelon mosaic virus 2 (WMV2) and zucchini yellow mosaic virus. Other GE crop plants that have been field tested, but have not been commercialized, include fungal resistant strawberry and peanut, and virus resistant cassava/yucca.

GE microbial pesticides include bacteria, fungi, viruses, protozoa, or algae that have been modified to express or enhance pesticidal properties. For example, certain species of fungi can be used to control the growth of weeds, while other species can kill certain insect pests. The EPA regulates the sale, distribution, and use of pesticides, including GE microbial pesticides that

are produced through techniques of modern biotechnology. To date, the EPA has registered eight microbial pesticides.

For matters of brevity, this section summarizes the most important pests and pathogens of the major crops planted in the United States. Any of these could be the subject of plant improvement for management of the pest or disease, to include utilization of biotechnology to develop GE varieties resistant to pests or disease. Consequently, future APHIS review for authorization of movement of field testing under 7 CFR part 340 could be considering GE plants developed for resistance to these pests and diseases.

3.6.3.1 Corn

There are numerous arthropod pests of corn production (Table 3-20), as well as fungal, bacterial, and viral diseases of corn. Pests or pathogens are more significant problems in some regions than in others. Major corn production states include Illinois, Iowa, Kansas, North Dakota, and Texas.

Table 3-20. Corn Pests and Disease

Invertebrate Pests	**Fungal Cont'd**
Billbug, *Sphenophorus venatus vestitus*	Crazy top (*Sclerophthora macrospora*)
Brown stink bug, *Halyomorpha halys*	Diplodia ear rot (*Fusarium graminearum*)
Corn earworm (*Heliothis zea)*	Diplodia stalk rot (*Diplodia zeae*)
Corn flea beetle, (*Chaetocnema pulicaria*)	Exserohilum root rot (*Exserohilum pedicellatum*)
Corn leaf aphid (*Rhopalosiphum maidis*)	Eyespot (*Aureobasidium zeae*)
Corn leafhopper (*Dalbulus maidis*)	Fusarium ear rot, seedling blight (*Fusarium verticillioides*)
Corn rootworm (*Diabrotica* spp.)	Fusarium stalk rot (*Fusarium* spp.)
Corn (dusky) sap beetle (*Carpophilus dimidiatus*)	Gibberella ear/stalk rot (*Gibberella spp.*)
Cutworms (Family Noctuidae)	Gray leaf spot (*Pyricularia grisea*)
European corn borer (*Ostrinia nubilalis*)	Head smut (*Sphacelotheca reiliana*)
Fall armyworm (*Spodoptera frugiperda*)	Nigrospora ear rot (*Nigrospora sphaerica*)
Grasshoppers (Family Acrididae)	Northern corn leaf blight (*Setosphaeria turcica*)
Japanese beetle (*Popillia japonica*)	Penicillium ear rot (*Penicillium* spp.)
Seedcorn maggot (*Delia platura*)	Physoderma brown spot (*Physoderma maydis*)
Slugs (several genera)	Root rot (*Phoma terrestris*)
Stalk borer (*Elasmopalpus lignosellus*)	Southern corn leaf blight (*Cochliobolus heterostrophus*)
Thrips (*Frankliniella occidentalis, F. williamsi*)	Southern corn rust (*Puccinia polysora*)
Two-spotted spider mite (*Tetranychus urticae*)	**Bacterial Diseases**
Wireworms (*Limonius* spp.; *Conoderus vespertinus*)	Bacterial soft rot (Erwinia (Pectobacterium) spp.)
Fungal Diseases	Corn stunt (Spiroplasma kunkelii)
Anthracnose (*Colletotrichum spp.*)	Goss' wilt (*Clavibacter michiganensis* subsp. *nebraskensis*)
Aspergillus ear rot (*Aspergillus flavus*)	Holcus leaf spot (*Pseudomonas syringae*)
Carbonum leaf spot (*Cochliobolus carbonum*)	Stewart's bacterial wilt (*Pantoea stewartii*)
Charcoal rot (*Macrophomina phaseolini*)	**Oomycetal Disease**
Cladosporium ear rot (*Cladosporium* spp.)	Pythium stalk rot (*Pythium* spp)

Table 3-20. Corn Pests and Disease	
Common rust (*Puccinia sorghi*)	**Viral Diseases**
Common smut (*Ustilago maydis*)	Corn chlorotic dwarf virus (Family Sequiviridae)
Crazy top (*Sclerophthora macrospora*)	Corn dwarf mosaic virus (Family Potyviridae)

Source: (Jasinski, Precheur, Welty et al. 2008, ISU-UE 2009, Foster 2010)

3.6.3.2 Soybean

Some of the most significant soybean pests and diseases are listed in Table 3-21. Major soybean production states are Illinois, Indiana, Iowa, and Minnesota.

Table 3-21. Soybean Pests and Diseases	
Invertebrate Pests	**Fungal and Oomycetal**
Bean leaf beetle (*Cerotoma trifurcata*)	Anthracnose stem blight (*Colletotrichum truncatum*)
Blister beetles (Epicauta spp.)	Brown stem rot (*Phialophora gregata*)
Colaspis beetles (Colaspis spp.)	Cercospora leaf blight and purple stain (*Cerospora kikuchii*)
Cutworms (Family Noctuidae)	Charcoal rot (*Macrophomina phaseolini*)
Armyworms (Family Noctuidae)	Downy mildew (*Peronospora mashurica*)
Corn earworm (*Heliothis zea*)	Frogeye leaf spot (*Cercospora sojina*)
Dectes stem borer (*Dectes texanus*)	Fusarium root rot (*Fusarium* sp.)
Garden fleahopper (*Halticus bractatus*)	Phomopsis seed decay (*Phomopsis longicolla*)
Grasshoppers (*Melanoplus* sp.)	Phyllosticta leaf spot (*Phyllostica sojicola*)
Green cloverworm (*Hypena scabra*)	Phytophthora root rot (*Phytophthora sojae*)
White grubs (*Phyllophaga* sp.)	Pod and stem blight (*Diaporthe phaseolorum* var. *sojae*)
Imported longhorned weevil (*Calomycterus setarius*)	Powdery mildew (*Mirosphaera diffusa*)
Japanese beetle (*Popillia japonica*)	Pythium root rot (*Pythium spp*)
Kudzu bug (*Megacopta cribraria*)	Red leaf blotch (*Phoma glynicola*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)	Rhizoctonia stem and root rot (*Rhizoctonia solani*)
Mexican bean beetle (*Epilachna varivestis*)	Sclerotinia stem rot/white mold (*Scretonia sclerotiorum*)
Pillbugs (Order Isopoda)	Septoria brown spot (*Septoria glycines*)
Potato leafhopper (*Empoasca fabae*)	Soybean rust (*Phakopsora pachyrhizi*)
Saltmarsh caterpillar (*Estigmene acrea*)	Stem canker (*Diaporthe phaseolorum* var. *merdionalis*)
Seedcorn maggot (*Delia platura*)	Sudden death syndrome (*Fusarium virgulifome*)
Seedcorn beetle (*Stenolophus lecontei*)	**Bacteria**
Soybean aphid (*Aphis glycines*)	Bacterial blight (*Pseudomonas syringae* pv.)
Soybean leaf miner (*Odontata dorsalis*)	Bacterial pustule (*Xanthomonas axonopodis* pv. *glycines*)
Soybean looper (*Pseudoplusia includens*)	Bacillus seed decay (*Bacillus subtilis*)
Spotted cucumber beetle (*Diabrotica undecimpunctata howardii*)	**Nematodes**
Stalk borer (*Papaipema nebris*)	Soybean cyst nematode (*Hetrodera glycines*)
Stink bug, green (*Acrosternum hilare*)	**Viruses**
Stink bug, brown marmorated (*Halyomorpha halys*)	Alfalfa mosaic virus
Thistle caterpillar (*Vanessa carduii*)	Beanpod mottle virus

Table 3-21. Soybean Pests and Diseases	
Twospotted spider mite (*Tetranychus urticae*)	Soybean mosaic virus
Threecornered alfalfa hopper (*Spissistulus festinus*)	Tobacco ringspot virus
Velvetbean caterpillar (*Anticarsia gemmatalis*)	
Webworms (Family Arctiidae)	
Wireworms (Family Elateridae)	
Yellow woolly-bear caterpillar (*Spilosoma virginica*)	

Source: (Mueller, Robertson, Sisson et al. 2010, Whitworth, Michaud and Schwarting 2015, ISU 2016, UoI 2016, UoM 2016)

3.6.3.3 Cotton

Cotton pests and diseases are listed in Table 3-22. The state with the highest cotton production is Texas, followed by Georgia.

Table 3-22. Cotton Pests and Diseases	
Cotton Invertebrate Pests	**Fungal**
Seedling Feeders	Boll rot (*Diplodia gossypina, Fusarium*)
Cutworms (family Noctuidae)	Cornylespora leaf spot (*Cornylespora* cassiicola
False wireworms (family Tenebrionidae)	Cotton root rot (*Phymatotrichum omnivorum*)
True wireworms (family Elateridae)	Fusarium wilt (*Fusarium oxysporium* f. sp.)
Thrips (*Frankliniella* spp., *Thrips tabaci*)	Leaf rolls/leaf spots (*Alternaria* sp., *Cercospora* sp., *Rhizoctonia* sp., *Stemphyllium* sp.)
Foliage Feeders	Rhizoctonia (*Rhizoctonia solani*)
Aphid, green peach (*Myzus persicae*)	Pythium (*Pythium spp.*)
Aphid, Cotton (*Aphis gossypii*)	Rust (*Puccinia cacabata*)
Aphid, Cowpea (*Aphis craccivora*)	Seedling disease complex (*Rhizoctonia solani, Fusarium sp., Pythium sp., Thielaviopsis basicola*)
Armyworm, beet (*Spodoptera exigua*)	Verticillium wilt (*Verticillium albo-atrum*)
Armyworm, yellow-striped (Spodoptera ornithogalli)	Wet weather blight (*Ascochyta gossypii*)
Armyworm, fall (*Spodoptera frugiperda*)	**Bacteria**
Cabbage looper (*Trichoplusia ni*)	Bacterial blight (*Xanthomonas campestris* pv. *malvacearum*)
Grasshoppers (family Acrididae)	Cotton blight (*Xanthomonas anonopodis* pv. *malvacearum*)
Saltmarsh caterpillar (*Estigmene acrea*)	**Nematodes**
Spider mite, carmine (*Tetranychus cinnabarinus*)	Lance (*Hoplolaimus* sp.)
Spider mite, twospotted (*Tetranychus urticae*)	Lesion (*Pratylenchus* sp.)
Whitefly, bandedwing (*Trialeuroides abutilonea*)	Reniform (*Rotylenchus reniformis*)
Whitefly, silverleaf (*Bemisia argentifolii*)	Root-knot (*Meloidogyne incognita*)
Boll Feeders	Spiral (*Helicotylenchus* sp.)
Boll weevil (*Anthonomus grandis*)	Sting (*Benlonolaimus longicaudatus*)
Bollworm (*Helicoverpa zea*)	Stunt (*Tylenchorhyncus* sp.)
Tobacco budworm (*Heliothis virescens*)	
Clouded plant bug (*Neurocolpus leucopterus*)	
Western tarnished lygus bug (*Lygus hesperus*)	

Table 3-22. Cotton Pests and Diseases	
Tarnished plant bug (*Lygus lineolaris*)	
Pale legume bug (*Lygus elisus*)	
Cotton fleahopper (*Pseudatomoscelis seriatus*)	
Cotton square borer (*Strymon melinus*)	
Creontiades plant bug (*Creontiades signatus*)	
Fall armyworm (*Spodoptera frugiperda*)	
Stink bugs (Family Pentatomidae)	

Source: (TAMU 2016a, TAMU 2016b, UGA 2016, UoA 2016)

3.6.3.4 Potato

Potato pests and diseases are listed in Table 3-23. Major potato-producing states are Colorado, Idaho, Michigan, Minnesota, North Dakota, Oregon, and Washington.

Table 3-23. Potato Pests and Diseases	
Invertebrate Pests	**Fungi**
Colorado potato beetle (*Leptinotarsa decemlineata*)	Late blight (*Phytophthora infestans*)
Green peach aphid (*Myzus persicae*)	Pink rot (*Phytophthora erythroseptica*)
Wireworms (*Limonius californicus, L. canu, Ctenicera pruinera*)	Early dying (*Verticillium* spp.)
Potato leafhopper (*Emposasca fabae*)	Sclerotinia stalk rot or white mold (*Sclerotinia sclerotiorum*)
Pea aphid (*Acyrthosiphon pisum*)	Canker or black scurf (*Rhizoctonia solani*)
Soybean aphid (*Aphis glycine*)	Scab (*Streptomyces scabies*)
Thrips (*Franklinella* spp., *Thrips* spp.)	Dry rot (*Fusarium* spp.)
Flea beetle (*Epitrix* spp.)	Fusarium wilt and dry rot (*Fusarium solani* var *eumartii, Fusarium oxysporum*)
European cornborer (*Ostrinia nubilalis*)	Water or shell rot (*Pythium ultimum*)
Potato psyllid (*Bactericera (Paratrioza) cockerelli*)	Early blight (*Alternaria solani*)
Potato Tuberworm or Tuber Moth (*Phthorimaea operculella*)	Gray mold (*Botrytis cinerea*)
Bacteria	Black dot (*Colletotrichum coccodes*)
Aster Yellows MLO (Member of Acholeplasmataceae)	Ring rot (*Clavibacter michiganensis* subsp. *sepedonicus*)
Bacterial ringrot (*Corynebactium sepedonicum*)	Powdery scab (*Spongospora subterranea*)
Bacterial brown rot (*Ralstonia solanacearum*)	Silver scurf (*Helminthosporium solani*)
Bacterial soft rot (*Pectobacterium carotovorum*)	Wart (*Synchytrium endobioticum*)
Blackleg (*Erwinia carotovora*)	**Nematodes**
Golden nematodes (*Globodera rostochiensis*)	Golden nematodes (*Globodera rostochiensis*)
Potato tuber rot (*Ditylenchus destructor*)	Potato tuber rot (*Ditylenchus destructor*)
Root knot (*Meloidogyne* spp.)	Root knot (*Meloidogyne* spp.)
Columbia root knot (*Meloidogyne chitwoodi*)	Columbia root knot (*Meloidogyne chitwoodi*)
Root lesion (*Pratylenchus penetrans*)	Root lesion (*Pratylenchus penetrans*)
Viruses	
Potato Leafroll Virus (*Luteovirus*)	

Table 3-23. Potato Pests and Diseases	
Potato Spindle Tuber Viroid (Member of Pospiviridae)	
Potato Virus A,M, X, Y (Members of Potyviridae, *Carlavirus*)	
Tobacco Rattle Virus (*Tobravirus*)	

Source: (Johnson, Stevenson and Miller 2010, Radcliffe 2010)

3.6.3.5 Forest Related Insects and Disease

As with commercial crop production, insects and diseases can cause catastrophic forest loss. For example, in 2011, tree mortality caused by insects and diseases was reported on more than 6.4 million acres nationally (USDA-FS 2012). Major forest insects and diseases in the United States are listed in Table 3-24.

Table 3-24. Common Forest Insect Pests and Diseases	
Mountain Pine Beetle (*Dendroctonus ponderosae*)	Sirex Woodwasp (*Sirex noctilio*)
Gypsy Moth (*Lymantria dispar dispar*)	Dwarf Mistletoes (*Arceuthobium* spp.)
Southern Pine Beetle (*Dendroctonus frontalis*)	Asian Longhorned Beetle (*Anoplophora glabripennis*)
Emerald Ash Borer (*Agrilus planipennis*)	White Pine Blister Rust (*Cronartium ribicola*)
Sudden Oak Death (*Phytophthora ramorum*)	Oak Wilt (*Ceratocystis fagacearum*)
Spruce Beetle (*Dendroctonus rufipennis*)	Fusiform Rust (*Cronartium fusiforme*)
Western Bark Beetles (*Dryocoetes* spp.)	Dogwood Anthracnose (*Discula destructiva*)
Western Spruce Budworm (*Choristoneura* spp.)	Beech Bark Disease (Neonectria spp.)
Hemlock Woolly Adelgid (*Adelges tsugae*)	Butternut Canker (*Sirococcus clavigignenti-juglandacearum*)
Laurel Wilt Disease (*Raffaelea lauricola*)	

Source: (USDA-FS 2012)

3.6.4 Non-target Species

Non-target species include any species that may be impacted from the importation, interstate movement, containment, restricted field testing, or unrestricted environmental release of GE organisms for which imposed impacts are not targeted or intentional. The effects of GE organisms could potentially extend beyond their intended use and impact non-target species that provide ecological and pest-management services. Non-target species that could be affected by GE organisms include herbivores (i.e., small mammals, nematodes); pollinators (i.e., bees, birds); predator species (i.e., beetles); pathogens and parasites (i.e., bacteria, fungi, viruses); decomposers (i.e., soil microorganisms); and plant symbionts (rhizobacteria).

There has been considerable focus on the effects of GE plants containing PIPs, such as Bt based proteins that confer insect resistance to the GE plant. For example, there has been concern that GE crop plants expressing Bt based insecticidal proteins (Cry and Cyt toxins) could adversely affect non-target insects if they are closely related to the target pest. Many invertebrates are exposed to PIPs even if they are not plant pests. For example, pollinators may consume pollen or nectar from a flower, or detritus-eating insects may consume plant litter in fields. Aquatic insects may be exposed to a PIP when plant litter finds its way into streams or other waterways.

Many studies have been done on the currently available PIPs to examine direct toxicity to non-target insects (Marvier, McCreedy, Regetz et al. 2007).

Cry proteins are toxic to the insect orders Lepidoptera (moth and butterfly larvae), Coleoptera (beetles), Hymenoptera (sawflies, wasps), and Diptera (flies), and also to nematodes. Cyt toxins are mostly found in Bt strains active against Diptera. The Cry and Cyt group of toxins are considered relatively harmless to humans and most non-pest species. These toxins are highly specific to target insects, harmless to vertebrates and plants, and biodegradable (Bravo, Gill and Soberón 2007, Koch, Ward, Levine et al. 2015). Various studies examining the transport and fate of Bt proteins in the environment indicate relatively short half-lives and rapid dissipation in soil, and binding and dissipation in aquatic sediments can greatly limit their availability to aquatic organisms (Carstens, Anderson, Bachman et al. 2012).

With GE IR crop plants, predator-prey relationships in the local environment can be also altered when prey populations are impacted by PIPs, if there are pleiotropic effects on the crop plant that alter the nutritional quality and/or abundance of plant food sources such as nectar and pollen, or the structure of the vegetation on which non-target species feed is changed (Lundgren, Gassmann, Bernal et al. 2009). For example, impaired growth or development of prey resulting from their consumption of GE plant tissue may affect the population structure of their natural enemies (Lundgren, Gassmann et al. 2009). The prolonged consumption of low-quality or otherwise impaired prey could result in smaller predator populations, and slower growth rates in the area where a GE plant or other organism is cultivated.

The potential hazards posed by RNA interference (RNAi) based PIPs to non-target organisms include off-target gene silencing, silencing of the target gene in unintended organisms, and alteration of the RNAi processes (Lundgren and Duan 2013). Non-target organisms will vary in their exposure to small RNAs produced by GE crops, but exposure to insecticidal small RNAs will probably occur at a previously unrealized scale for many. Areas of concern regarding RNAi based PIPs include their persistence in the environment, understanding of the food webs of non-target species that could be affected, and the power of predictive analyses in accurately capturing the potential field-level effects GE plants or other organisms comprised of an RNAi PIP (Lundgren and Duan 2013).

The EPA has reviewed all currently registered Bt derived PIPs and determined that these GE PIP products would not pose unreasonable risk to human health or the environment.[77] In general, extensive investigation has not identified any significant adverse effects of GE Bt crop varieties on non-target insects and other species (Koch, Ward et al. 2015).

There has also been some concern that herbicides used with GE HR crop plants adversely affect soil or aquatic invertebrates and bacteria community structures (Lancaster, Hollister, Senseman et al. 2010). For example, some studies suggest that the changes in the degradation or distribution of glyphosate following repeated applications may be related to shifts in the soil microbial community composition (Lancaster, Hollister et al. 2010, Allegrini, Zabaloy and Gómez 2015).

[77] EPA - Current and Previously Registered Section 3 Plant-Incorporated Protectant (PIP) Registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

Assessment of the effects of GE plants or other organisms on non-target species is part of the risk assessment process under the Coordinated Framework. Current strategies for assessing the impact of GE crop plants on non-target species are primarily based on the toxicity of the herbicides used in conjunction with GE HR crop plants, or the PIP produced by GE plants or other organisms, to specific indicator species representing various taxonomic or functional guilds (Lundgren, Gassmann et al. 2009). Any future introduction of GE plants or other organisms would be evaluated for potential impacts on non-target species. For example, the EPA conducts ecological non-target organism risk assessments for PIPs on a case-by-case basis (US-EPA 2015e).

3.6.5 Agricultural Weeds and Noxious Weeds

Weeds are generally defined as any plant growing where it is not wanted. Weeds can be native or non-native plants, invasive or non-invasive, and noxious or not noxious. Noxious weeds are those that are particularly problematic, and designated by a federal, state or county government as injurious to public health, agriculture, recreation, wildlife or property.[78] A noxious weed is also defined as a plant that is competitive, persistent, and pernicious. In accordance with the Plant Protection Act of 2000, Federal Noxious Weed Act of 1974, and the Noxious Weed Control and Eradication Act of 2004 APHIS identifies and regulates noxious weeds capable of affecting agricultural production. Federal and state noxious weed lists are provided on the NRCS Introduced, Invasive, and Noxious Plants website.[79]

Not all weeds are classified as noxious. There are other plants identified as weedy or invasive, or that have the potential to become weedy or invasive in all or part of their U.S. range, that are not subject to laws and regulations governing noxious weeds. A complete list of agricultural weeds is provided on the APHIS Weed Program website, and various state agricultural extensions websites (e.g., see (AU 2015, USDA-NRCS 2015b)).

Weeds are common on all 400 million acres of U.S. cropland and almost one billion acres of range and pasture. As with plant pests and diseases, weeds can cause significant yield and economic losses in crop production. Farmers traditionally used tillage of fields to manage weeds; however, tilling can contribute to the erosion and compaction of soils, reducing their capacity to absorb water, and lead to runoff that can pollute rivers with sediments and agronomic inputs. The use of herbicides to manage weeds began in the late 1940s, and was widely adopted to reduce labor costs in weed management, improve weed management efficiencies, and increase crop yields (Fernandez-Cornejo, Nehring et al. 2014). Herbicides are currently used on more than 90% of U.S. crop acreage. Exemplary of the significance of weed management in crop production; agricultural expenditures on herbicides are currently around $400 billion annually (Fernandez-Cornejo, Osteen et al. 2014).

Concomitant with the adoption of herbicides to manage agricultural weeds has been the development of herbicide resistant weeds. Overreliance on a single weed management strategy, particularly utilization of a single mode of action herbicide, imparts selection pressure on weed

[78] Section 403 of the PPA defines Noxious Weed as:" any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment."
[79] USDA-NRCS, Introduced, Invasive, and Noxious Plants: http://plants.usda.gov/java/noxiousDriver

populations. When only one herbicide is used year after year as the primary means of weed control, herbicide resistant weeds can quickly reproduce and spread to dominate the weed population and seed bank. Herbicide resistant weeds are becoming increasingly common since the first reports of their occurrence in the 1950s.

Herbicide resistant weeds, or their development, are not subject to regulation under 7 CFR part 340 unless the herbicide resistant weed is a potential plant pest, or believed to be a plant pest. However, a discussion of this agricultural issue is provided here as there has been some concern regarding the relationship between the development of weed resistance and use of GE HR cropping systems.

3.6.5.1 Herbicide Resistant Weeds in the United States

There are currently 158 unique cases of herbicide resistant weeds in the United States (Heap 2015). A detailed and continuously updated list of herbicide resistant weed biotypes is maintained on the International Survey of Herbicide Resistant Weeds website (Heap 2015).

Development of herbicide resistant weed biotypes is a consequence of basic evolutionary processes driven by selection pressure. Herbicide resistance in weeds naturally evolves when a plant survives and reproduces after exposure to an herbicide, usually lethal to the plant species, and passes the resistant trait on to future generations of the plant. With repeated herbicide use, selection pressure for resistant weed biotypes can increase, and resistant biotypes can flourish by deposition of resistant seed types in the soil seed bank.

Weed management decisions are a vital aspect of this process, as certain weed management practices impart strong selection pressures[80] on weed communities, which can result in shifts of weed species at the local level (Owen 2011, Owen 2012, Vencill, Nichols et al. 2012). Fundamentally, overreliance on a single weed management strategy, particularly utilization of a single mode of action herbicide, can cause intense selection pressure on weed populations. In particular, when only one herbicide is used year after year as the primary means of weed control, the naturally occurring herbicide resistant seeds in the seedbank can survive as plants, reproduce, and spread to dominate the weed population and seed bank. Over time, with no change in weed control strategies, the weed population selected will be for those species naturally resistant to an herbicide. In this context, selection pressure is the extent to which plants are either eliminated or favored by environmental conditions and herbicide exposure (Vencill, Nichols et al. 2012).

Given that some weeds have evolved with resistance to several herbicide mechanisms of action, it is important that growers use herbicides with diverse mechanisms of action to avoid imparting selection pressure on plants from only one or a few herbicides (Wilson, Hooker, Tucker et al. 2009, Shaw, Owen, Dixon et al. 2011, Vencill, Nichols et al. 2012). Consequently, current practices in managing weeds involve an IWM approach that diversifies weed management tactics and includes timely herbicide applications, use of herbicides with multiple modes of action, crop rotation, tillage practices, and weed surveillance (Owen 2011, Brookes 2014, Garrison, Miller et

[80] Selection pressure may be defined as any event or activity that reduces the reproductive likelihood of an individual in proportion to the rest of the population of that one individual. In agriculture, selection pressure may be imparted by any facet of management in the production of a crop, including the type of crop cultivated, strategy of pest management, or when and how a crop is planted or harvested.

al. 2014, CLI 2015). To assist growers in managing weeds, individual states, typically through state agricultural extension services, track the prevalent weeds in crops in their area and the most effective means for their management (see, e.g., (IPM 2015)).

The key consideration to managing herbicide resistant weeds is to ensure that the herbicides used continue to have efficacy on the target weeds. Weed scientists recommend the use of an IWM approach that includes science-based crop improvement and farm management tools developed over the last 60 years (e.g., (Weller, Owen et al. 2010, Owen 2011, Vencill, Nichols et al. 2012)). In general, weed population densities may be decreased in weed resistant cropping systems incorporating IWM strategies, although shifts in the density of high-risk weed species may take from two to six years (Gibson, Young et al. 2015). While IWM strategies are successful in the short term for reducing herbicide resistant weed infestations while maintaining crop yield potential, it may take many years to affect the weed seedbank, particularly for those species with a high risk for resistance to an herbicide, and cropping systems using a single-trait herbicide resistant crop variety (Gibson, Young et al. 2015).

Current strategies to prevent the development of new resistant weeds requires implementation of diverse IWM practices that may include the following (Norsworthy, Ward, Shaw et al. 2012):

- the rotation of herbicides with different modes of action;
- site specific herbicide applications;
- use of maximum permitted (labeled) application rates;
- crop rotation;
- use of tillage for supplemental weed control;
- cleaning equipment between fields;
- controlling weed escapes;
- controlling weeds early; and
- scouting for weeds before and after herbicide applications.

3.6.6 Soil Biota

Soil biota (i.e., earthworms, nematodes, fungi, bacteria) play a key role in soil structure formation, decomposition of organic matter, biodegradation of pesticides, nutrient cycling, suppression of plant diseases, promotion of plant growth, and most biochemical soil processes (Parikh and James 2012). Soil biota can also cause plant diseases, which can result in substantial economic losses in crop production (e.g., see subsection 3.6.3 – Plant Pests and Disease).

Various factors affect soil biota populations and diversity. First is soil type, which includes the inherent texture, structure, organic matter, aggregate stability, pH, and nutrient content of the soil, which varies by geographic area. Second is the plant type, as plant and soil health are dependent on mutualistic and symbiotic relationships between plants and soil fungi and microorganisms (i.e., carbon, nitrogen, phosphorus cycling), which can vary by plant. Third, climate, and climate changes (Brevik 2013) influence the water and heat content of soil; these being the principal determinants of soil biological activity. Agronomic practices such as crop rotation, tillage, herbicide and fertilizer application, and irrigation, can also affect soil biota (Garbeva, van Veen and van Elsas 2004, Gupta, Neate and Leonard 2007) This is particularly

relevant as most GE organisms are crop plants, and the potential impact of GE crop plants on soil communities has been a topic of interest since the introduction of GE crop plants in the late 1990s (e.g., (Locke and Zablotowicz 2004, Motavalli, Kremer, Fang et al. 2004, Icoz and Stotzky 2008, Kremer and Means 2009, Carpenter 2011, Kremer 2014, Turrini, Sbrana and Giovannetti 2015)).

Most of the scientific literature is in regard to the potential impacts of GE plants on (1) the soil communities near plant roots, as root exudates influence soil fungal and microbial community composition and diversity (Broeckling, Broz, Bergelson et al. 2008); and (2) the potential effects GE trait genes and/or gene products on soil biota, which could be transferred to soils via plant detritus or root exudate. In assessing the potential effects of trait genes and gene products on soil biota, research has considered both direct effects from the gene product itself, and whether there may be pleiotropic effects as a result of insertion of the gene into the plant genome – whether insertion of the gene in the host plant may alter the expression of other genes, or gene regulation, which may in turn may have adverse environmental effects.

Many of the current GE crop plants, such as beet (*Beta vulgaris* L.), corn (*Zea mays* L.), and canola (*Brassica napus* L.) have been genetically engineered for expression of bacterial gene products that confer resistance to specific herbicides. Glyphosate resistance is conferred through a gene (CP4 EPSP) derived from the naturally occurring soil bacterium, *Agrobacterium* (Funke, Han, Healy-Fried et al. 2006). Once incorporated into the plant genome, the gene product, CP4 EPSP synthase,[81] confers resistance of the plant to the adverse effects of glyphosate. EPSP synthase is not unique to *agrobacterium*; it is an enzyme naturally produced by plants, bacteria, and fungi. Similarly, the phosphinothricin N-acetyltransferase (pat) gene from *Streptomyces viridochromogenes* and bar gene from *Streptomyces hygroscopicus* , both naturally occurring soil bacterium, provide GE plant resistance to the herbicide glufosinate. A further example is a GE plant engineered with a demethylase gene from *Stenotrophomonas maltophilia,* which confers plant resistance to the herbicide dicamba. *S. maltophilia* is ubiquitous in both aqueous and soil environments.

Literature reviews of both the PAT and EPSP genes and gene products, which encompass data from peer-reviewed research and regulatory assessments, concluded that for the species and environments that were evaluated, the expression of the PAT protein and EPSP enzyme in GE plants has not been found to have negative impacts on other organisms in the environment (ILSI-CERA 2011b, ILSI-CERA 2011a). Due the negligible risk posed by these genes and their products, the EPA has exempted both PAT and EPSP from food tolerance limits from products derived from GE plants that are comprised of the PAT and EPSP traits (US-EPA 2007c, US-EPA 2007b).

Over the last 20 years, GE glyphosate resistant plants, in particular, have been extensively studied. In general, while some studies have found that glyphosate resistant cropping systems, one of the most abundant in the United States, may affect soil microbial populations, most studies have found only minor, transient effects. For example, studies have examined the potential effects of glyphosate on soil communities. Most pesticides are degraded by soil biota, which break pesticides down into their constituent ingredients. Haney et al. reported that

[81] EPSP: 5-enolpyruvylshikimate-3-phosphate synthase

glyphosate is mineralized (degraded to primary nutrients such as carbon, nitrogen, phosphorus) by soil microorganisms leading to an increase in the population and activity of soil biota (Haney, Senseman and Hons 2002). Likewise, Imparto et al. reported that glyphosate use may alter the bacterial and protist communities and their interactions through an increase in the availability of organic carbon (Imparato, Santos, Johansen et al. 2016). Weaver et al. reported similar findings in that glyphosate was mineralized (degraded) by soil biota, although in these studies no meaningful shifts in microbial communities were observed (Weaver, Krutz, Zablotowicz et al. 2007). Hart et al. found that neither crop type (transgenic or conventional) nor glyphosate had a significant effect on denitrifying or fungal communities. Their findings, instead, suggested that seasonality was a primary determinant of abundance and diversity of soil microbial communities (Hart, Powell, Gulden et al. 2009). In another field study investigating the impact of field application rates of glyphosate on soil microbial communities, no adverse effects on soil microbial communities were observed, suggesting that glyphosate use at recommended rates poses low risk to the microbiota (Zabaloy, Carné, Viassolo et al. 2016). Hence, minor effects have been observed, although no long term adverse impacts to soil communities as a result of glyphosate use have been identified.

Some research, however, has suggested that the use of glyphosate on glyphosate resistant crops increases the colonization of soil-born fungal pathogens such as *Fusarium*, relative to non-glyphosate resistant cultivars or glyphostate resistant cultivars not treated with glyphosate (Kremer and Means 2009, Kremer 2010). For instance, *Fusarium* [82]colonization was found to be higher on glyphosate resistant soybeans treated with glyphosate throughout the growing season, as compared with soybean receiving no herbicide or a non-glyphosate herbicide (Kremer and Means 2009). A study by Camberato et al. found that some weeds treated with glyphosate and other herbicides had increased incidence of fungal infection, suggesting that certain soil fungi are more able to infect a weed after it has been weakened by glyphosate (Camberato, Casteel, Goldsbrough et al. 2011). They point out, however, that plant pathologists have not observed widespread increases in plant diseases in glyphosate resistant corn and soybean crops. In a recent review of the scientific literature, Duke et al. concluded that mineral nutrition in glyphosate resistant crops is not affected by either the glyphosate resistant trait or the application of glyphosate; (2) that most of the available data indicate that neither the glyphosate resistant transgenes nor glyphosate use in glyphosate resistant crops increases crop disease; and (3) that crop yield data from glyphosate resistant crops do not support the hypotheses that there are mineral nutrition or disease issues that are specific to these crops (Duke, Lydon, Koskinen et al. 2012).

There has been some concern regarding the potential effects of Bt crops, which release Cry proteins, on soil microbial communities. In general, the Cry proteins released from root exudate and the plant residues of Bt crops appear to have no significant long-term impacts on the diversity and function of soil communities (e.g., see (Ahmad, Wilde and Zhu 2006, Icoz and Stotzky 2008, Naranjo 2009, Liu, Li, Stewart et al. 2015, Turrini, Sbrana et al. 2015)). Some differences in total numbers and community structure of soil microorganisms in Bt and non-Bt crops have been observed. However, many of these observations were not statistically

[82] Some species of Fusarium produce mycotoxins in cereal crops, which can be harmful to human and animal health if they enter the food chain. The primary mycotoxins produced by Fusarium species are fumonisins and trichothecenes.

significant, were transient, were not related to the inserted transgene, or were the result of altered plant characteristics (e.g., lignin content) (Icoz and Stotzky 2008).

In addition to GE plants with herbicide resistant traits and those expressing Bt derived proteins, other plants have been developed for resistance to bacterial and fungal pathogens. For instance, GE rice resistant to pathogenic fungi has been developed by inserting genes encoding pathogenesis-related proteins such as chitinases, and potato plants developed express the cysteine proteinase inhibitors to control potato-cyst nematode (Turrini, Sbrana et al. 2015). While there have been studies conducted on the potential effects of these types of GE varieties on soil biota, findings to date provide no clear data that distinguishes between potential pleiotropic effects and effects due to the transgene products (Turrini, Sbrana et al. 2015).

Findings from studies investigating the potential impact of GE Bt based plants on soil biota are somewhat mixed, although no significant adverse effects have been identified (Icoz and Stotzky 2008). An early review of studies conducted by Kowalchuk et al., largely of studies prior to 2003, found that GE crop plants had only minor or no effects on soil microbial communities. Only a few studies were noted to have found alterations to the composition of the community structures associated with GE crop plants (Kowalchuk, Bruinsma and van Veen 2003). A similar review of the early literature by Motavalli et al. found no conclusive evidence that cultivation of GE crops resulted in any substantial impacts on soil nutrient cycling (Motavalli, Kremer et al. 2004). More recent reviews suggest that GE crop plants currently cultivated have had no significant adverse effects on soil biota (Icoz and Stotzky 2008, Carpenter 2011, Turrini, Sbrana et al. 2015).

One of the more common themes that has emerged from the literature reviews addressing current GE crop plants is that crop and soil management practices in association with environmental factors appear to be much more significant in affecting the biotic composition and function of soils, as these practices can contribute to, or detract from, sustaining soil quality (Sanvido, Romeis et al. 2007, Naranjo 2009, Kolseth, D'Hertefeldt, Emmerich et al. 2015, Turrini, Sbrana et al. 2015). Conflicting results on the potential effects of GE crops on soil biota are often attributed to the understandable variance in findings that can derive from laboratory based studies on single species, or a select group of species, and field studies that more naturally reflect the ecosystem dynamics extant in commercial cropping systems. For field studies, the agronomic practices employed, soil properties, soil communities, and climate can likewise vary from study to study depending on location and time of year. Hence, elucidating the potential effects, or absence thereof, of GE plant trait genes and gene products can be challenging.

Relative to new GE organism-trait combinations that may be developed, whether for a crop plant, ornamental, phytoremediation, or pharmaceutical or industrial purposes, these would obviate the need for understanding the GE plant-soil relationships, or at least a basic understanding of the relative safety of such a plant, prior to commercial introduction.

3.6.7 Biodiversity

Biodiversity refers to the variety and abundance of biota and their functions in ecosystem dynamics. In an agricultural setting, growers are concerned with biodiversity to the extent that it supports species conducive to crop production. Such species include pollinators (i.e., bees and butterflies), species that control insect pests (i.e,, beneficial avian species), and some members of

the plant community. Biodiversity also affects biogeochemical cycling, soil structure, and local hydrologic processes, all of which support crop production. A loss of biodiversity in an agricultural setting can result in the need for costly external inputs in order to provide these types of functions to a crop (Altieri 1999).

Typically, agricultural fields are managed to encourage the growth of the planted crop while controlling competing species (e.g., weeds, insects, pathogens) that could negatively impact plant health and crop yields. In general, species abundance and variety will be less on and around intensively managed agricultural lands than in undisturbed ecosystems. The highly managed landscape impacts biodiversity largely due to the loss of habitat caused by conversion of unmanaged environments to cropland.

Intensively cultivated agricultural lands provide less suitable habitat for wildlife than that found in fallow fields or adjacent natural areas. Accordingly, the types and numbers of animal species found on agricultural lands are less diverse than on unmanaged lands. A variety of crops, however, can provide both food and cover for wildlife, including birds and large and small mammals. Some birds and mammals may use cropped fields at various times throughout the crop production cycle for feeding and reproduction, although many of the birds and mammals that use agricultural lands are ground-foraging omnivores that feed on crop residue following harvest.

Although some crop production practices, such as planting a single crop type (monoculture), applying pesticides and fertilizers, and harvesting crops, limit habitat and thereby the diversity of biota, other practices can be used to foster habitat and biodiversity (Scherr and McNeely 2008). Conservation tillage practices can have a positive impact on wildlife through decreased soil erosion, improved water quality, increased retention of ground cover, greater availability of surface waste grain for animal food, and increased populations of invertebrates to serve as both predators and prey (Altieri 1999, Landis, Menalled et al. 2005, Sharpe 2010, Towery and Werblow 2010). Likewise, crop rotations can reduce the likelihood of crop disease, and weed and pest populations, thereby reducing the need for pesticides. This encourages biodiversity by limiting the potential exposure of biota to pesticides. Crop rotations can also result in preservation of wildlife habitat; crop rotations with legumes and small grains have been shown to provide nesting cover, food, and brood-rearing habitat (Sharpe 2010). For example, allowing field edges to harbor non-crop vegetation can provide nesting and brood habitat for birds, support beneficial arthropods that suppress herbivore insect pests, and provide food and habitat for natural predators of crop pests (Sharpe 2010).

The potential impacts of GE crops on biodiversity, in particular, have been a topic of interest due to increasing use of these crops in agriculture since the mid-1990s. A recent review by Carpenter (2011) suggests that commercial GE crops can reduce the impacts of agriculture on biodiversity by facilitating adoption of conservation tillage practices, potentially reducing insecticide use, facilitating use of more environmentally benign pesticides, and increasing yields that can alleviate pressure to convert additional land into agricultural uses (Carpenter 2011). Such a conclusion is consistent with that of the National Research Council, which in a 2010 review found that GE crops have had no more, or fewer adverse effects on the environment than non-GE crops produced conventionally (NRC 2010a).

3.7 Climate Change

Climate change can affect agricultural crop production through changing patterns in precipitation, temperature, and duration of growing season, as well as through influencing weed and pest pressure, or lack thereof (Backlund, Janetos et al. 2008, IPCC 2014). For instance, the current range of various species of agricultural weeds and pests are expected to shift in response to changes in regional climates, which could present new challenges to crop production in certain areas (Backlund, Janetos et al. 2008). On the other hand, Field et al. found that most studies projected likely climate-related yield increases of 5% to 20% for corn, rice, sorghum, soybean, wheat, common forages, cotton, some fruits, and irrigated grains (Field, Mortsch, Brklacich et al. 2007). However, such a beneficial impact would not be evenly distributed across all geographic areas as certain regions of the United States are expected to experience substantial reductions and/or variability in water resources (as described in subsection 2.6.2 – Water Resources). In general, the wide variability in climate across the United States is expected to result in differing responses of the agricultural sector to climate change, both in terms of yield and the agronomic practices used in crop management (Hatfield, Takle et al. 2014).

Agriculture can in turn influence climate change through various aspects of the production process such as combustion of fossil fuels in farm equipment, fertilizer application, tillage and manure management practices, and decomposition of agricultural waste products - all of which can result in emission of greenhouse gases (GHG). The major types and sources of GHG emissions associated with agricultural production are soil derived N_2O emissions, methane (CH_4) from agricultural inputs, PM derived from tillage, and carbon dioxide (CO_2) emissions associated with farm equipment operation.

GHG emissions from agriculture have increased by approximately 17% since 1990, and agriculture is currently responsible for an estimated 8% of total GHG emissions in the United States (US-EPA 2013a). Methane and N_2O are the primary GHGs emitted by agricultural activities. Methane emissions from enteric fermentation and manure management represent 25.9% of emissions from agricultural activities (US-EPA 2011, US-EPA 2013a). Soil management activities such as fertilizer application and other cropping practices are the largest source of N_2O emissions nationally, accounting for 74.2% (US-EPA 2011, US-EPA 2013a). To a much lesser degree, CO_2 is also a GHG associated with agricultural land uses and energy consumption.

Factors influencing agricultural GHG emissions are the agronomic practices specific to various crop production systems, the region in which commodities are grown, and the individual choices made by growers. For example, emissions of N_2O, which is produced naturally by soil microbes through nitrification and denitrification[83] processes, can be influenced by fertilizer application practices, cultivation of nitrogen-fixing crops and forage, crop residue management (e.g., conservation tillage), irrigation, and fallowing of land (US-EPA 2013a). Similarly, on-site emissions associated with fossil fuel burning farm machinery can be reduced by half for some

[83] Nitrification and denitrification are natural processes involved in what is termed the "nitrogen cycle", or natural biogeochemical cycling of nitrogen. Nitrification is where soil bacteria convert ammonia to nitrate (nitrification). Denitrification is the opposite, where soil bacteria convert nitrate to gaseous nitrogen which is lost from the soil by release into the atmosphere.

crops when changing from conventional tillage to no-till systems (Nelson, Hellwinckel, Brandt et al. 2009).

Both GE and non-GE crop production can contribute to GHG emissions, as well as result in carbon capture and sequestration. The net effect of emissions and sequestration on climate change is, however, difficult to quantify, and will depend on the cropping system, production practices, soil types, and individual grower decisions used in crop production. For instance, conservation tillage, in particular, has been observed to contribute to soil carbon sequestration on croplands through the conservation of biomass (Franzluebbers 2005). Similarly, rotation of crops, such as with grains and legumes, and reduced nitrogen inputs, has been noted to result in carbon footprint reduction of certain crops (Ma, Liang, Biswas et al. 2012). No-till practices generally sequester more carbon in the soil due to less soil disturbance, higher soil moisture, and increased biomass inputs from surface residues. For example, a recent review of the literature suggests that no-till practices can provide small but important reductions in GHG emissions (Powlson, Stirling, Jat et al. 2014).

3.8 Human Health

3.8.1 Consumer Health

Human health considerations are those related to (1) the safety and nutritional value of food derived from GE crops, and (2) the potential health effects of pesticides that may be used in association with GE crops. As for food safety, consumer health concerns are in regard to the potential toxicity or allergenicity of the introduced gene products (proteins) and any significant dietary changes in levels of key nutrients, anti-nutrients, and toxicants in food derived from the plant. Consumers may also be concerned about the potential consumption of pesticides used on foods derived from GE crops.

In the United States, GE plants and other organisms are regulated to ensure public health and environmental safety under the Coordinated Framework for the Regulation of Biotechnology, described in Section 1.8.1. The Coordinated Framework defines the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: (1) APHIS, (2) the EPA, and (3) FDA. The safety assessment of crop plants derived through biotechnology includes characterization of the modified genetic material/processes (i.e., DNA, RNAi),[84] characterization of the biochemical and functional properties of the gene products, and compositional analysis of the GE plant.

3.8.1.1 FDA: Food Safety

Under the FFDCA, human and animal food manufacturers are required to ensure that the products they introduce into commerce are safe and in compliance with applicable laws and regulations.

Human and animal food derived from GE plants or other organisms must be in compliance with the FFDCA, and all other applicable legal and regulatory requirements. GE plants that will be

[84] RNA interference (RNAi) is a biological process where RNA is used to inhibit gene expression or protein function.

used for human or animal food purposes may undergo a voluntary consultation process with the FDA prior to release into commerce.[85] The FDA established this voluntary premarket consultation process to help ensure that all safety and regulatory questions are addressed prior to marketing foods derived from GE crop plants. Developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006).

As part of the voluntary premarket consultation process, developers of GE plants that may be used as food for humans or animals submit a summary of their safety and nutritional assessment to FDA. These summaries commonly contain information on the genetic characterization and function of the introduced gene(s) and any newly expressed protein(s). These summaries also include data on the levels of key nutrients, anti-nutrients, and potential toxicants in food from the new variety as well as a scientific and regulatory assessment of the food.[86] The FDA consultation considers whether any newly introduced protein is likely to be allergenic or toxic and whether levels of important nutrients or anti-nutrients have been changed in a way that is relevant to food safety or nutrition.

Various developers have completed premarket consultations on food from GE plant varieties (e.g., those submissions available at (US-FDA 2015, USDA-APHIS 2015a)). Once FDA is satisfied that all food safety and regulatory questions have been addressed, FDA sends the developer a letter explaining that FDA has no further questions concerning food derived from the variety and that the consultation is complete.

Although this is a voluntary process, thus far all applicants who have wanted to commercialize a GE food product derived from a GE crop have completed a consultation with the FDA or were the subject to an evaluation in another more relevant premarket process (see (US-FDA 2015)). APHIS considers the outcome of voluntary consultations with FDA in evaluating the potential impacts of a determination on non-regulated status of GE plants or other organisms.

In addition to FDA consultation, foods derived from GE plants typically undergo a safety evaluation among international agencies before entering foreign markets, including reviews under Codex Alimentarius guidelines, the European Food Safety Agency (EFSA), and Australia and New Zealand Food Standards Agency (ANZFS) (e.g., see (WHO 2005, FAO 2009, EFSA 2015a)).

Based on over 15 years of peer reviewed research and regulatory review, rather broad agreement among the international scientific and regulatory communities has emerged that food products derived from GE plants currently on the market are as safe as and nutritionally equivalent to their non-GE counterparts, and pose no more risks than foods derived from conventional crop varieties (e.g., see (CAST 2005, Batista and Oliveira 2009, Ronald 2011, AAAS 2012, AMA 2012, Bartholomaeus, Parrott, Bondy et al. 2013, Goldstein 2014, Nicolia, Manzo, Veronesi et al. 2014, WHO 2015), and memorandums by FDA (US-FDA 2015), EFSA (EFSA 2015a), and ANZFS (ANZFS 2015)).

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[85] Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096126.htm

[86] Compositional characteristics evaluated in these comparative tests may include plant components such as protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and anti-nutrients.

A recent literature review by Nicolia et al. (2014) compiled a list of scientific papers on the safety of GE crops, covering studies published from 2002 to 2012. This review cited a total of 1,783 reports, including original research papers, reviews, relevant opinions, commentaries, and reports addressing all the major issues that emerged in the debate on GE crops (Nicolia, Manzo et al. 2014). Of these 1,783 papers, 770 were related to GE crop food safety issues. In general, the vast majority of recent scientific literature and reviews conclude foods derived from current commercialized GE crops are as safe as their conventional counterparts (AAAS 2012, AMA 2012, Herman and Price 2013, Nicolia, Manzo et al. 2014, Sanchez 2015, WHO 2015), and others). These studies have spanned the crops of corn, soybean, cotton, canola, wheat, potato, alfalfa, rice, papaya, tomato, cabbage, pepper, raspberry, and a mushroom; not all of which have been commercialized in the United States. The scientific literature encompassed the traits of herbicide resistance, insect resistance, virus resistance, drought tolerance, cold tolerance, and nutrient enhancement (e.g, see review (Herman and Price 2013)).

While the safety of foods derived from current GE crops has been established through peer reviewed research and regulatory evaluation (e.g., (Batista and Oliveira 2009, AAAS 2012, AMA 2012, DeFrancesco 2013, Goldstein 2014, WHO 2015), some consumers may worry about potential negative health effects from food derived from GE plants; such as through the consumption of introduced DNA, or changes in nutritional quality or allergenicity. Consequently, consumer preferences can tend towards avoidance of food derived from GE plants unless such food contains perceptible benefits (Lucht 2015). While some consumers may have concern food derived from GE plants, there is currently sufficient science based evidence to establish the safety of foods derived from current commercial GE crops; namely that foods derived from GE crop plants have been demonstrated to be as safe as foods derived from non-GE, conventionally bred crop plants. However, few if any of the published studies reviewed describe benefits over that of foods derived from conventionally bred crops. Any future GE plant derived foods introduced into the U.S. market place would be expected to comply with relevant food safety laws enforced by relevant authorities, described herein, to ensure protection of public health.

3.8.1.2 EPA: Pesticide Safety

The risk of potential adverse health effects from pesticides depends on the toxicity of the ingredients, and dose, duration, and frequency of exposure to a pesticide. Certain people, such as children, pregnant women, and the elderly may be more sensitive to the effects of pesticides than others.

Before a pesticide can be used on a food crop, the EPA, pursuant to the FFDCA and FQPA, establishes tolerance limits, which is the amount of pesticide residue allowed to remain in or on each treated food commodity (21 U.S.C § 346a - Tolerances and Exemptions for Pesticide Chemical Residues). Pesticide tolerance limits established by the EPA are to ensure the safety of foods for human and animal consumption (US-EPA 2015f). These tolerances include traditional pesticides, such as herbicides and insecticides, as well as genetic elements that may be introduced through GE processes, such as PIPs (e.g., Bt Cry proteins) or proteins that confer herbicide resistance (e.g., PAT). If pesticide residues are found above the tolerance limit, the commodity is subject to seizure by the government.

The EPA has established tolerance limits for pesticides in 40 CFR part 180. Both the FDA and USDA monitor foods for pesticide residues to enforce these tolerance limits, and ensure protection of human health. For example, the USDA Pesticide Data Program collects data on pesticide residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities frequently consumed by infants and children (USDA-AMS 2015a). The EPA uses data from the USDA Pesticide Data Program to prepare pesticide dietary exposure assessments pursuant to the FQPA. Pesticide tolerance levels have been established for a wide variety of commodities, as described in 40 CFR part 180. The CFR is revised once a year, in July. Information on new or changed tolerance limits is published by the EPA in Federal Register notices when a tolerance limit is modified.

To ensure the continued safety of pesticides and public health, the EPA conducts pesticide registration reviews. This ensures that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects (US-EPA 2015h). Pesticides, when used in accordance with EPA pesticide label requirements, are considered to present negligible risk to human health. When pesticides are not used in accordance with label requirements, the statutory standard of no "unreasonable adverse effects" may not be attained.

3.8.2 Worker Safety

Agriculture is considered one of the most hazardous industries in the United States. Worker hazards common to agricultural production include those associated with the operation of farm machinery, vehicles, and pesticide application. Agricultural operations are covered by several Occupational Safety and Health Act standards including Agriculture (29 CFR 1928), General Industry (29 CFR 1910), and the General Duty Clause. Further protections are provided through the National Institute of Occupational Safety and Health, which in 1990 began development of an extensive agricultural safety and health program to address the high risks of injuries and illnesses experienced by workers and families in agriculture.

In consideration of the risk of pesticide exposure to field workers, the EPA's Worker Protection Standard (WPS) (40 CFR part 170) was issued in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. The Occupational Safety and Health Administration also requires employers to protect their employees from hazards associated with pesticides and herbicides.

On February 20, 2014, the EPA announced proposed changes to the agricultural WPS to increase protections from pesticide exposure for agricultural workers and their families. The EPA is proposing to strengthen the protections provided to agricultural workers and handlers under the WPS by improving elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies.

The proposed changes to the current WPS requirements will improve training on reducing pesticide residues brought from the treated area to the home on workers' and handlers' clothing and bodies. It will also establish a minimum age for handlers and early entry workers, other than

those covered by the immediate family exemption to mitigate the potential for children to be exposed to pesticides directly and indirectly. The EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations; child farmworkers and farmworker families; and the general public.

All pesticides labeled for use on crops in the United States must be evaluated for safety and registered by the EPA. The EPA pesticide registration process includes the development of use restrictions that, when followed, have been determined to be protective of worker health. Farm workers are required to use pesticides consistent with the instructions provided on the EPA-approved pesticide labels, which may include instruction on personal protective equipment, specific handling requirements, pesticide equipment application specifications, and field reentry procedures. Any revisions to 7 CFR part 340 would not alter the standards or processes by which worker safety is ensured and decisions are made under the coordinated framework.

3.9 Animal Food and Welfare

Animal food refers to food products used as food for pets, and food animals (livestock).[87] The composition of animal food derived from non-GE and GE crops is a critical issue for food animals as they are fed tailored formulated diets for optimal health, growth, and product quality. Hence, even a small change (decrease) in an essential nutrient (for example, methionine, an essential amino acid) can lead to adverse effects as the animal consumes a nutritionally inadequate diet.

Livestock for purposes of this proposed rule includes the animal species defined as livestock and poultry in Title 7 of the United States Code, section 182 (7 U.S.C. 182), i.e., cattle, sheep, swine, horses, mules, goats, chickens, turkeys, ducks, geese, and other domestic fowl. It also may include other animals raised for food, fiber, or labor. Livestock eat a wide variety of agricultural products such as corn, soybeans, alfalfa, wheat, cotton seed, sorghum, legumes, clover, oats, millet, and their byproducts, some of which may be obtained from GE organisms. Pets include dogs, cats, and other animals. Animal food for pets can be comprised of a variety of plant materials, such as corn, wheat, soybeans, which can also be from GE sources. Human and animal food derived from GE plants or other organisms must be in compliance with the FFDCA and all other applicable legal and regulatory requirements.

Since 2000, more than 100 billion food animals raised in the United States have consumed GE food (Van Eenennaam and Young 2014). During this time numerous animal feeding studies have been conducted with various species of animals, including sheep, goats, pigs, chickens, cattle, rabbits, and fish utilizing food derived from GE crops. Findings from these studies, summarized in several review papers (e.g., (Snell, Bernheim, Berge et al. 2012, Bartholomaeus, Parrott et al. 2013, Deb, Sajjanar, Devi et al. 2013, Ricroch 2013, Van Eenennaam 2013, Nicolia, Manzo et al. 2014, Van Eenennaam and Young 2014)), have not shown any unique risks associated with animal food derived from GE crops. An extensive body of peer-reviewed literature and field observations of animals fed diets containing GE crop products have revealed

[87] The Federal Food, Drug, and Cosmetic Act defines "food" as "articles used for food or drink for man or other animals; chewing gum; and articles used for components of any such article".

no adverse effects or disturbing trends in animal performance or health (Van Eenennaam and Young 2014).

There have been some studies published outside of peer review, and a few peer-reviewed publications, which suggested animla food derived from GE plants had adverse health effects on animals. However, findings from these studies have not withstood scientific scrutiny, nor have they been reproduced (see review by (Van Eenennaam 2013)).

In general, the weight of scientific evidence (regulatory and peer-reviewed studies) garnered over the last 15 years, in tandem with empirical evidence that consumption of food derived from GE plants has had no adverse effect on food animals or pets, has led to the general consensus among most scientists that animal food derived from current GE crops is as safe as, and comparable in composition and nutrition to that derived from conventional crops (Snell, Bernheim et al. 2012, Van Eenennaam and Young 2014).

As described in detail in Section 3.8.1.1 – FDA:Food Safety, human and animal food derived from GE plants or other organisms must be in compliance with the FFDCA, FSMA, and all other applicable legal and regulatory requirements. The FDA recommends that developers of GE plant varieties intended for food use consult with the FDA about the safety and composition of the GE variety prior to its introduction into the food supply. Developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006). Although this is a voluntary process, thus far all applicants who have wanted to commercialize a human or animal food product derived from a GE crop have completed a consultation with the FDA or the GE product was evaluated in another more relevant premarket process (see (US-FDA 2015)).

Before a pesticide can be used on a human or animal food crop, the EPA establishes tolerance limits under Section 408 of the FFDCA and Section 405 of FQPA, which is the maximum amount of pesticide residue that can remain on the crop or in food processed from that crop.[88] Similar to tolerance values for human food, these EPA tolerance values for animal food are set to ensure safety of raw or processed commodities for animals and may include conventional pesticides and proteins from GE crop derived food, such as PIPs or proteins conferring herbicide resistance.

Animal food derived from GE crops is also reviewed by international authorities such as the European Food Safety Authority (EFSA) (EFSA 2015b). Animal food made of or containing plant material from a GE crop is regulated in the European Union (E.U.) by Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Regulation (EC) No1829/2003 on GE food. U.S. companies seeking to market animal foods derived from GE crops in the E.U. must have regulatory approval of the product prior to doing so.

Animal food derived from GE crops undergoes substantive review in the United States and by international authorities. APHIS expects that developers of GE plant varieties intended for food will consult with the FDA about the safety and composition of GE varieties prior to their

[88] EPA - Setting Tolerances for Pesticide Residues in Foods: https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods

introduction into the animal food supply. Developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006).

3.10 Socioeconomics

Executive Orders (E.O.) 12866, "Regulatory Planning and Review," and 13563 "Improving Regulation and Regulatory Review" direct agencies to evaluate the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic benefits, environmental, public health and safety effects, and equity. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Regulatory Flexibility Act of 1980 requires federal agencies to review regulations for their impact on small businesses, small organizations, and small governmental jurisdictions, and consider less burdensome alternatives.

In compliance with these requirements, and in addition to this dPEIS, APHIS has conducted a Regulatory Impact Analysis (RIA) and Initial Regulatory Flexibility Analysis of the proposed rule and Alternatives (USDA-APHIS 2016c), and the reader is referred to this document for review of the analysis. This section summarizes the RIA analyses, entities potentially affected by changes to 7 CFR part 340, and the current socioeconomic environment. The potential economic impacts of changes to regulations are discussed in Chapter 4 – Environmental Consequences.

3.10.1 Affected Entities

The proposed changes to regulations may affect a range of public and private plant biotechnology research facilities, producers of GE seeds and crops, food processors, grain processors, and paper producers that fall into various categories of the North American Industry Classification System. For the purpose of this dPEIS and following the Small Business Administration guidelines, the potentially affected entities are classified within the following sectors: Agriculture, Forestry, Fishing and Hunting (Sector 11), Manufacturing (Sectors 31-33), Wholesale Trade (Sector 42), Retail Trade (Sectors 44 and 45), Transportation (Sectors 48 and 49), and Professional, Scientific and Technical Services (Sector 54) (USDA-APHIS 2016c). Direct effects would be felt by biotechnology companies and research institutions that develop products of biotechnology, farmers, and those federal agencies regulating GE organisms under the Coordinated Framework; APHIS, EPA, and FDA. These potential impacts are discussed below.

3.10.2 Domestic Agricultural Commodity Markets

3.10.2.1 Grower Choice

U.S. farmers produce 25% of the world's food supply and use a variety of commodity and specialty crops to meet demands for human and animal food, fiber, and biofuel across domestic and foreign markets. In the United States, there are three production systems: (1) conventional non-GE crops, (2) organic crops, and (3) biotechnology based (GE) crops. Each of these systems

can employ different production and crop product standards.[89] Additionally, domestic and international commodity handling systems may maintain different standards for identical products. Consequently, a diverse set of production and distribution systems must co-exist to meet specific market demands (Van Deynze 2011).

In meeting market demand, farmers will adopt and maintain production of a GE plant variety over a conventional or organic crop relative to the benefits they derive from that GE crop, such as increased yields, increased farm net returns, time savings (by making production less intensive), and reduced exposure to chemicals (Fernandez-Cornejo, Klotz-Ingram and Jans 2000).

Net benefits derived from a GE crop are a function of chosen crop and location, output and input prices, farmer abilities and preferences in managing crop production, and unforeseen circumstances such as drought (Fernandez-Cornejo, Wechsler et al. 2014a). Based on the 2010 USDA Agricultural Resource Management Survey, farmers indicate that they adopted GE corn, soybean, and cotton varieties primarily to increase yields, to save management time to facilitate other production practices (e.g., crop rotation and conservation tillage), and to reduce pesticide input costs (Figure 3-27) (Fernandez-Cornejo, Wechsler et al. 2014a). The profitability of GE crops for individual farmers depends largely on the value of maximum yield achieved relative to the associated costs of pesticide and seed. Fundamentally, farmers may adopt but will not continue production of a GE plant variety where that variety does not provide economic and other benefits over that of non-GE crops.

[89] Identity Preservation (IP) is the process of differentiating commodities by requiring strict separation, which typically involves containerized shipping be maintained at all times. IP is often used to market commodities like food-grade corn and soybeans, but it may be used for any differentiated product that has special characteristics that purchasers wish to protect, and are willing to pay for the increased handling costs. There are IP contracts for conventional, organic, and GE crops. The vast majority of IP crops are grown using conventional seed. Organic standards are prescribed by the USDA National Organic Program (NOP).

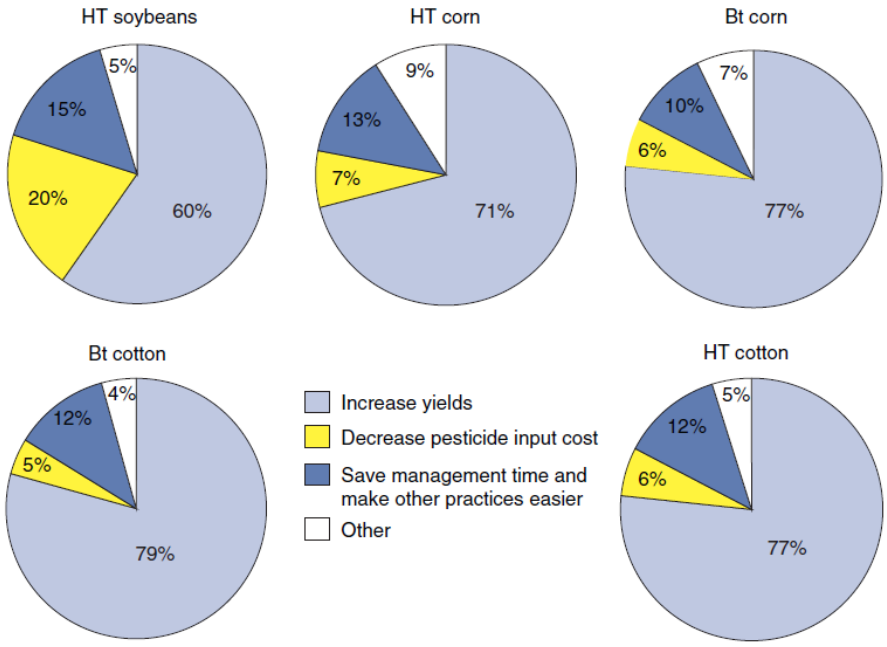

Figure 3-27. Common Reasons Growers Adopt GE Corn Varieties
Sources: (Fernandez-Cornejo, Wechsler et al. 2014a)

3.10.2.2 GE Crop Commodities

Agricultural commodities derived from GE crops are recognized as economically beneficial to domestic markets, and the adoption of GE crops in the United States has generally reduced costs and improved profitability at the farm level (Brookes and Barfoot 2013a, Fernandez-Cornejo, Wechsler et al. 2014a, Klümper and Qaim 2014, Brookes and Barfoot 2015). For example, a recent review found that U.S. farmers have realized higher incomes due to their use of GE crops, totaling approximately $58.4 billion in extra income between 1996 and 2013 (Brookes and Barfoot 2015).

In general, cultivation of Bt crops is associated with mitigating yield losses to insects, leading to increased yields and higher net returns when pest pressure is high (Fernandez-Cornejo, Wechsler et al. 2014a). Data from the USDA Agricultural Resource Management survey show that Bt corn yields were 17 bushels per acre higher than conventional corn yields in 2005 and about 26 bushels higher in 2010. Studies by ERS found that a 10% increase in the rate of Bt corn adoption was associated with a 1.7% yield increase in 2005, and a 2.3% yield increase in 2010 (Fernandez-Cornejo, Wechsler et al. 2014b). These findings are similar to those reported by Brookes and Barfoot (2013), where yield gains in the United States for Bt corn crops ranged from 5% to 7% over the years 1996-2013, and yield gains for Bt cotton averaged almost 10% over the same time period. Note that yield increases are not due to higher genetic yield potential, but to more effective pest control and thus lower crop damage.

Yields gains and reductions in pesticide and crop management costs have translated into increase net returns per acre for some GE crops. Generally, about 70% of the gains have derived from yield and production gains with the remaining 30% coming from cost savings (Brookes and

Barfoot 2015). Over the years 1996-2013, Brooks and Barfoot (2015) found average farm income benefits of GE IR cotton to be $44/acre, GE IR corn around $32/acre, GE soybean $57/acre, GE HR corn around $10/acre, GE HR cotton around $9/acre, GE HR canola $21/acre, and GE HR sugarbeet $46/acre.

The extent to which GE HR crops affect net returns is mixed and relative to how much weed control costs are reduced and seed costs are increased. Some researchers have found no significant difference between the yields of conventional and GE HR crops; others found that GE HR crops had higher yields (as mentioned above), while still others found that GE HR crops had lower yields (e.g., see review by (Fernandez-Cornejo, Wechsler et al. 2014b)).

Recent USDA Agricultural Resource Management Survey data indicates that stacked-trait seeds, the use of which is increasing, can have higher yields than conventional seeds or seeds with only one GE trait. For example, 2010 Agricultural Resource Management Survey data show that conventional corn seeds had an average yield of 134 bushels per acre. By contrast, seeds with two types of herbicide resistant traits (glyphosate and glufosinate) and three types of insect resistant traits (Bt specific for corn borer, corn rootworm, and corn earworm) had an average yield of 171 bushels per acre (Fernandez-Cornejo, Wechsler et al. 2014b). Adoption rates of stacked-trait varieties have increased in recent years, with stacked-trait corn expanding from < 1% of planted acres in 2000, to 76% in 2014 (Fernandez-Cornejo, Wechsler et al. 2014a, Fernandez-Cornejo, Wechsler et al. 2014b). GE varieties incorporating three or four traits are now common, and will likely remain so in the coming years.

Other benefits to growers from adoption of GE crops have included (Carpenter, Felsot, Goode et al. 2002, Brookes and Barfoot 2010):

- reduced harvesting costs;
- higher quality crop product;
- an improvement in soil quality as growers expand limited tillage practices; and
- overall improvements in human health costs associated with use of less toxic pesticides and reduction in aflatoxin.

Globally, the average agronomic and economic benefits of GE crops are significant. Impacts vary by GE crop trait and geographic region, although on average, GE technology adoption has been found in one review to reduce chemical pesticide use by 37%, increase crop yields by 22%, and increase farmer profits by 68% (Klümper and Qaim 2014). Yield gains and pesticide reductions are larger for insect resistant crops than for HR crops. Yield and farmer profit gains are higher in developing countries than in developed countries.

3.10.2.3 Gene-Flow Among Cropping Systems

Gene flow among conventional, organic, and GE cropping systems can occur as a result of cross-pollination and seed dispersal, as described above, and such gene flow can have economic consequences for farmers, as well as result in repercussions in the marketplace. Consequently, as summarized in subsection 3.4.2, the management of gene flow will remain a basic component of commercial crop production for those wishing to maintain levels of genetic purity required for marketing certain types of agricultural commodities. This is particularly important for the for

identify-preserved and organic markets, which are required to maintain their crops and crop products free of the presence of GE material. The unintended presence of genes or gene products from deregulated GE crops in IP/organic agricultural commodities, and non-GE seed, and can interfere with both domestic markets and international trade. Unintended presence of GE plant material can occur not only from gene flow, but also due to failed crop segregation during harvesting, shipping, and processing. Hence, the maintenance of crop product identity is fundamental to ensuring the sustainability of GE, conventional, organic, and IP crop production systems, maintenance of price premiums in the market, and avoidance of trade disruptions due to unintended presence.

Producers of non-GE and GE commodities have methods available to prevent gene flow and the unintended presence of GE plant material, so that their products meet standards specified by USDA's National Organic Program (NOP), the Association of Official Seed Certifying Agencies (AOSCA) (AOSCA 2015, USDA-AMS 2015b, USDA 2015b), or individual contracts, as applicable. For all crop production systems, 100% purity (or 0% impurities) of any crop commodity or constituent is not possible and costs increase exponentially to achieve this goal (Van Deynze 2011, Kalaitzandonakes and Magnier 2013). As a result, farmers and agricultural groups have adopted process-based strategies such as those developed by the USDA NOP and AOSCA[90] that allow a low and acceptable level of impurities, including pesticides, weed seed, or varietal seed, in the final crop product.

Similarly, the American Seed Trade Association (ASTA), with 700-plus members, works with the global seed industry to ensure that practical standards are developed to support international markets. ASTA has recently released guides for co-existence (ASTA 2015b) and seed production practices (ASTA 2015a).

Generally, gene flow mitigation strategies in agriculture are well-established and can meet current domestic and international trade needs. Producers of GE and non-GE crops may use practices prescribed by the NOP, ASTA, and AOSCA to protect their crops from pollen and seed in order to meet market standards for IP and the presence of off-types, and certification as applicable. However, the presence of GE crop material in non-GE crop products can and does occur in rare instances. On average, around 1 to 3% of non-GE farmers have reported crop commodity rejection by suppliers due to the presence of GE crop material (USDA-APHIS 2015b).

The organic industry in particular is sensitive to the unintended presence of GE material when it can compromise contractual requirements with businesses that market and sell their products, or consumer demand for non-GE agricultural products fails to be met. From 2011 to 2014, eighty-seven of the more than 12,000 USDA certified organic farms collectively lost approximately $6.1 million due to the presence of GE material in the organic cropping system. This equates to an average loss of $70,099 for the 87 organic producers who reported losses for removal of the GE material, remediation, lost sales, or lost price premiums (USDA-NASS 2015b).[91] From 2006 to 2010, nine of more than 9,000 certified organic farms collectively lost $68,976, at an average

[90] The Association of Official Seed Certifying Agencies (AOSCA) develops, monitors, and coordinates standards for seed purity.
[91] The bulk of reported losses, approximately 3.8 million, were isolated to 3 farms in Texas, which somewhat skews the statistics.

loss of $7,664 for the nine organic farms that reported losses (USDA-NASS 2015b). As the number of organic farms and adoption of GE crops increased over this period, the incidence of organic farms reporting economic losses increased from 0.1% to 0.7%.

As a consequence of the increasing importance of meeting industry standards for IP and product integrity, the concept of coexistence among conventional, organic, and GE cropping systems has emerged as a central theme in modern agriculture (Van Deynze 2011). For example, around 2% of IP cropping systems report rejection of their IP commodity as a result of the unintended presence of GE material (USDA-APHIS 2015b). Coexistence, and gene flow among conventional, organic, and GE cropping systems, discussed below, is fundamentally an economic issue, not an environmental issue, nor unique to GE crops.

3.10.2.4 Coexistence Among GE and Non-GE Production Systems

As described throughout this section, GE crop technologies have provided economic benefits at the farm and market levels. However, there can also be potential conflicts at the farm level for some non-GE cropping systems. Potential negative economic impacts to non-GE agriculture can result from unintended trace quantities of GE crop materials found in organic or other non-GE crops/crop products as a result of impurities in seeds, cross-pollination between fields, GE plants that grow where they were not intentionally planted, and accidental mixing during harvesting, storage, transport, and processing. Comingling of GE and non-GE plant material can be of considerable economic importance, as consumer confidence in non-GE agricultural commodities may be affected by the real or perceived occurrence of the presence of GE material, and associated costs incurred by producers of non-GE crop products. Consequently, an important consideration in modern agriculture is the preservation of crop and crop commodity identity across GE, organic, and conventional production and marketing systems, the management of which is commonly referred to as coexistence. Coexistence is not an environmental safety or health issue; rather, it is an agronomic practice and economic issue regarding the marketing of commodities derived from non-GE, GE, and organic cropping systems.

The USDA defines coexistence as the "concurrent cultivation of crops produced through diverse agricultural systems including traditionally produced, organic, identity preserved, and genetically engineered crops." In practice, coexistence means growing, handling, and transporting agricultural commodities derived from different characteristics and intended markets with the goal of preserving agricultural commodity integrity, economic value, and market stability (both domestic and international).

The organic market requires organic crop production systems to be certified by the USDA under the NOP. The NOP is responsible for developing national standards for organically-produced agricultural products. These standards assure consumers that products with the USDA organic seal meet consistent, uniform standards. IP refers to a system of production, handling, and marketing that maintains the integrity and purity of agricultural commodities (Sundstrom, Williams, Van Deynze et al. 2002). IP has been practiced since the beginning of agriculture, and as seed and food industries evolved, the expectations for purity and quality among food processors and buyers increased, and market standards established. Agricultural commodity traders, marketing organizations, and food processors have established purity and quality tolerances for specific end uses of commodities. Seed certification programs such as AOSCA

help maintain the seed purity standards established by industry for domestic and international trade. As crops and production systems have diversified to meet market demands, the need for segregation and IP of agricultural commodities has increased (Sundstrom, Williams et al. 2002).

As previously described, producers and handlers of non-GE and GE agricultural commodities have available production and handling methods to prevent the unintended presence of GE material so that their product meets standards specified either by the NOP (AOSCA 2015, USDA-AMS 2015b, USDA 2015b), or through contracts and standards, as relevant. Likewise, ASTA has released guides for co-existence (ASTA 2015b) and seed production practices (ASTA 2015a).

However, where many producers of GE and non-GE crops use practices prescribed by NOP and AOSCA to protect their crops from pollen and seed in order to maintain crop/seed identity and certification as applicable, the presence of GE crop material in organic cropping systems remains an issue where stakeholders are concerned, as commingling of GE and non-GE crop products is not conducive to economic efficiencies. While the production of agricultural commodities and seed from non-GE, GE, and organic systems provides a range of ways to meet consumer needs and preferences, and market demands, both in the United States and abroad, preserving agricultural commodity identity in the market can present challenges. Developers and users of GE crops and crop products desire the ability to use the technology to efficiently meet market demand for food, fiber, and fuel, in the United States and abroad, and the organic and identity preserved sectors are required to preclude or limit the unintended presence of GE material in those product streams.

In most instances, the unintentional mixing of GE crop plants with non-GE crops is not associated with regulated field trials, but rather with commercially grown GE crops that are not regulated by APHIS. Under current regulations, APHIS has no authority over the cultivation of GE crops after a GE plant or other organism has been determined to be outside the purview of the PPA and 7 CFR part 340; therefore the Agency has no regulatory oversight of the segregation of GE and non-GE cropping systems. However, more broadly, the USDA is developing ways to improve coexistence among various agricultural sectors.[92] These include:

- USDA's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21), which is considering approaches by which farmers could be encouraged to work with their neighbors to develop joint coexistence plans at the state or local level, and how the federal government can assist this process;
- development of a Coexistence Education and Outreach Strategy;
- guidance for coexistence best practices in GE, conventional, and organic crop production;
- a USDA-ERS study to investigate the economic implications of coexistence (Greene, Wechsler et al. 2016); and

[92] See USDA-Agricultural Coexistence: http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=coexistence.html

- toolkits providing resources that encourage communication, planning, and crop-specific practices to reduce unintended gene flow or post-harvest mixing, as well as information on contract issues and incentives.

3.10.2.5 Herbicide Resistant Weed Costs

Approximately 97% of U.S. acreage devoted to major crops was treated with herbicides in 2014 (USDA-NASS 2014e). It is well recognized that the singular, long-term use of an herbicide can promote the development of resistant weeds. This is not unique to GE crop varieties; herbicide resistance has routinely occurred with conventional crops and herbicides since their introduction in the1950s, and can continue to occur. Historically, adoption of a GE HR weed control system corresponds to reduced grower costs and increased profitability. However, a well-recognized concern currently facing U.S. farmers is the emergence of glyphosate-resistant weeds resulting from the repeated, wide spread, and sometimes exclusive use of this herbicide. Considering that a substantial portion of major crops are planted to GE varieties (i.e., corn, soybean, cotton), such cropping systems and the agronomic practices employed can affect the development of resistant weed biotypes, or, conversely, contribute to the effective management of weeds and weed resistance.

As described in subsection 3.6.5.1 - Herbicide Resistant Weeds in the United States, there are currently 158 unique cases (plant species and site of action) of herbicide resistant weeds in the United States (Heap 2015). The resistance exhibited by these plants includes resistance to pesticides with varying modes of action (Heap 2015).

The presence of resistant weeds in crop fields increases the cost of production and can reduce net returns (Fernandez-Cornejo, Wechsler et al. 2014a). The extent to which weed control affects net returns is highly variable and depends on the type and abundance of problem weed(s) present; costs associated with herbicide, tillage, and other weed management practices; and the cost of seed. For example, stacked-trait crops are now commonly planted to manage weed resistance, and stacked seeds are currently more costly. The economic consequences and cost of resistant weed management can be considerable. For corn, soybean, and cotton, the mean and standard deviation of weed control costs per acre has been reported to be $40.17 (33.68); $33.45 (26.73); and $55.57 (40.74), respectively (Hurley, Mitchell and Frisvold 2010). In another study of 400 corn, soybean, and cotton producers in 17 states, growers estimated that glyphosate-resistant weeds increased their costs by $14-16/acre (Owen 2010).

Current IWM strategies use stacked-trait GE varieties along with crop and herbicide rotation as a tool to manage resistant weeds (Owen 2011, Owen 2012, Vencill, Nichols et al. 2012). The ERS analyses suggest that employment of such strategies in managing glyphosate resistance can be cost effective in the long run and that after about 2 years, the cumulative impact on net returns is higher when managing instead of ignoring weed resistance (Livingston, Fernandez-Cornejo et al. 2015). Similarly, Weirich et al. investigated the effect of grower adoption of glyphosate weed resistance management programs and found weed resistance best management practices (BMPs) initially more costly, but providing yields and net economic returns that offset weed resistance management costs over the long term (Weirich, Shaw, Owen et al. 2011).

The potential impacts of GE cropping systems and development of weed resistance on net returns for farmers, and in turn on domestic markets, is uncertain. There have been no new

herbicides developed with new modes of action and made commercially available in over 20 years, and the likelihood of novel herbicides for treatment of weeds in the next ten years is not considered a likely event (Owen 2012). To mitigate or preclude weed resistance and associated costs, producers of both GE and non-GE crops must employ a variety of weed control tactics that include the judicious and diversified use of herbicides, crop rotations, tillage, and scouting practices that minimize for selection of resistant weeds (Vencill, Nichols et al. 2012). Fundamentally, it is the producers of GE and non-GE crops that will decide which set of IWM practices will best support the sustainability, efficiency, maximum yields, and net returns in the particular crop(s) they are producing (e.g., (Owen 2011, Vencill, Nichols et al. 2012)).

3.10.3 International Trade of GE Agricultural Commodities

3.10.3.1 APHIS Regulatory Scope

Because the United States is both an agricultural exporter and importer, it is important to consider the ways imports and exports are different with respect to APHIS regulation, regardless of the proposed Alternatives. The United States does not have regulations or restrictions specifically related to the export of GE organisms or products, although most importing countries have requirements for import of GE organisms or products, discussed below. In 7 CFR part 340, exportation of regulated GE organisms is not specifically addressed, as APHIS has no authority outside the United States and its territories. Imports of regulated GE organisms into the United States, on the other hand, are specifically addressed in 7 CFR part 340. Any GE organism that may be, or is believed to be, a plant pest pursuant to 7 CFR part 340 must undergo APHIS notification or permitting processes prior to importation.

3.10.3.2 Status of Global Trade

The export of deregulated GE organisms has largely been limited to commercial crops such as corn, soybean, and cotton. The export of these deregulated GE crop products will continue, and it is expected a greater variety of GE crop commodities will be exported in the future, due to increased use of GE crop plants in agricultural production. Any potential impacts on U.S. exports of GE crop plants relative to APHIS decisions under 7 CFR part 340 would be indirect. Namely, if APHIS determines a GE crop plant to be regulated, this would restrict or preclude its use in commerce in the United States. When GE crop plants are determined not to be subject to 7 CFR part 340, they may subsequently be adopted as an agricultural commodity, and traded internationally.

Globally, the socioeconomic results from commercial cultivation of GE crops have been beneficial. These benefits vary by GE crop trait and geographic region, although a recent review has found that, since adoption of GE crops in 1995, crop yields have increased by 22%, farmer profits increased by 68%, and chemical pesticide use (cost) has been reduced by 37% (Klümper and Qaim 2014). Similar findings on the socioeconomic benefit of GE crops have been reported by Brooks and Barfoot (e.g., (Brookes and Barfoot 2010, Brookes and Barfoot 2013b, Brookes and Barfoot 2015)). The most recent analysis from Brooks and Barefoot found that plant biotechnology has made significant contributions to increasing global production levels of major crops, having added, for example, 122 million tons and 230 million tons to the global production of soybeans and corn, respectively, since the introduction of the technology in the mid-1990s (Brookes and Barfoot 2015). Net economic benefits at the farm level over the period 1996–2013

were found to amount to $116.6 billion (Brookes and Barfoot 2015). These economic gains were divided fairly equally among farmers in developed and developing countries. Yield gains and pesticide reductions have been found to be larger for IR crops than for HR crops (Brookes and Barfoot 2013b, Fernandez-Cornejo, Wechsler et al. 2014a, Brookes and Barfoot 2015), and yield and farmer profit gains higher in developing countries than in developed countries (Brookes and Barfoot 2015).

As of 2014, GE crops were grown commercially on all 6 continents of the world, in 28 countries. Of these, 19 countries planted 100,000 acres or more to GE crops (James 2014). The largest producers of GE crops include the United States, Brazil, Argentina, India, Canada, China, Paraguay, Pakistan, South Africa, Uruguay, Bolivia, Philippines, Australia, Burkina Faso, Myanmar, Mexico, Spain, Colombia, and Sudan (James 2014). Four crops account for the vast majority of GE crop production; these are soybean (51%), corn (31%), cotton (13%), and canola (5%) (James 2014). In 2014, the global market value of GE crops was $15.7 billion representing around 22% of the global crop market, and 35% of the global commercial seed market. Of the $15.7 billion GE crop market, around $11.3 billion (72%) was in industrialized countries and $4.4 billion (28%) in the developing countries (James 2014). The cumulative global value of GE crops since 1996 is estimated at $133.5 billion.

Because of the socioeconomic benefits that can derive from cultivation of GE crops, international trade of commodities derived from GE crops has increased substantially during the last 15 years. While GE crops have been on the market since the late 1990s, and comprise a substantial portion of international trade, they currently account for only around 9% of the total land used for global primary crops (James 2014). It is expected that both commercial import and export of GE products will increase globally as more countries develop and produce commodities derived from GE crops (James 2014).

3.10.3.3 Competitiveness and International Markets

Global trade of agricultural commodities, including seed, is driven by the growth and stability of world markets, which is affected by changes in population, economic growth, and per capita income. Other factors affecting agricultural trade are global supplies and prices of a given crop commodity, changes in monetary exchange rates, government support for agricultural production, pest and disease outbreaks, severe weather events such as prolonged drought, and international trade policies and agreements (USDA-ERS 2015c). Collectively, these factors render agricultural commodity markets competitive, both domestically and internationally.

Because U.S. agricultural production is growing faster than domestic food and fiber demand, U.S. farmers and agricultural firms rely heavily on export markets to sustain commodity prices and revenues (USDA-ERS 2015g). The leading U.S. exports are grains and animal foods, soybeans, livestock products, and horticultural products. The largest U.S. imports are horticultural and tropical products. U.S. exports grew by 8% on average annually from 2000 to 2014 while imports increased by 7.8%. Rising global demand, primarily in developing country markets, along with the dollar's competitive exchange rate helped U.S. exports grow faster than imports over the past decade. As a result, the U.S. agricultural trade surplus widened to $38.8 billion in 2014 (USDA-ERS 2015b). This surplus in agricultural trade helps counter the persistent deficit in nonagricultural U.S. merchandise trade (USDA-ERS 2015g).

Currently exported U.S. GE crop commodities are those derived from soybean, corn, cotton, canola, sugarbeet, and alfalfa (e.g., cornmeal, oils, animal food, and sugars). U.S. producers rely on and prosper from access to foreign markets that seek to import commodities derived from these crops. For example, during the 2010-2012 production years, U.S exports comprised more than 40% of soybean production; more than 75% of cotton production; 29% of poultry and pork production; 10% of beef production; and around 10% of corn production (USDA-FAS 2014). Poultry, pork, and beef exports are important considerations as these exports also are derived from GE crops and crop products as the majority of animal food in the United States. For example, some of the most common GE animal food ingredients are derived from GE soybean, cotton, corn, canola, sugar beets, and alfalfa. The majority of corn and soybean crops are used for livestock food. Moreover, the global demand for meat products is anticipated to increase as population increases. Global demand for meat is forecast to increase some 55% of current consumption by 2020, with most of the increase occurring in developing countries (ISAAA 2014b). Accordingly, demand for animal food grain is expected to increase by 3% per year in developing countries and 0.5% in developed countries (ISAAA 2014b).

Demand from developing countries, along with higher agricultural commodity prices, explains recent growth in the value of U.S. exports. Foreign demand for wheat, soybeans, cotton, corn and their processed products accounts for about half of U.S. export value. Among these GE soybean, cotton, and corn are primary U.S. crops. U.S. farm exports to developing countries are now more than double what are exported to developed countries. Purchases by developing countries have been consistently greater than developed countries since 1994 (USDA-ERS 2015b).

As for developed countries, China is currently the primary destination for U.S. agricultural exports. U.S. farm exports to China more than doubled from $12.1 billion in 2008 to $24.6 billion in 2014, which is $2.7 billion more than exports to Canada, the second largest market (USDA-ERS 2015b). Both Mexico and Japan are also strong export markets.

Fundamentally, international competition in the development of GE crops and trade restrictions imposed on GE products affect the potential size and distribution of economic gains that may be derived from adoption of GE crops and their commercial products (Frisvold 2015).

Producers of agricultural commodities rely on plant biotechnologies to lower the cost of production, improve the quality of products, and maintain competitiveness in international markets. Currently available GE products have been adopted by farmers for the purpose of potentially increasing yields, reducing management time and inputs, and reducing pesticide inputs and associated costs (Fernandez-Cornejo, Wechsler et al. 2014a). All of these can improve efficiency and reduce the overall cost of production. Future products of plant biotechnologies providing similar agronomic advantages will affect the competitiveness of U.S. agricultural products in export markets, particularly if other producing countries continue to develop and use available biotechnologies.

3.10.3.4 International Standards and Regulations

Globally, the trade of GE agricultural products is subject to the laws, regulations, and policy of the importing country, and is impacted by international treaties, agreements and other arrangements. Bilateral, multilateral, and regional trade agreements to eliminate trade barriers

among member countries have taken on greater significance amidst an evolving international trading environment (e.g., North American Free Trade Agreement, Trans-Pacific Partnership) (USDA-ERS 2015f), which include major U.S. trading partners such as Japan, Mexico, and Canada. The United States has recently concluded trade agreements with South Korea, Colombia, and Panama. Major trading partners also include the E.U. and China.

International trade among these and other countries is facilitated by the World Trade Organization (WTO) and the Organization for Economic Cooperation and Development (OECD 2015, WTO 2015b). Standards and guidelines for the safety evaluation and trade of GE crop commodities are established under international policy and agreements such as the Codex Alimentarius (FAO 2009), the WTO International Plant Protection Convention (WTO 2015a), WTO Sanitary and Phytosanitary Measures (WTO 2015b), WTO Technical Barriers to Trade (TBT) Agreement (WTO 2015c), and the Cartagena Protocol on Biosafety (CBD 2015).

Regulatory systems among the various importing and exporting countries are diverse and evolving; efforts to improve international harmonization of standards and guidelines in the trade of GE crop commodities have achieved moderate results (Josling 2015). Many countries require a food safety evaluation and potentially an environmental analysis of a GE crop commodity before it can be imported, and the regulatory requirements and timelines for reaching a decision for each country can be different. Because a GE crop can be legally grown commercially or marketed as human and/or animal food in some countries, but not others, the low level presence (LLP) [93] of GE crop material in internationally traded non-GE crop commodities has become a focus of discussion (FAO 2014c). LLP situations occur in the importing country when there is asynchrony between the authorization of the exporting country and that of the importing country; an issue described as an "asynchronous approval". LLP is generally described as a situation where there is authorization of a particular GE commodity by one or more exporting countries, but authorization is still pending or has not been requested in the importing country. The issue of asynchronous authorization (AA), and resulting LLP situations, can lead to trade delays, shipment rejection, and costs to traders (FAO 2014c).

Asynchronous authorization can also result in the diversion of shipments to other markets by some exporters, and rejection of agricultural products by importers due to zero tolerance policies for the presence of unauthorized GE materials in shipments (Frisvold 2015, WTO 2015b). Incidents of LLP can lead to income loss for exporters and importers, and consequently for producers, and consumers in importing countries can potentially face higher domestic commodity prices when import is deterred or directed to another trading partner (Atici 2014). In addition to situations arising from AA and LLP, trade can also be impacted by moratoria, or bans on the import or use of GE crops or crop products. These bans can be explicit as a result of legislation, or de facto. De facto bans may occur if a country does not have a GE product decision making framework, or chooses to take no action regardless of its existing decision making framework.

[93] Low level presence (LLP): Once a GE crop is authorized for commercial use in a given country, trace amounts of that GE crop may become mixed with other crop varieties in that country during processing or transit. As a result, a GE crop that is authorized in an exporting country may be present at low levels in grain, or human and animal food that is imported into another country, where that particular variety of GE crop has not been authorized.

4 Environmental Consequences

Pursuant to CEQ regulations APHIS must consider the direct, indirect, and cumulative effects on the human environment that may derive from implementing the Alternatives considered in revision of 7 CFR part 340 regulations. An effect would be any change, beneficial or adverse, from the existing (baseline) conditions as described in Chapter 3 - Affected Environment. Direct effects are those caused by a decision or action, and occur at the same time and place. Indirect effects are those which are caused by the decision or action but occur later in time or farther removed in distance from the site of action. Indirect effects include socioeconomic growth inducing effects, changes in the pattern of land use, population density or growth rate, and effects on natural resources and ecosystems (40 CFR 1508.8). Direct or indirect effects on the human environment may be beneficial or adverse, and can vary in the degree of significance.

For APHIS authorizations of importation, interstate movement, or environmental release of a regulated GE organism, there may derive potential direct and indirect effects on the human environment. For example, gene flow from a regulated GE plant to a non-GE plant during APHIS authorized field testing would be a direct effect. A beneficial indirect effect would be any socioeconomic benefits that derive from utilization of the GE organism, such as a GE crop plant. As discussed in section 3.10.2, agricultural commodities derived from GE crops are recognized as economically beneficial to domestic markets, and the adoption of GE crops in the United States has generally reduced costs and improved profitability at the farm level (Brookes and Barfoot 2013a, Fernandez-Cornejo, Wechsler et al. 2014a, Klümper and Qaim 2014, Brookes and Barfoot 2015). An adverse indirect effect would be an increase in the selection of herbicide resistant weed populations as a result of the use herbicides to manage weeds in GE herbicide resistant crops.

A cumulative impact is an effect on the environment which results from the added, incremental impact of past, present, and reasonably foreseeable future actions. Cumulative impacts can derive from a single entity, or multiple entities, over an extended period of time. A cumulative impacts analysis is discussed in Chapter 5.

As a programmatic analysis, the potential environmental outcomes considered are those that may derive from the regulatory frameworks under the Alternatives evaluated, and the decision options available to APHIS under these regulatory frameworks. Specific regulatory decisions and actions taken in the future would be evaluated by APHIS on a case-by-case basis in NEPA analyses, as appropriate.

4.1 Area Used for Agriculture and Forestry

Currently, APHIS may authorize the importation, interstate movement, or field testing of a regulated GE organism in any of the 50 states or U.S. territories. Once APHIS determines that a GE organism is not subject to 7 CFR part 340 regulations that organism may be introduced into any environment in the United States or its territories without an authorization pursuant to 7 CFR part 340. This section addresses the potential effects on land use that may derive from the Alternatives considered in revision of 7 CFR part 340 regulations. Emphasis is given to GE plants, namely GE crop plants, GE commercial forestry

and orchard trees, GE ornamentals, GE grasses, and GE plants developed for pharmaceutical and industrial purposes, as these comprise that vast majority of GE organisms that have been and are expected to be subjected to APHIS review.

4.1.1 Overview of Commonalities Among Alternatives

4.1.1.1 Potential Impacts on Land in Farms

Areas of cropland and rangeland are expected to marginally decline over the next several decades largely due to an increase in U.S. population and expansion of urban and suburban areas, and increased crop yields/acre through technological enhancements (Alig, Plantinga et al. 2010, Westcott and Hansen 2015). However, cropland and rangeland will continue to be dominant land uses in the United States (Westcott and Hansen 2015). The total acreage and the areas used for production of major crops are not expected to significantly deviate from current trends over the next decade (Westcott and Hansen 2015).

The Alternatives considered in revision of 7 CFR part 340 regulations would have only a minor effect on these projections as the acreage and area of agricultural land use is primarily determined by market forces (see Section 3.10 – Socioeconomics), and federal and state laws and policy governing land use, outside of APHIS authority.[94] Minor fluctuations in total farmland will occur on an annual basis relative to domestic and international demands for food, fiber, and fuel, although USDA projections have farmland remaining fairly steady over the next decade for the major crops produced in the United States.

4.1.1.2 Potential Impacts on the Types of Agricultural Land Uses and Principal Crops

Regardless of the Alternative selected, the types of traits developed and used in GE crops would likely continue to include stacked-trait GE varieties which provide resistance to plant pests and diseases, and/or those that help control agricultural weeds, as these have been and will remain among the most pressing issues facing commercial crop production in the United States and abroad. GE crops with new traits would be expected to be developed for commerce where there were issues with a particular type of plant pest or disease, or changes in climate necessitated shifts in the production of a particular crop variety. The types of traits that are expected to be incorporated into future GE crop plants include:

- Bacterial resistance (e.g., citrus greening resistant)
- Fungal resistance (e.g., soybean rust resistant)
- Virus resistance (e.g., corn streak mastrevirus)
- Improved product quality (altered fatty acid, amino acid, or noxious compound content)
- Desired agronomic properties such as stress tolerance (e.g., improved cold or drought tolerance)

[94] In the United States authority to regulate land use is held by the states. All states delegate some or all of this authority to local governments, usually to municipalities.

Hence, new GE crop varieties would be expected to be developed and adopted where there were issues with a particular type of plant pest or disease, to reduce farmer inputs such as water, pesticides, or nutrients, to facilitate adaptation to climate change or extend the geographic range, or meet a consumer related need.

Apart from the factors described above, market factors, such as cost of production inputs, pest and disease control, and price of commodity outputs, are primary drivers in determining whether a particular GE crop plant will be selected for production, versus a conventionally bred crop plant. As an example, there are several GE crop plants that have been deregulated by APHIS that have not been adopted for commercial production, such as GE tomato, rice, and flax. GE tomato was introduced but unsuccessful due to lack of demand for the particular variety in the marketplace. There are more than 100 varieties of rice commercially produced in the United States, largely in Arkansas, Texas, Louisiana, Mississippi, Missouri, and California. However, GE rice has not been adopted in the United States, or in other countries, largely due to a lack of export markets and concerns regarding potential for unintended mixing of GE and non-GE rice.

In general, grower adoption of GE crops is largely determined by market forces, and the economic risks and benefits associated with a particular GE crop plant. Under each of the Alternatives considered, there would be variance in the availability GE crop plants that were not subject to APHIS regulation, and hence, available for commercial adoption subject to EPA review and approval, and the FDA's voluntary consultation or premarket evaluation, as appropriate. However, APHIS's determinations of regulatory status of GE crop plants is not considered the driving factor in grower adoption of GE crop plants. Under all the Alternatives, market forces, the economic risks and benefits associated with a particular GE crop plant, would be the primary factor in grower adoption of a GE crop plant, and crop type, or the particular species of plant, determinant of where and on what types of land that crop can be grown. None of the Alternatives considered would affect the overall acreage of cropland in the United States; cropland acreage is determined by domestic and international market demand for human and animal food, and fiber, as well as emerging markets for biofuels. Slight variations in the cropland allotted to conventional, organic, and GE crops may result from APHIS regulation under the Alternatives considered, and these are discussed under each Alternatives in the following sections of this chapter.

4.1.1.3 Potential Impacts on Forest Use Lands

Forest area in the continental United States is projected to decline from current estimates of around 400 million acres to 375 million acres in 2062, largely due to urban development (Alig, Plantinga et al. 2010). Timber harvesting during the past 50 years has remained well within sustainable limits and is expected to continue. For example, timber removals have remained below 2% of U.S. standing tree inventory, while net tree growth has been near 3% (Alvarez 2007).

Forestland in U.S. territories is projected to increase in coming years due to conservation efforts in the U.S. Virgin Islands and Puerto Rico. In general, there is little potential in Puerto Rico for full scale commercial timber production due to limited acreage, land holdings, and local law. There are no forests in the U.S. Virgin Islands owned by the forest industry and no

significant export market for timber products on the U.S. Virgin Islands (Chakroff 2010). Hence, it is unlikely that a commercial forestry market would develop in Puerto Rico or the U.S. Virgin Islands, or that there would be any commercial cultivation of GE forestry trees. Likewise, field testing of GE trees has not been conducted in these territories, and unlikely for the foreseeable future.

As with food crops, the acreage and areas of commercial forest land uses in the continental United States is affected by market demand (i.e., lumber, paper products, fine woods for furniture), and federal and state laws and policy.[95] Currently there are no GE forest trees grown in the United States. While APHIS regulates GE forest trees and development of GE trees is being sought for commercial forestry purposes, none of the Alternatives considered in the revisions to 7 CFR part 340 regulations is expected to alter the areas or acreage of U.S. forests, although Alternative 3 could present a barrier to the adoption of GE forest trees which could influence the type of trees grown in these forests. For example, freeze tolerant eucalyptus could extend the range of where eucalyptus is grown in the United States replacing some of the pine plantations in the Southeast. Blight resistant chestnut could restore chestnut as the dominant hardwood tree in the Northeast forest replacing some oak forest and under Alternative 3, it is expected that either possibility is less likely.

4.1.2 Factors Potentially Affecting the Types of Agricultural and Forestry Land Uses and Principal Crops

Within the context of agricultural and forestry land uses described above there are several factors that can influence the future development of GE organisms for commercial purposes. These factors in turn will determine the types of GE plants and other organisms that APHIS will be evaluating and could be regulating, the types of GE organisms that may be field tested, and the areas of the United States where GE plants may be cultivated, or other organisms utilized, if approved for commercial use U.S. government agencies.

4.1.2.1 Pests and Disease

The prevalence and persistence of known plant pests and disease could increase in certain areas of the United States, or a plant pest or disease could emerge as result of importation or natural means. In these instances GE plants or trees may be developed, or adopted in greater numbers if they exist, to help mitigate the effects of the pest or disease on agricultural and forestry commodity production. Prediction of where, when, and what type of agricultural or forestry related pest or disease will emerge is not an exact science, and can be challenging. Consequently, this draft programmatic environmental impact statement (dPEIS) does not propose to provide estimates on where and what type of pest or disease may emerge. However, the increase in prevalence of current pests and diseases, and the emergence of new pests and diseases, will serve as a key determinant of the types of traits and varietals of GE plants and trees that may be presented to APHIS. The incidence and prevalence of pest and disease can also determine whether a GE plant resistant to pest or disease is developed, and where and at what scale a GE crop resistant to pest or disease is grown. Other organisms,

[95] For example, the National Forest Management Act of 1976, Forest Land Policy and Management Act of 1976, and Wilderness Act of 1964. All 50 states have laws governing forest land uses.

such as GE arthropods, may be developed as biocontrol agents to help manage or eradicate certain plant pests.

For example, citrus greening, a bacterial disease spread by two species of psyllid insects, is one of the more serious diseases of citrus trees worldwide. Citrus greening was first detected in the United States in Miami-Dade County, Fla., in 2005, and is known to be present in the United States in Florida, Georgia, California, and the territories of Puerto Rico and the U.S. Virgin Islands, two parishes in Louisiana and two counties in South Carolina. Other than tree removal, there is no effective control once a tree is infected and there is no known cure for the disease. Once a tree is infected, it will die. Despite generations of breeding, no citrus plants have been produced that resist citrus greening; however, GE orange trees have recently been developed to help allay potential adverse effects of citrus greening on commercial citrus crops.[96]

4.1.2.2 Climate

Changes in regional weather patterns will likely occur as a result of global climate change (Hatfield, Takle et al. 2014, IPCC 2014). Changes in annual mean temperature, precipitation patterns, and the frequency and severity of weather events such as drought, could affect what type of GE plants are developed, and where a GE plant is field tested. Likewise, these factors could determine shifts in the type and location of GE plants cultivated for commercial purposes. Such changes in regional climate would affect agricultural land uses for all crops, not just GE-crops. However, where a GE crop provides benefits compared to a non-GE cultivar, it may be preferred and adopted by growers. For example, development of drought tolerant corn or soybean might allow these crops to be cultivated in areas with less available water supplies. This may be especially valuable to allow the same crops to be produced in areas that have become drier due to climate change.

Development of GE plants for cultivation in areas that otherwise would be inhospitable to the plants thriving, or development of GE plants in response to changes in climate, is expected to continue. This will allow these crops to be grown with fewer inputs (water, nutrients, pesticides) potentially making them more profitable to grow and potentially extending the areas where crops can be cultivated. Genetic engineering of plants tolerant of drought or other extreme conditions could result in use of marginal lands to grow crops, assuming the grower could acquire a benefit (usually economic) from doing so. Marginal lands include those somewhat unsuitable for growing most row crops due to water availability (too much or too little), soil suitability (e.g., extreme pH, limited nutrients, high salinity, etc.), extreme temperatures (too high or too low), high slopes, high altitudes, and other factors. The same general concept applies to developing any stress tolerant plant and possible expansion or shifting of growing regions. Cultivar development to expand growing regions is likely to continue with or without the use of plant biotechnology (Ashraf 2010, Fita, Rodríguez-Burruezo, Boscaiu et al. 2015).

[96] EPA - Defensin Proteins (SoD2 and SoD7) Derived From Spinach (*Spinacia oleracea* L.) in Citrus Plants; Temporary Exemption From the Requirement of a Tolerance: https://www.federalregister.gov/articles/2015/05/06/2015-10486/defensin-proteins-sod2-and-sod7-derived-from-spinach-spinacia-oleracea-l-in-citrus-plants-temporary

4.1.2.3 Ecological Restoration and Bioremediation

GE trees have been considered for the ecological restoration of tree populations decimated by pests and disease. There are currently efforts to develop a GE blight resistant American chestnut for reintroduction into forests of the Eastern United States. The American chestnut, once one of the most dominant trees in Eastern forests, is effectively extinct as a result of a pathogenic fungus (*Cryphonectria parasitica*) that destroyed most of the U.S. population. The American Chestnut Research and Restoration Project (SUNY-ESF 2016) is developing a GE American chestnut tree that is resistant to the fungus, with the aim of reintroducing GE resistant trees back into forest ecosystems of the Eastern United States (reforestation).

GE plants and other organisms are also considered as a means to efficiently remove environmental contaminants from soils and water. Phytoremediation can include a range of technologies that use plants to sequester or degrade environmental pollutants, restoring polluted sites to their natural, unpolluted state (Pilon-Smits and Freeman 2006). Phytoremediation utilizes naturally occurring biological processes in which plants degrade, sequester, or transform inorganic and organic pollutants. Genetic engineering may be used to refine these processes for specific purposes – the removal of a specific type of contaminant. Whether these types of GE products will emerge as commercially viable means for bioremediation remains indeterminate, as considerable research and development is yet required to validate the environmental safety of such products. However, APHIS expects such GE organisms to continue to be developed for phytoremediation purposes, as development of such organisms is refined.

4.1.2.4 Tailored Qualities and Characteristics

Certain GE organisms may be developed to produce commodities with characteristics that improve their commercial use. For example, plant biotechnology research is exploring traits that can modify wood fibers to make them more amenable to paper and paperboard processing. The development of various desired traits across a range of commercial agricultural and forestry commodities may arise, and could influence where and what type of agricultural commodities may be grown.

4.1.2.5 Pharmaceutical and Industrial Products

Natural processes in plants and other organisms can be modified by biotechnology to produce proteins and other compounds with medical or industrial utility. Various plants are being explored for the production of pharmaceutical and biological products that can be used for the treatment, prevention, or diagnosis of disease in humans and animals; such as vaccines, hormones, and antibiotics. Plants are also being explored to produce industrial products such as detergent enzymes, polymers, and lubricating oils. The most commonly explored plants have been corn, rice, tobacco, flax, safflower, and barley. These types of GE plants have been field tested in areas that have low production geographies. Namely because of concern of any low level presence of pharmaceutical and industrial crops in crops used for human or animal food, they have been grown in areas where commercial production of that crop is limited so large isolation distances can be achieved. In some cases that means growing the crop in areas that are not optimal for their growth. One trend has been an increase in the production of plant made pharmaceuticals in tobacco indoors in highly

contained facilities. This trend is based on large improvements in the efficiency of production in tobacco combined with the fact that the amount of product needed is often relatively limited.

In general, APHIS has seen a decline in permit applications for the field testing of GE plants developed for pharmaceutical and industrial purposes. For example, from 2006 to 2011, APHIS received around 10 to 15 permit applications per year. Since 2012, APHIS has received around 5 to 9 permit applications per year.[97] It is expected that the plant species that may be used for pharmaceutical and industrial purposes in the future is likely to continue in those platforms previously developed, such as tobacco, potato, rice, corn, and soybean.

4.1.2.6 Fuel Crops

GE plants are also being explored as biofuel sources (Gressel 2008). For instance, there are a number of plants being explored as feedstocks for cellulosic ethanol and biodiesel including switchgrass, sorghum, miscanthus, short rotation woody crops, and algae to name a few (Wang, Wu and Huo 2007, Mullet, Morishige, McCormick et al. 2014). APHIS does not have particular authority over GE bioenergy plants[98] or other organisms used for fuel production, but could be involved in regulation of these types of GE organisms where they may present potential risks as plant pests or noxious weeds.

4.1.2.7 External Factors

Factors overseas could also affect agricultural land uses in the United States. If certain areas of the world suffered or were anticipated to suffer losses to crop production due to pests, disease, or changes in climate, growers in the United States may choose to adopt certain crops for export to meet overseas demand. These would include GE crop varieties. For example, U.S. farmers might choose to grow more wheat, corn, or soybean if international demand increased. This would affect the use of current croplands, and could result in a marginal increase in total cropland, although significant increases in new land used, conversion of unmanaged lands to cropland, would be unlikely.

4.1.2.8 Summary: Agricultural and Forestry Land Uses and Principal Crops

All of the factors described, individually or collectively, affect agricultural land uses in the Unites States, and the choice of GE plant cultivated. For biotechnology developers and farmers to alter their current development and production practices, respectively, or for growers to adopt new GE agricultural or forestry products, the new technology would have to provide tangible benefits. These include increased yields, better products, and better net profits from production. Similarly, products developed for pharmaceutical and industrial, phytoremediation, or biofuels purposes would likewise have to provide sound economic benefits to be seriously pursued and considered for commercial use. In general, socioeconomic forces, discussed later in this chapter (Section 4.6), serve as a primary driver

[97] APHIS Release Permits for Pharmaceuticals, Industrials, Value Added Proteins for Human Consumption, or for Phytoremediation: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/reports/pharma-table

[98] Unlike traditional domesticated crops, bioenergy crops are selected for their rapid aboveground biomass production, low input requirements, broad climatic suitability, and performance on marginal land.

in determining what biotechnology products will be developed, and which products will see adoption and continued use in commerce.

In the event a given GE organism is determined not to be subject to APHIS regulation, and subsequently adopted for commercial use, the acreage used in the commercial production of the GE commodity is almost exclusively determined by producers in response to market demand, and the location determined by regional environmental factors conducive to cultivation of a particular GE crop/tree, as well as various federal, state, and local land use requirements. APHIS decisions under the Alternatives considered would have little direct effect on land uses, other than where and when a regulated GE plant or other organism may be field tested. The size of APHIS regulated field trials would not be expected to significantly change under any of the Alternatives considered in this dPEIS. Consequently, field trials would have negligible impact on the acreage and areas used for agriculture and forestry in the United States. As summarized in section 3.3, field trials range between 1 and 50 acres, with most field trials being 30 acres or less. For any future field releases APHIS would review and authorize proposed field releases, to include the location and acreage, prior to authorization of the activity under regulations implementing the PPA.

4.1.3 No Action Alternative: Acreage and Area of Agricultural Production

4.1.3.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of GE organisms that are considered plant pests under permit or notification (USDA-APHIS 2011, USDA-APHIS 2012). These activities may be authorized in any U.S. state, commonwealth, or territory, as described in section 3.3.4.

4.1.3.2 Authorization of Interstate Movement and Importation

APHIS authorized movements and importations of GE organisms are required to adhere to the notification performance standards and permit conditions that ensure confinement of the GE organism during shipping or movement (USDA-APHIS 2011, USDA-APHIS 2012). When requests for import or movement are received, APHIS provides the necessary information to states for review and approval of import of a GE organism into the state.

Over the years APHIS has authorized thousands of importations and interstate movements. During 2015 APHIS issued permits or acknowledged notifications for 744 importations and 746 interstate movements. Of the imports, 617 were requested by academic and private research institutions for import of Drosophila (fruit fly).[99] For both import and interstate movements in 2015, around 1,025 authorizations were requested by universities or public research institutions (~ 69%). Hence, the majority of imports and movements are for basic and applied research purposes.

[99] Drosophila fruit flies are widely used in genetics and developmental biology research. In most instances, they do not contain genetic sequences from plant pests and are not listed as organisms that are or contain plant pests in current § 340.2. Therefore, they generally do not require permits for their movement under 7 CFR part 340. However, shipments labeled as "fruit flies, whether created through biotechnology or not, sometimes raise agricultural and environmental concerns because this common name also refers to regulated plant pests like the Mediterranean and oriental fruit flies. To alleviate concerns at border inspections, Drosophila shipments are often accompanied with a courtesy movement permit.

Most movements and importations under current regulations would have no to little effect on the area, acreage, or type of land uses in the United States. These activities typically involve small quantities of GE material transported in secure shipping containers between clearly defined locations. When entities authorized to move or import GE organisms adhere to current notification and permit requirements the potential for inadvertent release of GE organisms is limited to instances of accidents or human error. Accidental releases, such as spillage of seed as a result of container failure or human error are possible but infrequent, and when they occurred have resulted in remedial actions at the site of release. We know of no instance where spillage during conveyance had a lasting effect on the environment. If it occurred, any remedial actions would be transient in nature, and long term effects on land uses from such an incident are considered unlikely.

The number of annual requests for movement and importation are not expected to considerably change under the No Action Alternative, as the types of GE organisms within the scope current 7 CFR part 340 regulations will remain the same. There could be seen a marginal increase in annual requests, relative to innovation and the pace of development of GE organisms, both in the United States and abroad.

4.1.3.3 Environmental Release

Field testing is part of standard research and development practices and pre-market evaluation of GE organisms. To date, APHIS has issued more than 18,400 permits and notifications for field testing of GE organisms (the vast majority plants). In 2015, APHIS issued 37 permits or acknowledged 447 notifications for environmental release in 39 states, Puerto Rico, and U.S. Virgin Islands.[100] In contrast to importations and movements, only 32% of environmental releases in 2015 were authorized for academic or public research institutions. The majority of authorization requests for field trails are from commercial developers of GE crop plants, trees, ornamental plants, and microbial pesticides.

To control and minimize GE plants or other organisms occurring beyond the area where it is intended to be tested, notifications and permit criteria are designed to limit regulated GE organisms to the field site and preclude persistence of the GE organism beyond termination of the field trial.

Authorized field trials for GE plants have ranged in size from .001 acres up to 100,000 acres. The median size of an approved field trial is approximately 5 acres, and average size about 20 acres. Collectively, authorized field trials have comprised, in recent years, around 400,000 acres per year, and make up a small percentage of U.S. lands. By comparison, the United States is comprised of approximately 2.3 billion acres of land. Land in principal crops

[100] Permit and notification request information for import, movement, and field release is publically available on the USDA funded Information Systems for Biotechnology website ISB (2015). *Information Systems for Biotechnology (ISB)*. USDA Cooperative State Research, Education, and Extension Service (CSREES), USDA Agricultural Research Service (ARS), and Agricultural Experiment Station at Virginia Tech. Retrieved December 19, 2016, from http://www.isb.vt.edu/Default.aspx..

comprises ~ 326.5 million acres.[101] Farmland in Puerto Rico comprises ~584 thousand acres, and in the U.S. Virgin Islands, 5.8 thousand acres.

Potential impacts to lands and land uses that may derive from authorization of field trials are dependent on the variety of GE organism (e.g., insect or herbicide resistant), the management practices involved in field testing of the GE organism (e.g., tillage, pesticide use), and the environment in which the field trial is conducted (e.g., proximity to suburban areas, wildlife refuges, commercial farms). By example, pesticide use and spray drift may be a potential concern to adjacent land owners or managers, such as adjacent lands comprised of protected areas such as critical habitat. APHIS requires as part of the permitting request that applicants provide a preliminary critical habitat analysis, which is reviewed by APHIS and used in determination of approval of the application. These types of potential impacts on adjacent lands and land uses would be considered on a case-by-case basis as authorization requests are received by APHIS.

Certain GE organisms may present unique issues that warrant special restrictions during field release, and in some instances permit requests may be denied if the request does not meet APHIS regulatory requirements. Examples would be GE plants developed to produce pharmaceutical or industrial compounds, GE trees developed for commercial purposes, and certain GE grasses (which include rice) due to their capacity for outcrossing.

Plants genetically engineered to tolerate stressful climate conditions could result in use of marginal lands to field test such plants, or they could be tested in areas in which they are not native. Marginal lands are those unsuitable for growing most row crops due to water availability (too much or too little), soil suitability (e.g., extreme pH, limited nutrients, high salinity, etc.), extreme temperatures (too high or too low), high altitudes, and other factors. Freeze tolerant eucalyptus has been field tested in the Southern United States, a region in which unmodified populations of eucalyptus would not typically persist. The same general concept applies to development of any stress tolerant plant and possible expansion or shifting of the region in which it may be field tested. Development of GE plants for stress tolerance or for adaptation to marginal lands is likely to continue (with or without the use of plant biotechnology). Hence, these types of GE plants could see field testing in areas where GE plants have not commonly been introduced, such as desert and mountain regions, or regions with colder climates.

APHIS implements a compliance and enforcement program (discussed following) to respond to unauthorized releases. APHIS publishes major noncompliance incidences on its website. Noncompliance incidences have involved failure of permittees to maintain appropriate isolation distances, failure to maintain the regulated articles separate from other organisms, failure to devitalize GE plants on termination of the field trial, and failure to monitor for volunteer GE plants as required by permit. In all instances remediation was required by APHIS, and in most civil penalties issued.

[101] Crops included are corn, sorghum, oats, barley, rye, winter wheat, Durum wheat, other spring wheat, rice, soybeans, peanuts, sunflower, cotton, dry edible beans, potatoes, canola, proso millet, and sugarbeets. Harvested acreage is used for all hay, tobacco, and sugarcane in computing total area planted. Includes double cropped acres and unharvested small grains planted as cover crops].

As an example, GE creeping bentgrass, which was field tested in Oregon and Idaho, was dispersed from the authorized test site as a result of unanticipated strong winds, which transported seed and pollen out of the authorized areas of release. Potential impacts to land owners would derive primarily from socioeconomic impacts where the low level presence of regulated GE bentgrass may affect the marketability of seed crops (particularly grass seed) produced in the area, add incremental costs to processing the crop, and add incremental costs for eradication of the GE bentgrass where it occurs in unauthorized areas. The developer, The Scotts Company, has signed a memorandum with USDA-APHIS and will implement a 10-year management plan to control the grass. Scotts has been purchasing and cleaning commingled seed as well as funding eradication efforts.

When field testing is conducted pursuant to the present notification and permitting requirements (USDA-APHIS 2011, USDA-APHIS 2012) the likelihood of escape or unauthorized release of a GE organism is considered minimal. Unauthorized releases largely derive from weather events (strong winds or rain), human error, or in rare instances, neglect. The safeguards used to prevent escape and dissemination of the GE organism during field trials include physical isolation distances (segregation from other crops and sexually compatible species), temporal isolation, flower removal, or other appropriate controls. Under the current regulatory framework, APHIS authorized field testing has negligible impacts on the acreage or types of land uses in the United States and its territories. No adverse effects on cropland, rangeland, forestlands, or other land uses has been identified in over 20 years of field testing. Any future requests for APHIS authorization of environmental releases of GE organisms would be assessed on a case by case basis, and permit conditions prescribed as necessary to preclude dissemination or persistence of the GE organism beyond the authorized area of release.

4.1.3.4 Compliance, Enforcement, and Remediation

APHIS compliance and enforcement activities help ensure confinement of the GE organism to the areas authorized for import, movement, or field testing. APHIS works with state and other federal agencies, including the FDA, EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations. The PPA provides for penalties in the event of serious infractions, including the possibility of criminal prosecution.

Monitoring is essential to ensuring that permit and notification requirements are being met. Under current regulations APHIS performs targeted and random inspections of field tests to evaluate potential noncompliance incidents. APHIS also evaluates facilities, equipment, records, and potential incidents reported by those authorized to move or field release a GE organism. Permit and notification criteria require that noncompliance incidents be reported to APHIS within designated time frames. Recordkeeping, reporting, and inspection requirements work in concert to monitor the authorized environmental release of regulated GE organisms.

If an incident occurs, APHIS requires that authorized entities quickly comply with regulations to protect U.S. agriculture, the food supply, and the environment. Incidents with low potential impacts may require simple remedial actions, such as correcting clerical errors or improving monitoring procedures. Serious incidents may require destruction of field test

sites, quarantine of harvested crops, formal corrective action plans, or other long-term measures. APHIS reports major incidents of noncompliance on its APHIS-BRS website.[102]

Remediation can be required if a violation has occurred and APHIS determines that action must be taken to control or eradicate the GE organism. Remediation can involve disturbance of land and altered land uses. For example, monitoring of an area for the presence of unauthorized GE organisms, which can alter land uses, may be required for an extended period of time. The effects of remedial actions on lands where such activities occur, and adjacent land uses, would generally be transient in nature and have no lasting effect on the continued use of the affected lands once remediation actions were determined to be completed.

4.1.3.5 Determination of Regulatory Status

When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance with EPA, FDA, and other federal and state agency requirements. Agricultural lands will continue to comprise the dominant use of GE plants APHIS determines are not subject to 7 CFR part 340. However, where GE plants are developed for ecological restoration or forestry purposes, various locales outside of the agricultural landscape, to include plantation forest lands, could see cultivation of GE plants – again, subject to federal and state requirements outside of 7 CFR part 340.

Growers in different regions of the United States are faced with different issues ranging from pests and disease, to water resources and soil conservation. Consequently, growers will choose to produce certain GE crop plants, to include ornamentals and orchard trees, depending on which region they live in and what issues they face. The availability of land suitable for crop production includes obvious factors such as climate, available water resources, soil type and quality, and less obvious factors such as potential pests and disease that could be present or may emerge in a given area. Such factors, along with market demand, determine whether, where, and at what scale a GE plant will be cultivated, as summarized in section 4.1.2. APHIS determinations of non-regulated status under current regulations, which render a GE organism available for commercial production, are not expected to significantly affect the area and acreage utilized for crop production in the United States or its territories. Minor shifts in the production of certain crops may, and likely will, occur relative to environmental and market factors. The total acreage and area of agriculture lands are not expected to significantly detour from current USDA projections, as described in section 3.1.

4.1.4 Preferred Alternative: Acreage and Area of Agricultural Production

4.1.4.1 Regulatory Scope

The Preferred Alternative would incorporate the noxious weed authority provided APHIS in the PPA into 7 CFR part 340; expand the range of organisms considered and potentially regulated using the revised definitions for “genetic engineering” and “GE organism”; remove

[102] USDA-APHIS: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_compliance_and_inspections/ct_compliance_history

the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures; and strengthen the compliance and enforcement program by clarifying APHIS authorities under the PPA and augmenting current approaches used to prevent or remediate potential risks to plant health.

4.1.4.2 Authorization of Interstate Movement and Importation

Movement and importation of regulated GE organisms would require an APHIS permit. APHIS would prescribe permit conditions, as applicable, designed to preclude unauthorized release. APHIS would use a performance-based approach for shipping of regulated GE organisms and require they are handled in such a way to secure the shipment and maintain labeling and identity.[103] Movements of regulated organisms would have to meet containment and handling requirements to prevent release into the environment. Specifics regarding labeling/marking and the methods of secure shipment would be prescribed as part of the permit conditions.

All locations where regulated organisms are received, stored, distributed, or released into the environment would have to be identified within a permit if movement occurs. Locations include but are not limited to greenhouses; laboratories; growth chambers; field trial locations; and production, propagation, sale, distribution, and manufacturing locations. Unauthorized environmental releases during interstate movement of regulated organisms, whether under authorized permit or not, must be reported to APHIS.

Authorization of the movement or importation of GE organisms, which occurs between distinct locations, would have little effect on the area and acreage of land uses, or land management practices in the United States or its territories.

4.1.4.3 Authorization of Environmental Release

Under the Preferred Alternative APHIS would be considering a broader range of organisms that would include not only potential plant pests, but potentially noxious weeds, and other organisms subject to the definitions for "genetic engineering" and "GE organisms." While the scope would be broadened, the revisions would focus and limit regulatory oversight to GE organisms that posed a plant pest or noxious weed risk. This will be accomplished by instituting a more efficient plant pest and weed risk analysis process to distinguish those GE organisms that merit regulation from those that do not. The notification process (7 CFR § 340.3) and courtesy permits (§340.4(h) would be eliminated, and all environmental releases of regulated GE organisms would require a permit. APHIS would prescribe permit conditions to prevent the unauthorized release of the regulated GE organism from the test site and its persistence in the environment, as well as impose limits on the areas and acreage used for environmental release. APHIS compliance and enforcement actions (discussed in the following section) would also be revised under the Preferred Alternative. Collectively, the proposed revisions constitute a broadening of APHIS' oversight of the field testing of GE

[103] APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation".

organisms, which was suggested by the USDA OIG (USDA-OIG 2015) and 2008 Food, Conservation, and Energy Act of 2008 (Farm Bill).

During the last 15 years the median size of an approved field trial has been around 5 acres and average size about 20 acres. Total annual acreage for authorized releases has comprised, over last few years, around 450,000 acres per year. While the Preferred Alternative provides APHIS consideration of a broader scope of GE organisms under 7 CFR part 340, the total number of organisms permitted by APHIS under the Preferred Alternative is expected to diminish because it is expected that most organisms will not be considered likely to present a plant pest or noxious weed risk after PPRA and WRA evaluations. Consequently, the total acreage for authorized field testing is likely to diminish.

Under the Preferred Alternative APHIS would regulate a GE organism and require a permit only when, based on a risk assessment, they are determined to pose plant pest or noxious weed risks. APHIS would no longer regulate an organism solely because the vector or vector agent used in development of the GE organism was a plant pest. APHIS would regulate and require a permit when it determines that the GE organism-trait combination associated with the GE organism causes it to pose a risk as a plant pest or noxious weed. In brief, APHIS would analyze plant pest and noxious weed risk first, and only require permitting for those GE organisms that are determined to pose such risks.

Consequently, it is expected that the number of GE organisms requiring permits for importation, interstate movement, and environmental release under the Preferred Alternative would decline, as the list of regulated organisms would be limited to those organisms that are determined by APHIS to pose a plant pest or noxious weed risk. Hence, the total annual acreage for APHIS authorized field releases is expected to decline under the Preferred Alternative. However, developers would continue to field test non-regulated GE organisms to comply with EPA requirements (as applicable), to gather data needed for consultation with the FDA (as applicable), and to improve the quality of their products. Hence, the total annual acreage for field testing of GE organisms (both regulated and nonregulated) would likely continue along current trends, perhaps ranging are 400,000 to 500,000 acres. There could be an increase, relative to grower preference for new varietals of GE crop plants. For those GE organisms that APHIS determines are unlikely to pose a plant pest or noxious weed risks, and therefore are not subject to regulation, those GE organisms may be field tested in any U.S. state, commonwealth, or territory, subject to EPA, state, and county or local requirements.

Considering the revisions proposed and factors discussed above, regulation of environmental releases under the Preferred Alternative would have negligible impact on the acreage and areas of land used for field testing, or land uses in the United States or territories, as compared to the No Action Alternative. Total acreage for field testing of regulated and unregulated organisms would increase or decrease commensurate with the variety and number of GE organisms developed, which is not expected to significantly deviate from current trends (described in section 3.1). For future field releases of regulated organisms, APHIS would review and authorize proposed releases on a case by case basis, to include review of the location and acreage, prior to authorization of the activity.

4.1.4.4 Compliance, Enforcement, and Remediation

Under the Preferred Alternative APHIS would strengthen its compliance and enforcement program by augmenting the approaches currently used and clarifying its enforcement authority under the PPA. APHIS would require that the responsible person provide APHIS inspectors access to all relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other aspects related to the importation, interstate movement, and environmental release of organisms regulated under 7 CFR part 340.

APHIS would revise reporting requirements. Permits would require plant biotechnology developers to track and record the plantings, acreage, and location of their GE products being grown as well as implement a GE plant volunteer management program. Records required to be maintained would include all locations and acreage where the regulated organism was planted during field testing; records for transport; and copies of contracts between the responsible person and all of his/her agents as well as copies of other records (e.g., emails, telephone records). APHIS would require that records for import or movement of a regulated organisms be retained for at least 2 years, and records for environmental releases to be retained for at least 10 years after completion of all obligations required under a relevant permit or exemption. APHIS would increase these time frames because many of APHIS' investigations into instances of noncompliance involve activities that were conducted a number of years before noncompliance was discovered. Maintenance of these records would facilitate the efficient enforcement of the regulations, and remedial measures and penalties issued by APHIS in the event of an unauthorized release of a regulated organism (i.e., where a regulated organism was planted in area not authorized by APHIS).

Failure to comply with the regulations could include denial of future permits; revocation of current permits; destruction, treatment, and removal of regulated organisms; issuance of penalties; and a means to settle civil violations prior to the issuance of an administrative complaint. A responsible person could be held liable for the violation of any APHIS requirement by any agent working for the responsible person (including persons contracted to conduct or carry out the controlled outdoor use on their own or on leased properties).

Through the use of an upfront risk assessment, authorized actions are expected to be fewer allowing the Agency to focus oversight more effectively on those releases that represent a plant pest or noxious weed risk. Furthermore, Agency actions will not be expended to enforce measures unrelated to protection against plant pest and noxious weed risk. As a result, compliance, enforcement, and remediation actions are expected to be more effective.

The potential impacts of compliance and enforcement actions on land uses would be the same as that described for the No Action Alternative. If an incident occurs, APHIS may require remediation actions. Remediation can be required if a violation has occurred and APHIS determines action must be taken to control or eradicate the GE organism. Remediation can involve disturbance of land and altered land uses. Incidents with low potential impacts may require simple remediation actions, such as improving monitoring procedures. Serious incidents may require destruction of field test sites, quarantine of harvested crops, formal corrective action plans, or other long-term measures. For example,

monitoring of an area for the presence of unauthorized GE organisms, which can alter land uses, may be required for an extended period of time. The effects of remediation actions on lands where such activities occur, and adjacent land uses, would generally be transient in nature and have no lasting effect on the continued use of the affected lands once remediation actions were determined to be completed.

4.1.4.5 Determination of Regulatory Status

Under the Preferred Alternative, the petition procedure for determination of non-regulated status would be eliminated (7 CFR 340.6) and APHIS would conduct plant pest risk assessments (PPRA) and/or weed risk assessments (WRA)) to inform the determination of whether a GE organism is a regulated organism and subject to permitting requirements under 7 CFR part 340. GE organisms whose regulatory status had been determined would be listed on a regulatory status register on APHIS' website as regulated or not regulated. Regulated organisms would include those that present a plant pest or/and noxious weed risk, or is a GE organism that has otherwise been determined by the Administrator to pose a risk as a plant pest or noxious weed. If APHIS determined a GE organism was not subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined is unlikely to pose a plant pest or noxious weed risk could be grown or utilized without a permit anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

In regard to the area and acreage of lands used for cultivation of non-regulated GE organisms, the Preferred Alternative would differ little from the No Action Alternative. As described for environmental releases it is expected that the total number of GE organisms regulated under the Preferred Alternative would likely decline; that the list of regulated organisms would be limited to those GE organisms that are known by APHIS to pose a risk as a plant pest or noxious weed as determined via a PPRA or WRA, or GE organisms that have otherwise been determined by APHIS to pose a plant pest or noxious weed risk. This in turn could result in an increase in innovation as small companies and academic investigators will be less hampered by the high cost of regulation. The rate of availability of GE organisms for commercial uses is not expected to significantly change because these organisms will still be subject to those laws and regulations implemented by the FDA (e.g., FFDCA) and EPA (e.g., FIFRA, FFDCA), as applicable, which are not anticipated to change.

If APHIS' process in determining the regulatory status of GE organisms is more efficient, and the rate of determinations of non-regulated status increases, this is not expected to affect the areas and acreage of lands used for cultivation of commercial crops or forestry, as compared to the No Action Alternative. Acreage used for commercial agriculture and forestry is determined by market demand for food, fiber, and wood products, and the areas of

cultivation determined (apart from climate) by various federal and state laws and regulations, as well as local requirements (e.g., zoning, local ordnance). Certain GE crop plants may supplant conventionally bred crop plants in some areas where the grower found benefits from cultivation of the GE plant variety. This, however, would not affect the areas or total acreage utilized for commercial crop production.

GE organisms developed for human or animal food, fiber, wood, or other purposes, and not regulated by APHIS, would still subject to compliance with laws and regulations implemented by the EPA and FDA, as applicable. As with field releases, the areas and total acreage used for commercial cultivation would increase or decrease commensurate with the variety and number of GE organisms developed, which is respondent to market demand.

4.1.5 Alternative 3: Acreage and Area of Agricultural Production

4.1.5.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it incorporates noxious weed authority, utilizes the revised definitions for "genetic engineering" and "GE organism", and risk analyses would be conducted via the PPRA and WRA. However, it expands the scope of regulation to encompass GE organisms that pose potential economic impacts. Under Alternative 3, APHIS' proposed regulatory framework would implement many of the revisions described for the Preferred Alternative. However, under this alternative APHIS would incorporate the noxious weed authority under the PPA to regulate GE plants that cause economic harms due to the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means.

Under Alternative 3, the WRA would include an economic effects analysis, and APHIS would review the potential economic impacts of GE organisms in addition to the plant pest and noxious weed risks as outlined in the Preferred Alternative. If, after conducting a PPRA and/or WRA, APHIS determines that a GE organism poses a plant pest or noxious weed risk in the traditional sense (biotic effects), then it would be regulated under 7 CFR part 340 just as described under the Preferred Alternative. However, if APHIS concludes that a GE organism is unlikely to pose a plant pest or noxious weed risk (biotic), the Agency would still consider whether the organism could result in economic harms from mere presence. If so, APHIS would then regulate that product and require APHIS permitting for commercial uses. For the purposes of this dPEIS, those GE plants with market impacts as a result of mere presence, but which otherwise are not considered plant pests or noxious weeds, are termed mere presence noxious weeds (MPNW). All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. Hence, under Alternative 3 potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that in addition to having no biotic effects, had no economic impacts on non-GE crop producers as MPNW. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.1.5.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative the notification process would be eliminated. The importation and interstate movement of regulated plant pests and noxious weeds would be conducted solely under APHIS permit. The importation and interstate movements of GE organisms that presented potential economic harms as MPNWs to non-GE producers would not require a permit for interstate movement or importation, although environmental release would.

The potential impacts to the area and acreage of lands affected by interstate movement and importation is expected to be the same because interstate movement and importation generally have no to little effect on land uses in the United States or its territories. These activities occur between distinct locations for a limited period of time, and require no special conditions relative to the acreage of area of land over/on which regulated organisms may be transported. Consequently, the benefits of this and the Preferred Alternative over the No Action Alternative would be marginal relative to potential impacts on land uses.

4.1.5.3 Authorization of Environmental Release

Under this alternative authorized environmental releases would include GE plants grown for both field testing and commercial purposes. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have the same requirements under this Alternative as the Preferred Alternative. The conditions would be more stringent than permits for commercial cultivation of MPNW, as MPNW would not present any biological plant pest or noxious weed risks. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, save for inclusion of MPNW.

The number of regulated organisms would significantly increase under Alternative 3 due to inclusion of MPNW, and consequently, the number of APHIS permits required for environmental release (permitted planting) would also increase. As APHIS would require buffer zones to isolate GE and non-GE crops where there was the potential for economic harms, this requirement would be expected to reduce the land used for crop production or necessitate the buffer zones be planted with a different crop or non-GE variety. Because management costs would be expected to increase under this Alternative, most likely this level of regulation would dissuade growers from adopting certain GE crops. If so, fewer buffer zones would be needed and land use would not change as much. However, insect resistant GE crops can result in greater yields due to more effective insect pest control (close the gap between potential and actual yield). If crop yields diminish because insect protection traits are no longer widely used, there may be more pressure to increase land use for certain crops where insect pressure is high.

All non-GE crop producers that desired to receive protections under APHIS' regulatory program would need to register their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning map on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

One consideration relative to wide-scale permitting is that, where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate conventional non-GE crops, or organic crops. If this were to occur, the use of conventional tillage practices may increase in areas where GE HR crops were abandoned and agricultural weeds were particularly problematic (see section 3.4.3). An increase in insecticide use could also occur where an insecticide-resistant (IR) GE crop plants were abandoned for use of the non-IR crop plant in a conventional cropping system. Were this to occur, this Alternative could potentially lead to land management practices used in crop production that were environmentally less desirable. The likelihood of some farmers opting to produce a particular non-GE plant utilizing a conventional or organic cropping system, as opposed to the GE plant variety as a result of APHIS regulation under Alternative 3, and the degree to which it may occur, is indeterminate. Potential changes in agronomic practices associated with such a shift in the choice of crop cultivation are discussed under the relevant sections (e.g., soil, air, and water quality) later in this chapter.

4.1.5.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be extended to MPNW and as a result greatly expanded. A heavy burden of compliance and enforcement actions would be imposed on all parties. Biotechnology developers would be required to track and record the plantings, acreage, and location of the GE plants cultivated and ensure that adequate isolation distances were maintained between GE and non-GE crops, and growers would be accountable for stewardship measures that included management of GE crop volunteers. The USDA would need to implement a voluntary national pinning system to identify the location of non-GE crops seeking protection from GE crops as well as a registration system for non-GE crop producers to ensure their legitimacy. USDA would need to conduct many more inspections to investigate cases where commingling occurred and ascertain whether the commingling resulted from a failure to follow permit conditions. Growers would be held accountable by biotech developers to follow additional stewardship requirements and maintain records. Records required to be maintained would include the locations and acreage where the regulated organism was planted, documentation that adequate isolation distances were maintained, documentation of volunteer plant management, and copies of contracts between the responsible person and all of his/her agents as well as copies of other records (e.g., emails, telephone records). Non-GE crop producers would need to maintain records of testing results and their copies of contracts between the responsible person and all of his/her agents. Maintenance of these types of records, conjoined with inspections would facilitate preventing non-compliance incidents, and remediation of unauthorized releases of a regulated organism in the event they occur. Regulations under this Alternative would be designed to strengthen coexistence between GE and non-GE organisms and to protect crop product identity across conventional, organic, and GE crops.

Under Alternative 3, no to slight differences in cropland use are expected relative to the other Alternatives, despite the increased regulatory activity expected. If fewer growers cultivate GE crops due to the additional regulation, we expect them to still use their land for agriculture, be it conventional or organic. It is possible that if yields diminish, and there is some evidence certain GE crop plant varieties can contribute to increased yield (NAS 2016b), there will be increased pressure to convert additional lands into crop production.

4.1.5.5 Determination of Regulatory Status

Determinations of regulatory oversight would be based on the same criteria as described for the Preferred Alternative, with the exception of an additional risk assessment for MPNW. The petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and/or WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined was not a plant pest, noxious weed, or MPNW could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

4.2 Physical Environment

4.2.1 Soils

4.2.1.1 No Action Alternative: Soils

4.2.1.1.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of regulated GE organisms that are, or are believed to be, plant pests under permit or notification procedures (USDA-APHIS 2011, USDA-APHIS 2012). These activities may be authorized in any U.S. state, commonwealth, or territory, as described in section 3.3.4.

4.2.1.1.2 Authorization of Interstate Movement and Importation

APHIS authorized movements and importations of GE organisms are required to adhere to the notification performance standards and permit conditions that ensure confinement of the GE organism during shipping or movement (USDA-APHIS 2011, USDA-APHIS 2012). Conducted pursuant to APHIS requirements, movements and importations under current regulations present little risk to soils. These activities typically involve small quantities of GE material transported in secure shipping containers between clearly defined locations. When entities authorized to move or import GE organisms adhere to current notification and permit requirements the potential for inadvertent release of GE organisms, and adverse impacts on soil quality, is limited to instances of accidents or human error. Accidental releases, such as spillage of seed as a result of container failure or human error are possible. Even in the unlikely event of an inadvertent release occurring, APHIS experience with previous GE organisms suggests that the impact to soils will be minimal. If there were a noncompliance incident, any remediation actions taken would be transient in nature, localized to the site of release, limited in scale, and adverse effects on soils considered unlikely.

4.2.1.1.3 Authorization of Environmental Release

Field testing is part of standard research and development practices and pre-market evaluation of GE organisms. To date, APHIS has authorized more than 18,400 permits and notifications for field testing of GE organisms (the vast majority plants). In 2015 APHIS issued 37 permits and acknowledged 447 notifications for environmental release in 39 states, Puerto Rico, and U.S. Virgin islands.[104]

Agronomic practices such as pesticide and fertilizer inputs, tillage, irrigation, and cover crops used in the field testing of GE plants can potentially affect soil quality and the erosional capacity of soils. Soil erosion can occur through natural processes, and relative to soil type, local terrain and ecology, and weather. Tillage practices, along with crop rotation and cover crop practices, can significantly influence soil quality and the erosional capacity of soils, depending on how these practices are or are not implemented. Soil biota, which are major determinants of soil fertility, are also affected by agronomic practices. Potential impacts on soil biota are discussed in Subsection 4.3.1.

Authorized field trials have ranged in size from .001 acres up to 100,000 acres. The median size of an approved field trial is approximately 5 acres, and average size about 20 acres. Collectively, authorized field trials have comprised, in recent years, around 400,000 acres per year. Most field releases for notifications and permits are valid for one year. The exception is for release permits for perennial plants or plants where the life cycle is more than one year. Release permits for perennials can be up to 3 years. Post-harvest site inspections for volunteer monitoring occur in year one or year two following the harvest of field tested GE plants to ensure they do not persist in the environment.

Pesticides use during field trials are regulated by the EPA. Any pesticide used must be registered with the EPA and applied pursuant to EPA label requirements. The EPA also regulates the field testing of GE plants comprised of PIPs, as well GE microbial pesticides, under FIFRA. Specifically, the EPA regulates PIPs, the insect or disease resistant gene and gene product; the plant itself is not regulated by the EPA, the plant is regulated by APHIS.[105] The EPA issues Experimental Use Permits (EUPs) for field testing of PIPs (40 CFR 172). The EPA requires that a pesticide product, to include PIPs and microbial pesticides, undergo extensive chemical, toxicological, and field-testing before being registered as a pesticide. Field testing is done to study the PIPs properties, safety, and efficacy. Because field testing of new PIPs necessarily involves an unregistered product, or is for a use not previously approved in the EPA registration of the pesticide, the EPA will authorize the distribution and field testing of PIPs through an experimental use permit (EUP) under FIFRA. The regulations at 40 CFR 172.4 contain the requirements for applications for EUPs. EPA

[104] Permit and notification request information for import, movement, and field release is publically available on the USDA funded Information Systems for Biotechnology website ISB (2015). *Information Systems for Biotechnology (ISB)*. USDA Cooperative State Research, Education, and Extension Service (CSREES), USDA Agricultural Research Service (ARS), and Agricultural Experiment Station at Virginia Tech. Retrieved December 19, 2016, from http://www.isb.vt.edu/Default.aspx..

[105] Current and previously registered plant-incorporated protectant registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

regulations (40 CFR 172.2) provide that any person wishing to accumulate information necessary to register a pesticide under FIFRA may apply for an EUP.

Due to the small scale and transient nature of field trials (e.g., 1 to 3 years) the potential for adverse effects on soils at field release sites is rather limited. Where field trial activities such as fertilizer and pesticide inputs, and tillage, can potentially affect soils, these crop management practices would not be expected to have any lasting adverse effects on soil quality, or the erosional capacity of field site soils, beyond termination of the field trial. Agronomic practices employed in field trials are the same as those used in commercial crop production, unless the particular effects of various tillage, and weed and pest management practices are being investigated.

4.2.1.1.4 Compliance, Enforcement, and Remediation

APHIS compliance and enforcement activities are to ensure confinement of the GE organism to the areas authorized for import, movement, or field testing. APHIS works with state and other federal agencies, including the FDA, EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations. Authorizations under the permitting and notification procedures require that noncompliance incidents be self-reported within designated time frames. Recordkeeping, reporting, and targeted and random inspections all work in concert to monitor the authorized environmental release of regulated GE organisms.

If an incident occurs, APHIS requires that authorized entities quickly comply with regulations to protect U.S. agriculture, the food supply, and the environment. Incidents with low potential impacts may require simple remedial actions, such as improving monitoring procedures. Serious incidents such as unauthorized releases may require destruction of field test sites, quarantine of harvested crops, formal corrective action plans, or other long-term measures.

A limited number of major noncompliance incidences have occurred involving failure to monitor for volunteer GE plants, to comply with performance standards for field trials, to notify APHIS of an accidental/unauthorized release within the required time period, and to contain or devitalize regulated seed when it was no longer in use. In all instances remediation actions were taken, such as destruction of the GE plant, and in some cases civil penalties issued. APHIS reports major incidents of noncompliance on its APHIS-BRS website.[106]

Remediation of noncompliance incidents can adversely affect soils. Incidents with low potential impacts may require simple remedial actions, such as correcting clerical errors or improving monitoring procedures. Serious incidents such as unauthorized or accidental releases may require destruction of field test sites, quarantine of harvested crops, or treatment of the area involving noncompliant GE plants with herbicides. For example, if there were dispersal of GE seed via a severe weather event, and a GE plant occurred outside an authorized area, or a volunteer plant presented after termination of the field trial, APHIS

[106] USDA-APHIS: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_compliance_and_inspections/ct_compliance_history

could order treatment of the area with a broad spectrum herbicide, compliant with EPA registration requirements, or mechanical removal to eradicate the GE plants.

The effects of remediation actions on soils would generally be transient in nature and lasting effects on soils following remediation are highly unlikely. In the event of extenuating circumstances, some areas may require long term monitoring, and eradication of GE plants or other organisms could require months to years to complete. This considered, remediation actions taken in response to incidences of noncompliance would present little risk in the way of permanently altering soil quality, or the erosional capacity of soils, where remediation actions were taken.

4.2.1.1.5 Determination of Regulatory Status

When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance with EPA, and other federal, state, and county requirements. The vast majority of GE organisms that APHIS has regulated, reviewed, and issued determinations of non-regulated status for, are GE crop plants, and it is likely this trend will continue for the foreseeable future. Hence, agricultural lands are expected continue to comprise the dominant use of non-regulated GE organisms.

Due to the rate of soil formation, which is on the order of millimeters per year, soil is considered a nonrenewable resource that requires conservation and stewardship if it is to be used in a sustainable manner. Historically, conventional agriculture, by leaving soil without adequate plant cover between harvest and planting, aggressive tillage practices, and extensive irrigation, has accelerated rates of soil erosion that exceed that of soil formation (Parikh and James 2012).

Maintaining soil fertility and precluding soil erosion is a basic requirement of sustainable commercial crop production, as fertility determines crop product quality and yield, and erosion - loss of fertile topsoil - determines the availability of quality soils in which to grow crops.

In the cultivation of commercial crops, pesticide and fertilizer inputs, tillage, irrigation, and crop rotation and cover practices, influence the quality and erosional capacity of field soils. Soil quality loss occurs through declines in soil organic matter (SOM), vital minerals (magnesium, calcium), essential nutrients (nitrogen, phosphorus, potassium), soil biota, and physical alteration of soil structure (compaction).

Soil Erosion

Soil erosion has been and remains a key issue in the central United States. Excessively eroding cropland soils are concentrated in Midwest and Northern Plain States, and in the Southern High Plains of Texas, as described in section 3.5.1. Growers producing crops on highly erodible land are required to maintain and implement a soil conservation plan that substantially reduces soil loss, and is approved by the USDA National Resources

Conservation Service (NRCS).[107] These plans are prepared by the grower pursuant to the Food Security Act of 1985 (P.L. 99-198, Farm Bill), which included a number of provisions designed to conserve soil and water resources, and minimize erosion. The 2014 Farm Bill continues the requirement that producers adhere to conservation compliance guidelines to be eligible for conservation programs administered by USDA-FSA and USDA-NRCS.[108] State agencies likewise provide assistance in development and implementation of soil conservation plans.

While erosion can occur through natural processes, which is determined by soil type, local terrain and ecology, and weather; tillage, crop rotation, and crop cover managements practices highly influence the erosional capacity of soils, and soil fertility. Conventional tillage is well recognized as contributing to erosion and to the degradation of soil quality. Hence, the requirement for soil conservation plans, per the 2014 Farm Bill, discussed above, in areas with highly erodible soils. Conservation tillage systems, including no-till, are now widely recommended for commercial cropping systems as they contributes to higher soil quality and less erosion, as compared with conventional tillage. Under conservation tillage SOM increases, biological activity increases, and soil structure improves. In general, as conservation tillage practices increase, total soil loss on erodible croplands in the United States decreases. From 1982 to 2003, total soil loss on cultivated cropland decreased by 39.2 percent, from 462 to 281 million tons. Any decrease in erosion of cropland carries with it a corresponding decrease in runoff and introduction of NPS pollutants such as sediments, fertilizer, and pesticides into water bodies. In 2012, farmers applied tillage practices on 278.8 million acres of cropland, which included no-till on 96.5 million acres, conservation tillage on 76.6 million acres, and conventional tillage on 105.7 million acres.

Given the well-recognized positive correlation between cultivation of HR crops and use of conservation tillage, further utilization of these types of GE cropping systems would not be expected to present any increased risk to soil erosional capacity over existing conventional cropping systems. To the contrary, conservation tillage in commercial crop production has increased in part because of the adoption of GE HR crops (Brookes and Barfoot 2010, Vencill, Nichols et al. 2012, Brookes and Barfoot 2013b). Hence, where GE HR cropping systems were utilized, there would be an increased probability that conservation tillage would be employed, and adverse effects of tillage on soils and soil erosion reduced.

The association between insect resistant GE crops and increased used of conservation tillage is less evident. These varieties types of GE cropping systems may utilize conservation tillage, although insect resistance itself does not facilitate adoption of conservation tillage, as with herbicide resistant crops. Insecticide use, however, is reduced in insect resistant GE cropping systems, which benefits communities of soil biota and maintenance of soil quality.

[107] USDA-NRCS: Highly Erodible Land Conservation Compliance Provisions. http://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/alphabetical/camr/?cid=nrcs143_008440

[108] USDA News Releases - Release No. 0155.14: http://www.usda.gov/wps/portal/usda/usdahome?contentid=2014/07/0155.xml&contentidonly=true

HR Weeds

The development of herbicide resistant weeds continues to increase in some areas of the United States (Heap 2015) and problematic not only to the production of crops providing food and fiber, but also to soils. For example, most corn growing states have between 7 to 26 different species of weeds that are herbicide resistant (Heap 2015). Where HR weeds are particularly problematic, and other strategies are not effective, growers may have to forego conservation tillage and consider more aggressive tillage practices to control HR weeds, which can adversely affect soil quality and increase erosional capacity. This is in fact the case; in some areas of the country, such as Kansas and the Southeast, growers have returned to more aggressive conventional tillage to control resistant weed populations.

There have been assertions that GE HR cropping systems increase the selection of herbicide resistant weed populations and have resulted in more herbicide use (Benbrook 2012). As described in section 3.6.5, selection for herbicide resistant weeds can occur anywhere an herbicide is repeatedly used, especially when other methods of weed control are not also used, regardless of whether it is a GE or non-GE crop. Herbicide use in the United States initially declined commensurate with the adoption of HR crops, and subsequently increased with the well published rise of glyphosate resistant weeds. This increase was relative to the reductions that began around 1996 (Fernandez-Cornejo, Nehring et al. 2014). Since 1981, pesticide use in the United States has declined. Between 1987 and 1997, there was a modest increase in use, reaching 601 million pounds of active ingredient in 1997. However, by the end of 2008 pesticide use had declined to 516 million pounds of active ingredient. These declines were for all pesticides; herbicides, insecticides, fungicides, and other pesticides.

Lessons learned from the initial increase in glyphosate use and weed resistance were that diversified weed management practices are critical in suppression of resistance development. Weed and agronomic scientists widely recommend implementation of integrated weed management (IWM) programs, which employ a diversity of methods intended to synergistically suppress agricultural weeds, and conserve soils. IWM practices not only provide for effective weed control, they can sustain or improve soil quality through efficient use of fertilizers and pesticides; use of cover crops to limit the time soil is exposed to weathering; crop rotations; and conservation tillage practices (USDA-NRCS 2006b). Furthermore, herbicides remain an important component of the IWM program and growers are increasingly adopting best management practices for sustainable herbicide use (Norsworthy, Ward et al. 2012).

In summary, the agronomic practices used in commercial GE crop production can beneficially or adversely affect the quality and erosional tendencies of soils, and weed management programs are a significant determinant of soil conditions. The weed management strategies employed by an individual grower would be dependent upon several factors: the species and prevalence of agricultural weeds and HR weeds in the given cropping system; the availability of herbicides for control/eradication of HR weed populations; soil conditions (e.g., highly erodible soils); and cost-benefit factors among the options available to the grower. However, growers of GE cropping systems, as growers of non-GE cropping systems, will have to consistently implement sound, recommended, IWM and IPM practices, in tandem with soil conservation plans as applicable, to avoid degradation of soil quality, and

deter soil erosion. Agronomic practices that affect soils, including IWM and IPM practices, are likely to remain unchanged under the No Action Alternative.

The USDA-NRCS has established a Soil Health Division within the Science and Technology Deputy Area of NRCS.[109] The goals of the division are to increase long-term adoption of soil health-based practices and soil health management systems (SHMS) on working lands, and increase the education, awareness, and technical capacity of producers and stakeholders.

4.2.1.2 Preferred Alternative: Soils

4.2.1.2.1 Regulatory Scope

The Preferred Alternative would incorporate into 7 CFR part 340 the noxious weed authority provided APHIS in the PPA; expand the range of organisms considered and potentially regulated using the revised definitions for "genetic engineering" and "GE organism," remove the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures; and strengthen the compliance and enforcement program by clarifying APHIS authorities under the PPA and augmenting current approaches used to prevent or remediate potential risks to plant health.

4.2.1.2.2 Authorization of Interstate Movement and Importation

Movement and importation of regulated GE organisms would be conducted solely under APHIS permit. APHIS would prescribe permit conditions, as applicable, designed to preclude unauthorized release. APHIS would use a performance-based approach for shipping of GE organisms and require they are handled in such a way to secure the shipment and maintain labeling and identity.[110] Movements of regulated organisms would have to meet containment and handling requirements to prevent release into the environment. Specifics regarding labeling/marking and the methods of secure shipment would be prescribed as part of the permit conditions.

As with the No Action Alternative, conducted pursuant to APHIS requirements under the Preferred Alternative, movements and importations would have no effect on soils. These activities would typically involve small quantities of GE material transported in secure shipping containers between clearly defined locations. When entities authorized to move or import GE organisms adhered to permit requirements the potential for inadvertent release of GE organisms would be limited to instances of accidents, unforeseen and severe weather events, or human error. If an unauthorized or noncompliant release occurred and APHIS required remediation, any remediation actions would be transient in nature, localized to the site of release, and long-term adverse effects on soils highly unlikely.

4.2.1.2.3 Authorization of Environmental Release

Under the Preferred Alternative APHIS would be considering a broader range of organisms that would include not only potential plant pests, but potentially noxious weeds, and other

[109] USDA-NRCS, Soil Health: http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/soils/health/

[110] APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation".

organisms subject to the definitions for "genetic engineering" and "GE organisms." The notification process (7 CFR § 340.3) and courtesy permits (§340.4(h)) would be eliminated, and all environmental releases conducted solely under permit. APHIS would prescribe permit conditions to prevent the unauthorized release of GE organisms from the field site and their persistence in the environment on termination of field trial. APHIS compliance and enforcement actions (discussed following) would also be revised under the Preferred Alternative. Collectively, the proposed revisions constitute a broadening of APHIS' oversight of the field testing of GE organisms, which was suggested by the USDA OIG (USDA-OIG 2015) and 2008 Food, Conservation, and Energy Act of 2008 (Farm Bill).

As a result of institution of a more efficient risk-based regulatory review process, an analyze first and regulate when needed approach, it is expected that the total number of GE organisms regulated under the Preferred Alternative would likely decline, as the list of organisms requiring a permit would be limited to those GE organisms that are known by APHIS to pose a risk as a plant pest or noxious weed. While the total annual acreage for APHIS authorized field releases, or field testing of regulated organisms, may decline under the Preferred Alternative, developers, as part of standard research and development practices, would continue to field test GE organisms that were not subject to 7 CFR part 340, and total annual acreage for field testing of regulated and non-regulated GE organisms would likely continue along current trends, perhaps increasing, relative to market demand for agricultural commodities and grower preference.

Potential impacts to soils as a result of APHIS authorized field trials under the Preferred Alternative would be no different than that described for the No Action Alternative. Any adverse impacts on soils would derive from crop production practices, such as pesticide and fertilizer inputs, tillage, irrigation, and crop rotation, which can affect the quality and erosional capacity of soils.

GE organisms that APHIS determines do not present potential plant pests or noxious weed risks, and therefore do not require a permit, may be field tested anywhere in the United States or its territories, without APHIS oversight or permitting requirements. As with the No Action Alternative, field trials of non-regulated GE organisms would be subject to all federal and state regulations, as well as county and local requirements governing protections of natural resources (e.g., some counties and cities prohibit planting of GE organisms). As under the No Action Alternative, the EPA would continue to regulate pesticide use, field testing of GE plants that are PIPs, and field testing of GE microbial pesticides.

The duration of permitted field testing would be specified on the permit itself, as a permit condition. This would give APHIS the flexibility to issue permits with suitable durations to meet individual circumstances. Based on the last 20 years of field trials conducted, permits would likely average from 1 to 3 years, although could extend longer for certain GE plants (e.g., trees) and other organisms for which extended data sets may be required.

As with current regulations, due to the relatively small scale and transient nature of field trials anticipated under the Preferred Alternative, the potential for field releases to significantly alter soil quality, or the erosional capacity of soils at field release sites would be expected to be rather limited. Field trial activities such as fertilizer and pesticide inputs, and

tillage, would affect soils, although such affects would not be expected to persist for any significant period of time beyond termination of the field trial. It is generally the persistent conduct of crop management practices over an extended period of time at the same location that can adversely affect soils. Field trials, present far less stress on soils than well-established commercial cropping systems, which due to their far greater scale, may present greater impacts.

4.2.1.2.4 Compliance, Enforcement, and Remediation

Under the Preferred Alternative APHIS would strengthen its compliance and enforcement program by augmenting the approaches currently used and clarifying its enforcement authority under the PPA. Failure to comply with the regulations could include denial of future permits; revocation of current permits; destruction, treatment, and removal of regulated organisms; issuance of penalties; and a means to settle civil violations prior to the issuance of an administrative complaint. To the extent the proposed revisions help improve the management decisions of permit holders during field testing and transport of regulated organisms, and reduce instances of noncompliance, the potential for adverse impacts on soils could be reduced, relative to the No Action Alternative, largely in the way of reduction of remediation actions.

4.2.1.2.5 Determinations of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct plant pest risk assessments (PPRA) and/or a weed risk assessments (WRA) to inform the determination of whether a GE organism will be regulated and require a permit under 7 CFR part 340. GE organisms would be listed on a regulatory status register on APHIS' website as regulated or not regulated. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk. If APHIS determined a GE organism was not subject to regulation, and it were later found to pose a risk as a plant pest or noxious weed, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340 regulation.

Any person could consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS.

Because most plants are not plant pests, nor present noxious weeds issues, it is anticipated the many of the GE crop plants currently regulated, and many of those GE crop plants that may be developed in the future, would not be regulated under the Preferred Alternative. The majority of GE organisms regulated under the Preferred Alternative would likely be the GE plants with weedy characteristics or that could pass on fitness traits to sexually compatible weedy relatives and biocontrol organisms that are plant pests.

When APHIS determined that a GE organism was not subject to 7 CFR part 340, that organism would still be subject to compliance with EPA and other federal and state agency requirements, as well as county or other local requirements.

As with the No Action Alternative, where there were adoption of GE herbicide resistant crops, there would be expected to be seen a maintenance or potential increase in use of conservation tillage practices. Where insect resistant varieties were adopted, there is expected to be a decline in insecticide use. These two trends, which are facilitated by the use of GE crops, are beneficial to soils. Similarly, other practices affecting soil quality and erosional capacity are expected to be the same under both Alternatives. Hence, there are no foreseeable risks presented to soils that would derive from the Preferred Alternative, that are above and beyond those risks presented by current cropping systems, both GE and non-GE.

While the agronomic practices associated with cultivation of GE HR and IR crops can lessen the stress of crop production on soil quality and erosional capacity, HR weeds remain a persistent and increasing problem across the United States (discussed under sections 3.6.5.1 and 4.3.5). The extent and management of HR weeds is expected to remain unaffected by the proposed revisions to regulations. For GE crops adopted in the future, as well as current GE crops, it is incumbent upon the growers and developers of GE cropping systems to consistently implement IWM practices to preclude HR weed development, and preserve the utility of the particular GE HR or IR crop variety under use. Use of GE and HR resistant crops are expected to be comparable under the No Action and Preferred Alternatives. No differences are expected in HR weed selection or types of management practices employed under the two Alternatives.

Growers producing crops on highly erodible land would be required to maintain and implement a soil conservation plan that substantially reduces soil loss, and is approved by the USDA National Resources Conservation Service (NRCS), as under the No Action Alternative.[111] These plans are prepared by the grower pursuant to the Food Security Act of 1985 (P.L. 99-198, Farm Bill), which included a number of provisions designed to conserve soil and water resources, and minimize erosion. The 2014 Farm Bill continued the requirement that producers adhere to conservation compliance guidelines to be eligible for conservation programs administered by USDA-FSA and USDA-NRCS. State agencies likewise provide assistance in development and implementation of soil conservation plans.

4.2.1.3 Alternative 3: Soils

4.2.1.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it incorporate noxious weed authority, utilizes the revised definitions for “genetic engineering” and “GE organism,” and risk analyses would be conducted via the PPRA and WRA. However, it expands the scope of regulation to encompass economic harms that could derive from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether it occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. This is a broader

[111] USDA-NRCS: http://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/alphabetical/camr/?cid=nrcs143_008440

interpretation of the definition of noxious weed than has typically been applied in the PPA's implementing regulations.

The WRA would include an economic effects analysis, and APHIS would distinguish those GE organisms that presented only potential economic impacts (MPNW) from those that presented plant pest and noxious weed risks. If, after conducting a PPRA and/or WRA, APHIS determines that a GE organism is unlikely to pose a plant pest or noxious weed risk in the traditional sense (biotic effects), then it would not be regulated under 7 CFR part 340. However, if APHIS concludes that a GE organism is unlikely to pose a plant pest or noxious weed risk (biotic) but presented potential economic harms from mere presence, then APHIS would regulate that product and require APHIS authorization for use. All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. Hence, under Alternative 3, potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.2.1.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative, the notification process would be eliminated. The importation and interstate movement of regulated plant pests and noxious weeds would be conducted solely under APHIS permit. The importation and interstate movements of GE organisms that presented potential economic harms from mere presence (MPNW) to non-GE producers would not require a permit for interstate movement or importation, although environmental release would. Consequently, relative to potential impacts of APHIS authorized interstate movements and importations on soils; Alternative 3 is the same as or similar to that described for the Preferred Alternative, as the scope of GE organisms that would be permitted for transport, permit requirements, and compliance, enforcement, and remediation actions, would be the same.

4.2.1.3.3 Authorization of Environmental Release

Under Alternative 3 authorized environmental releases, conducted solely under permit, would include GE plants and other organisms that were field tested, as well produced or otherwise utilized for commercial purposes and presented an MPNW risk. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have more stringent requirements than permits for commercial cultivation of MPNW, as MPNW would not present any biotic risk as plant pests or noxious weeds. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, as for plant pests and noxious weeds. Permits would require identification of critical habitat in the proposed area of environmental release for compliance with the ESA. Agricultural lands would comprise the dominant use of regulated and non-regulated GE organism, hence, potential impacts on soils would be limited to these and surrounding areas. MPNW would require a different kind of permit with conditions that aimed to facilitate coexistence and is more fully described in section 4.1.6.3.

All non-GE crop producers wishing to receive protections under APHIS regulations would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations to APHIS on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

One consideration relative to wide-scale permitting is that, if extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate the traditionally bred crop plant under a conventional or organic cropping system. If this were to occur, there could be seen an increase in use of conventional tillage practices in areas where GE herbicide resistant crops were abandoned and agricultural weeds were particularly problematic (see section 3.4.3). An increase in insecticide use could also occur where an insect resistant (IR) GE crop plant were abandoned for use of the non-IR crop plant in a conventional cropping system. Were this to occur, this Alternative could potentially lead to agronomic practices that were less conducive to conservation of crop field soils.

The likelihood of some farmers opting to produce a particular non-GE crop plant utilizing a conventional or organic cropping system, as opposed to the GE plant variety, and the degree to which any such shift in choice may occur, is indeterminate. Potential changes in agronomic practices associated with such a shift in the choice of crop cultivation could potentially adversely affect soils, relative to the particular agronomic practices utilized in production of the non-GE crop plant under a conventional cropping system.

Where a grower decided to cultivate a traditionally bred crop plant under a USDA certified organic cropping system, these cropping systems would be expected to have lesser adverse effects on soils and soil communities. Organic systems commonly use soil conservation practices, cover crops, composting, organic mulches, green manures (crops grown specifically for soil improvement), and reduced synthetic chemical inputs relative to conventional systems. Organic systems also strive to retain field biodiversity that can help suppress plant pests and disease. However, conventional tillage is still practiced in organic cropping systems, and heavy reliance on conventional tillage for pest, disease, and weed control could be detrimental to field soil biota. The USDA National Organic Program assists certified organic farmers with implementing tillage practices that maintains or improves the physical, chemical, and biological condition of the soil and that minimize soil erosion (NOP section §205.203).

Bearing these considerations in mind, when APHIS determined that a GE organism is not subject to 7 CFR part 340, that organism would still be subject to compliance with EPA, and other federal and state agency requirements. Use of pesticides on GE and non-GE crops would be regulated by the EPA, as under the No Action and Preferred Alternatives. Likewise, commercial cultivation of GE crop plants comprised of an EPA registered PIP, and use of GE microbial pesticides in commercial cropping systems, would be regulated by the EPA.

As with the No Action and Preferred Alternatives, growers producing crops on highly erodible land would be required to maintain and implement a soil conservation plan that substantially reduces soil loss, and is approved by the USDA National Resources Conservation Service (NRCS).[112] State agencies likewise would provide assistance in development and implementation of soil conservation plans.

4.2.1.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be the same as described for the Preferred Alternative, albeit extended to MPNW as described in section 4.6.1.3. The extended oversight of MPNW could lead to increased tillage and use of more environmentally harmful pesticides and these agronomic practices could have an adverse impact on soils relative to the No Action and Preferred Alternatives.

4.2.1.3.5 Determination of Regulatory Status

Determination of regulatory oversight would essentially be the same as described for the Preferred Alternative. The petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and/or WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined was not a plant pest, noxious weed, or MPNW could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements. For those GE crop plants APHIS determined were not subject to regulation under Alternative 3, the potential impacts on soils, both beneficial and adverse, would be essentially the same as that described for the Preferred Alternative.

4.2.2 Water Resources

4.2.2.1 No Action Alternative: Water Resources

4.2.2.1.1 Regulatory Scope

The potential direct effects of regulatory decisions on water resources are those associated with APHIS authorizations for the movement and field testing of regulated GE organisms. Impacts on water resources could potentially occur as a result of the unauthorized entry of regulated GE trait material into water bodies (namely GE trait gene products), or runoff of NPS pollutants (pesticides, fertilizers, soils) into water bodies as a result of the agronomic practices used in cultivation of regulated GE plants during field testing.

[112] USDA-NRCS: http://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/alphabetical/camr/?cid=nrcs143_008440

The potential impacts of pesticides and other NPS pollutants on water resources are regulated by the EPA, state, and local authorities. The PPA and 7 CFR part 340 regulations provide APHIS limited authority to enforce protection of water resources, unless those waters interfere or are associated with the introduction and/or dissemination of a plant pest or noxious weed within the United States.

Specific water quality issues related to the importation, interstate movement, or environmental release of GE organisms would be considered on a case-by-case basis as notifications and permit applications were received. Water quality issues related to petitions for determination of non-regulated status would be evaluated in NEPA analyses, as appropriate to the petition.

4.2.2.1.2 Authorization of Interstate Movement and Importation

Potential impacts to water resources relates to how present regulations provide for the secure shipment of GE organisms. APHIS has specific requirements for the shipping of GE organisms under notification or permit (USDA-APHIS 2011, USDA-APHIS 2012), to include specifications for the types of containers (§ 340.8(b)), and marking and identity requirements (§ 340.7). There have been few major noncompliance incidents in the transport of GE organisms under current regulations (USDA-APHIS 2016b); none have been noted to affect water quality or availability.

Spillage, improper labeling, and shipping of regulated GE seed or other material without APHIS authorization is possible. The unintentional mixing of seed prepared for shipment or misidentification of shipping containers could also theoretically occur, such as at plant breeder sites and seed production stations. Spillage, misidentification, and unintentional mixing of seed could result in the unintended release of GE trait material during transport or authorized field tests. These types of unintended introductions are unlikely to present a hazard to water resources unless the spilled organisms grow aggressively or produce proteins or metabolites that harm other organisms which is rarely the case.

While these types of unauthorized releases are considered, the incidence of human error and container failure is low. If such events occur, APHIS would respond pursuant to compliance, enforcement, and remediation measures provided in the PPA and current regulations. Entities involved in the importation and movement of GE organisms are expected to adhere to the current notification and permitting requirements, which are designed to prevent unintentional releases during importation or movement of GE organism. Such incidents, if they occurred, would be limited to the route of transport or authorized field site. If such an incident occurred, potential impacts to water resources near sites of unauthorized release would be evaluated on a case-by-case basis and remediation actions implemented by APHIS as necessary.

Based on the evidence of over 20 years of movement and importation of GE organisms, it is unlikely that APHIS authorized movement or importation of GE organisms under current regulations would present a significant risk to water resources. It is assumed that human error will occur, and there will occasionally be inadvertent releases during the process of shipping GE organisms. Such events are expected to be rare, localized, involving small

quantities of the GE seed, plant, or other material, and remediation measures implemented sufficient to prevent significant impacts on water resources.

4.2.2.1.3 Authorization of Environmental Release

Authorizations for environmental release of GE organisms are issued for field tests in various U.S. states and territories. To date, APHIS has issued more than 18,400 permits and notifications for field testing of GE organisms. Field tests are part of standard research and development practices, and pre-market evaluation of GE organisms.

Environmental releases authorized via permit or notification may be located near streams, rivers, lakes, or drainage ditches and other water bodies. APHIS requires notification and permit applicants to provide a preliminary critical habitat analysis, which is reviewed by APHIS and used in determining if APHIS will acknowledge the notification or approve the permit. Most field tests for GE plants will utilize pesticides and fertilizers. Consequently, potential impacts at a field site are related to the introduction of the GE trait material, pesticides, fertilizers, and sediments into a stream or other water bodies. GE trait material could enter water bodies through pollen flow, seed, or other GE plant material. Dispersal could occur by animals, humans, wind, or rain.

The presence of the GE trait gene and/or gene products in water bodies could potentially impact aquatic biota and present a concern to some stakeholders. For example laboratory studies have suggested sublethal effects of Bt corn detritus on some aquatic insects, however field results have not substantiated these effects on a landscape level (Chambers, Whiles, Rosi-Marshall et al. 2010). The type and rate of agronomic inputs, such as pesticides and fertilizers, are also a concern, as well as any other crop production techniques that differed from those typically used for cultivation of the non-GE plant. Pesticides must be registered with the EPA for use during field tests. There are three categories of pesticides the EPA reviews for registration, these are antimicrobials, biopesticides (e.g., PIPs), and conventional pesticides. Before a pesticide can be used during field testing it has to be approved by the EPA to ensure that is it not harmful to humans or the environment. The EPA has reviewed all currently registered pesticides, to include PIPs, and determined that they do not pose unreasonable risk to human health or the environment when used according to EPA requirements (US-EPA 2007a). Any unregistered pesticide would require EPA consultation and approval prior to use during field testing. In registering biopesticides such as PIPs, the EPA conducts risk assessments for freshwater, estuarine, and marine biota (US-EPA 2015e). Any future field tested PIP would be subject to EPA review and requirements, and EPA Experimental Use Permit (EUP), and all federal and state laws and regulations protecting the waters of the United States.

Because potential impacts on water resources are dependent on multiple variables, these impacts would require consideration individually for permit applications or notifications on a case-by-case basis. Where potential impacts are a potential concern, APHIS may decide that certain restrictions are necessary to prevent GE material derived from the plant or other organism from entering aquatic environments where unwanted exposures could occur. If, in advance of the field test, APHIS determined that the GE organism could have an impact on water resources, APHIS would consult with the EPA and may require specific monitoring, mitigation, and reporting activities as part of the permit conditions. APHIS would have the

flexibility to modify permit conditions as needed, and revoke a permit when it deemed necessary to do so.

Currently, GE crop plants are the most common type of GE organism field tested. Being identical to their conventionally bred counterpart other than the incorporated genetic material conferring the trait(s), GE plants require no more or less water than their conventional counterparts. It is reasonably foreseeable that GE plants will be engineered for improved water use efficiency or their ability to scavenge for water. Under the No Action Alternative, if there were requests for field testing of GE plants that might place a high demand on local surface or groundwater, these requests would be analyzed on a case-by-case basis to ensure that potential impacts related to water resources are minimized. State and local authorities may be consulted where there are concerns on potential impacts on use of surface and groundwater.

Because most field trials are small in acreage and transient in nature, any potential adverse impacts on water resources would be negligible. For example, APHIS consulted with the Forest Service on the impact to hydrology on various sites in the Southeast from the release of GE freeze-tolerant eucalyptus. One finding from this study was that impacts on hydrology would be negligible where the eucalyptus stands represented less than 20% of the canopy cover in a watershed .

There are current interests in developing GE drought and saline tolerant crops (as well as in conventionally bred plants). There have in fact been over a hundred requests for APHIS authorizations of permits or notifications for drought tolerance alone (ISB 2015). To the extent GE plants decrease demand for water during field testing, then the burden on scarce water resources could potentially be reduced in areas where these types of GE plants are cultivated/field tested and water is scarce. Similarly, water inputs could be diminished in cases where plants are engineered to be more efficient at acquiring water because these plants could more effectively compete with weeds for water.

Conducted according to current APHIS notification and permit requirements for confinement, the risk to water resources from field testing of GE organisms are considered minimal. Where potential adverse effects on aquatic species such as daphnia, and aquatic insects have been observed in response to exposure to Bt crop residues (Rosi-Marshall, Tank, Royer et al. 2007, Chambers, Whiles et al. 2010), there are no known adverse effects on aquatic ecosystems, or ecosystem dynamics, that have derived from the field testing of GE organisms. GE plants and other organisms bearing newly introduced traits, and that may be field tested in the future, would require review as to their potential effects on aquatic environments.

4.2.2.1.4 Compliance, enforcement, and remediation

During the course of movement or field testing of a GE organism, persons authorized under permit or notification are required to keep records and report to APHIS breaches of permit or notification requirements. APHIS conducts targeted and random inspections to confirm that permit conditions or notification performance standards are being met. If there is an incident of noncompliance APHIS may require remediation actions.

In some instances the remediation effort itself could potentially result in an impact on water resources, albeit it would be localized and ephemeral. For example, eradication of noncompliant GE plants may require use of an herbicide, which could potentially enter waterways and result in exposure of aquatic biota to the herbicide. Similarly, if a developer plants a regulated crop in an unauthorized location, the developer may be asked to till up or burn the field site in order to eradicate the unauthorized GE plant. Such tilling might result in soil loss and runoff, and alter water quality for a limited period of time. Due to the limited scope and geographic scale of field tests (e.g., average size of around 20 acres), these types of impacts would be transient in nature, and likely result in no lasting effects on ecosystem dynamics, water quality, or aquatic biota.

Compliance, enforcement, and remediation under current regulations has and is expected to provide for sufficient protection of water resources. However, the Preferred Alternative and Alternative 3 are broader in scope in terms of the range of GE organisms that may be regulated under 7 CFR part 340, and augments permitting and reporting requirements in such a way that could, in terms of regulatory framework, strengthen protections for water resources.

4.2.2.1.5 Determination of Regulatory Status

Under the No Action Alternative APHIS conducts a PPRA in response to petitions for determinations of non-regulated status. As part of the decision-making process regarding a GE organism's regulatory status APHIS conducts the relevant environmental analyses in accordance with NEPA to provide the Agency information on potential environmental impacts associated with the petition request. This would include potential effects to water resources and aquatic biota. If the PPRA concludes the GE organism is unlikely to pose a plant pest risk, and after conducting appropriate NEPA analyses and considering other relevant information, APHIS may approve petitions and issue a determination of non-regulated status for a GE organism.

The vast majority of GE organisms that have been determined not to be subject to 7 CFR part 340 have been crop plants. Many, but not all of these, are commercially produced in the United States. APHIS expects that the majority of future GE organisms it will be evaluating pursuant to 7 CFR part 340, will be GE crop plants developed for numerous purposes. APHIS expects GE trees and ornamental plants will also be evaluated, and to a lesser extent bacteria, fungi, nematodes, and similar organisms that may be plant pests.

GE plants developed for agricultural, forestry, pharmaceutical, industrial, or other purposes, and adopted for use in commerce, could have beneficial, adverse, or no effects on water resources. These would include irrigation; the consumptive uses of water; competing demands for water resources; and water quality through the inputs of sediments, nutrients, pesticides, or/and GE-trait material that could derive from cultivation of the GE plant.

As summarized in section 3.5.2, cultivation of GE crop plants, like all non-GE crop plants, can adversely affect water quality through the use of pesticides, fertilizers, and soil management practices, and associated run-off into adjacent water bodies. The use GE IR crops can help diminish such impacts through reductions in the quantity and type of insecticides used, and to some extent the use of GE HR crops can facilitate use of herbicides

that have lower toxicity. To the extent that GE crops reduce insecticide use, and employ herbicides with reduced toxicity, commensurate improvements in water quality would be expected. However, development of weed resistance to herbicides can increase herbicide use in areas where resistance in weeds develop (Owen 2011). Any increases in the volumes and varieties of herbicides used to manage resistant weeds could have potentially adverse effects on aquatic ecosystems. The use of pesticides, and their impacts on water quality, are regulated by the EPA under FIFRA.

Similarly, to the extent that GE crops facilitate use of conservation tillage practices, including no-till, commensurate improvements in water quality through reductions in soil, pesticide, and nutrient runoff would be expected. Conservation tillage practices have been increasingly adopted for production of GE HR crops, and under the No Action Alternative this trend would be expected to continue, or at least sustained. However, a reversion to more aggressive conventional tillage has occurred in areas where herbicide weed resistance has become a problem, for instance, in Southern cotton producing states. The use of tillage practice is heavily influenced by grower choice in the production of HR crops, the prevalence of agricultural weeds, and particular mix of herbicides used to manage weeds.

All agricultural production, GE and non-GE alike, can result in well understood impacts on water resources as summarized in subsection 3.5.2. The potential impacts of agricultural run-off on water resources will remain a pressing problem in the United States, a problem shared by both GE and non-GE crop production systems. The potential impacts of regulated GE organisms on water resources would be evaluated on a case-by-case basis in NEPA analyses, as needed, when APHIS receives petitions for non-regulated status such GE organisms.

4.2.2.2 Preferred Alternative: Water Resources

4.2.2.2.1 Regulatory Scope

The Preferred Alternative extends APHIS regulatory scope in ways that could potentially broaden protections for water resources. APHIS would include the noxious weed provisions of the PPA (7 U.S.C. §7701(7));[113] expand the range of organisms considered and potentially regulated using the terms and definitions for "genetically engineered" and "GE organism"; require all authorizations for import, interstate movement, or environmental release be conducted solely under permitting procedures; and strengthen its compliance and enforcement program by clarifying authorities and reporting requirements.

4.2.2.2.2 Authorization of Interstate Movement and Importation

Movement and importation of regulated GE organisms would be conducted only under APHIS permit, and APHIS would assign permit conditions to make it unlikely these activities would result in an unauthorized release. Rather than the current prescriptive requirements, APHIS would issue performance-based requirements for shipping of GE organisms and require they be handled in such a way that their identity is maintained and that they are securely imported or moved in such a way that there is no release into the

[113] The definition of a noxious weed includes "any plant or plant product that can directly or indirectly injure or cause damage to… public health." [7 U.S.C. 7702(10)].

environment.[114] Specifics regarding labeling and the methods of secure shipment would be included in the permit.

Under this Alternative APHIS regulation of interstate movement and importation could potentially be more protective of water resources than the No Action Alternative due to: (1) the broader scope of GE organisms that could be considered under 7 CFR part 340 regulations, and range of potential plant pest and noxious weed risks that could be regulated; (2) revisions to permitting/authorization procedure; and (3) strengthening of the compliance and enforcement program (discussed subsequently). This considered, as described for the No Action Alternative, APHIS authorized movements and importations of GE organisms generally present little risks to water resources. Consequently, the protection of water resources conferred under the Preferred Alternative would be marginal, relative to importation and movement of GE organisms.

4.2.2.2.3 Authorization of environmental release

Environmental releases/field tests of regulated organisms would be conducted solely under APHIS authorized permits with protective conditions prescribed as necessary. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk.

As with interstate movement and importation, the Preferred Alternative is considered more protective of water resources than No Action Alternative as a result of the broader range of GE organisms considered under regulations and potentially regulated, refining of permitting procedure, and augmenting of the compliance and enforcement program. These proposed revisions would likely strengthen prevention of the unauthorized release and potential dissemination of GE organisms during field testing.

While this Alternative could potentially provide more protections for water resources in terms of preventing entry of trait genetic material into aquatic environments, and oversight of broader array of GE trait genes and their products, it would not alter agronomic inputs or tillage practices used during field testing of GE plants, which could serve as potential sources of NPS pollutants in local waterways. That said, field tests are generally small in nature, around 20 acres on average, and inputs such as pesticides, fertilizers, and soil sediments, if they occurred, would be rather limited in quantity. Pesticides and other NPS pollutants are regulated by the EPA, as described previously in section 3.5.2.

4.2.2.2.4 Compliance, Enforcement, and Remediation

The Preferred Alternative proposes to strengthen the compliance and enforcement program by augmenting the approaches currently used and clarifying enforcement authority under the PPA. APHIS would require that the responsible person provide APHIS inspectors access to inspect any relevant premises, facility, location, storage area, waypoint, materials, equipment, means of conveyance, and other articles related to the importation, interstate

[114] APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation".

movement, and controlled outdoor uses of organisms regulated under 7 CFR part 340. While this requirement is functionally the same as current inspection requirements, it clarifies what locations and regulated organisms may be subject to inspection as well as reporting requirements.

APHIS would also revise requirements for the establishment and maintenance of records, and provision of APHIS inspectors with all required records upon request. For instance, there would be specific provisions for keeping and providing detailed maps, and the identity and contact information for responsible parties. APHIS proposes to require that certain records would have to be retained for periods of up to 10 years after completion of obligations required under permit or exemption. Record keeping requirements would facilitate compliance, and administration of remedial measures and penalties in the event of an unauthorized release of a regulated organism.

The consequences of failure to comply with the regulations would include denial of future permits; revocation of current permits; destruction, treatment, and removal of regulated organisms; issuance of penalties; and a means to settle alleged civil violations prior to the issuance of an administrative complaint. A responsible person could be held liable for the violation of any APHIS requirement by any agent working for the responsible person (including persons contracted to conduct or carry out the controlled outdoor use on their own or on leased properties).

Considering the proposed revisions, and extended oversight of GE organisms that may present a plant pest or noxious weed risk, this Alternative is expected to strengthen prevention of the unauthorized release and dissemination of a regulated organisms during field testing, and the remedial measures available to APHIS in the event an unauthorized release occurs. Consequently, the Preferred Alternative could provide better protection of water resources relative to the No Action Alternative.

4.2.2.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct a plant pest risk assessment (PPRA) and/or a weed risk assessment (WRA) to inform the determination of whether the GE organism is subject to regulation and required a permit under 7 CFR part 340. As part of this evaluation APHIS would conduct an EA or EIS as required, on a case-by-case basis, which would evaluate potential impacts to water resources. If a GE organism were determined by APHIS not subject to regulation, and it were later found to present potential plant pest or noxious weed risks, or cause other agricultural harms, APHIS would have the authority revise its determination and regulate that GE product under 7 CFR part 340.

The explicit inclusion of noxious weed authority, expanded scope of organisms evaluated under regulations using the revised terms and definitions, and conducting of an upfront PPRA and/or WRA, and NEPA as required, provides a regulatory review framework that would make it unlikely that any GE organisms determined not subject to regulation would have an adverse impact on water resources.

As described, APHIS has no authority over the agronomic inputs or tillage practices that may be used in the production of unregulated GE crops, which are the primary sources of NPS pollutants in commercial crop production. The choice of weed management and tillage practices, and agronomic inputs, and potential beneficial or adverse effects of these practices would be no different than those under the No Action Alternative. The use of conservation tillage in production of GE HR crops would be expected to continue as under the No Action Alternative, as would the management of development of herbicide resistant weeds. GE HR crops can reduce, have no effect, or result in increased herbicide use. GE insect resistant crops generally result in reductions of insecticide use. Agricultural NPS pollutants and their potential impacts on water resources would continue to be monitored and regulated by the EPA, states, and local authorities.

Considering the proposed revisions, this Alternative could potentially be more protective of water resources than the No Action Alternative given that prior to determination that a GE organism is not subject to regulation, and introduction of a GE plant or other organism into commerce, APHIS would likely evaluate a broader range of GE organisms.

4.2.2.3 Alternative 3: Water Resources

4.2.2.3.1 Regulatory Scope

Under Alternative 3, APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in many respects, although, under this alternative, APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms that could derive from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. The only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.2.2.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative the importation and interstate movement of regulated organisms that presented a plant pest or noxious weed risk would be conducted solely under APHIS permit. The importation and interstate movements of regulated organisms that presented potential economic harms to non-GE producers from mere presence would not require a permit for importation or interstate movement, although their environmental release would.

The potential impacts to water resources as a result of interstate movement and importation under this Alternative would be similar to or the same as the Preferred Alternative because the scope of GE organisms evaluated and potentially regulated as plant pests and noxious weeds would be the same (save for economic risks), as well as permitting and technical review criteria. As with the Preferred Alternative, Alternative 3 would potentially provide better protections for water resources than the No Action Alternative and by virtue of the

expanded scope of GE organisms considered under regulations, and revisions to permitting and compliance programs (described following). That said, interstate movement and importation generally present little risk to water resources, and any benefits of this or the Preferred Alternative over the No Action Alternative would be marginal.

4.2.2.3.3 Authorization of Environmental Release

Environmental release of regulated organisms would be conducted solely under permit with prescribed conditions as required. Permits for field testing of regulated organisms that present risks as plant pests, noxious weeds, or were developed for pharmaceutical, industrial, or phytoremediation purposes, would have more stringent permitting requirements than those that presented only an economic risk.

All mere presence noxious weeds (MPNW) regulated by APHIS and desired for use in commerce would require a permit for cultivation. Plant biotechnology developers and growers of regulated organisms would be required to track and record the location and acreage of the MPNW being grown and implement a GE plant volunteer management program. In order to identify the location and proximity of non-GE crops to GE crops, all non-GE crop producers wishing to receive protections under APHIS regulations would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning system on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

While the number of regulated organisms would significantly increase under Alternative 3 due to inclusion of MPNW, and consequently, the number of APHIS permits required for environmental release, this would not necessarily translate to better protection of water resources as compared to the Preferred Alternative. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting of field testing, would largely be the same. The only difference would lay in regulation and permitting of MPNW, which would increase the volume of reviews and environmental release permits, but not the scope of environmental risks considered and regulated by APHIS. Alternatively, and more likely, the greatly increased regulatory burden will stifle innovation and reduce the overall number of permitted field trials.

In these respects, Alternative 3 would differ little from the Preferred Alternative in regards to protections for water resources. It would not significantly increase the type or quantity of GE organisms that were field tested and more likely would result in a decrease. Similarly, the environmental risks considered in authorizing permit requests, and the protective conditions that may be applied to the permit would be similar. Alternative 3, as the Preferred Alternative, might provide better protection than the No Action Alternative as a result of oversight of a broader array of GE organisms and traits.

Any potential impacts on water resources as result of environmental release of regulated organisms would be limited to the particular trait gene and gene product expressed by the organism. The potential environmental impacts of the trait genes and their products would be assessed on a case-by-case basis as part of the PPRA and WRA, and environmental release

permit issued by APHIS, with conditions prescribed to isolate cultivation to specific sites and preclude propagation beyond authorized areas of cultivation. If the trait gene and its product are a PIP, that PIP would be regulated by the EPA. As described, the most significant impacts to water resources derive from pesticides, fertilizers, and soil sediments in agricultural runoff. These types of NPS pollutants are regulated by the EPA, states, and local authorities. APHIS may take into consideration potential impacts to water resources when issuing permits for environmental releases, consult with EPA where such risks were present, and prescribe permit conditions as necessary to reduce the likelihood that these activities would result in adverse impacts on aquatic environments.

4.2.2.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities relative to water resources would be the same as described for the Preferred Alternative. Both this and the Preferred Alternative would strengthen APHIS' compliance program, and consequently could provide better protection of water resources than the No Action Alternative.

4.2.2.3.5 Determination of Regulatory Status

As with the Preferred Alternative, the petition process would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE products that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production, and those that would be introduced for commercial use in the future. As part of its PPRA and/or WRA, and NEPA analysis where applicable, potential impacts on water resources would be considered on a case-by-case basis relative to the specific GE organism being evaluated.

As described, under the PPA, APHIS has little authority over pesticide and fertilizer inputs, or tillage practices used in the production of unregulated GE crops; tillage and agronomic inputs being the primary sources of NPS pollutants from crop production. NPS pollutants and their potential impacts of on water resources would be regulated by the EPA, states, and local authorities.

As described under the Preferred Alternative, the commercial production of certain GE crops can affect the quantity and type of insecticides, fungicides, and herbicides used, as well as tillage practices. GE insect resistant crops can reduce insecticide use. GE herbicide resistant crops are associated with conservation tillage (Fernandez-Cornejo, Hallahan et al. 2012), and can reduce, have no effect, or result in increased herbicide use. Development of weed resistance to herbicides may increase herbicide use in some instances, and such increases in the volumes and varieties of herbicides used could have potentially adverse effects on aquatic ecosystems. To the extent that GE crop varieties facilitate use of conservation tillage practices, and may reduce insecticide use, commensurate improvements in water quality would be expected.

Bearing these factors in mind, one consideration is that, although the provisions of this Alternative may be more protective of water resources than the No Action Alternative, the

outcome of implementation could also, inadvertently, increase risks to water resources if the extensive permitting, monitoring, and reporting requirements prove to be burdensome for growers of GE crops, and some decide to return to conventional non-GE crops. If this were to occur, some increase in insecticide use could follow where IR GE crops were abandoned for their conventional counterparts. Where GE IR crops were replaced with conventional crops requiring chemical applications to combat crop damaging insects, there could be an increase in inputs of non-PIP insecticides to aquatic ecosystems. Similarly, were some HR GE crops to be abandoned, a decrease in conservation tillage is expected. Such a decrease is expected to be accompanied by an increase in soil erosion and sediment accumulation in streams. Were this to occur, this Alternative could potentially present increased risks to water resources relative to the other Alternatives. The likelihood of this occurring, or the degree to which it may occur, is indeterminate.

4.2.3 Air Quality

4.2.3.1 No Action: Air Quality

4.2.3.1.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of GE organisms that are considered plant pests under permit or notification (USDA-APHIS 2011, USDA-APHIS 2012). These activities may be authorized in any of the U.S. states, commonwealth, or territories.

The EPA establishes National Ambient Air Quality Standards (NAAQSs) pursuant to the Clean Air Act (CAA) that are intended to protect public health and the environment. NAAQS are established for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and particulate matter (PM). In addition to criteria pollutants, the EPA regulates hazardous air pollutants (HAPs) such as ammonia and hydrogen sulfide. States enforce NAAQS s through creation of state implementation plans (SIPs), which are designed to achieve EPA established NAAQS.

4.2.3.1.2 Authorization of Interstate Movement and Importation

APHIS authorized importations and interstate movements have negligible adverse effects on air quality. GE organisms are securely transported in sealed containers between defined locations via trucks, vans, ships, airplanes, and similar transport vehicles. During 2015 APHIS issued permits or acknowledged notifications for 744 importations and 746 interstate movements. Of the imports, 617 were requested by academic and private research institutions for import of Drosophila (fruit fly).[115] For both import and interstate movements, around 1,025 authorizations were requested by universities or public research institutions (~ 69%). Hence, the majority of imports and movements are for basic and applied research purposes. The number of authorized permits and notifications in 2015 (1490) is exemplary of the number of annual shipments that APHIS typically authorizes on an annual basis. To the

[115] Drosophila fruit flies are widely used in genetics and developmental biology research. In most instances, they do not contain genetic sequences from plant pests and are not listed as organisms that are or contain plant pests in current § 340.2. Therefore, they generally do not require permits for their movement under 7 CFR part 340. However, shipments labeled as "fruit flies," whether created through biotechnology or not, sometimes raise agricultural and environmental concerns because this common name also refers to regulated plant pests like the Mediterranean and oriental fruit flies.

extent authorized shipments utilize nonrenewable fossil fuels, there will be emissions of NAAQs air pollutants.

4.2.3.1.3 Authorization of Environmental Release

Field testing is part of standard research and development practices and pre-market evaluation of both GE and conventionally bred organisms. Field releases authorized under current APHIS permit or notification procedure, which have been conducted by industry, academia, and government, have taken place throughout the United States and its territories. To date, APHIS has issued more than 18,400 permits and notifications for field testing of GE organisms; the vast majority of these GE plants.

Authorized field trials can adversely affect air quality through the emissions of NAAQs pollutants, greenhouse gases, and pesticides. Emission sources include particulate matter (PM) from agricultural burning and tillage; emissions derived from fossil fuel burning equipment used in tillage, pesticide application, and harvest (CO_2, NOx, SOx); and soil nitrous oxide (N_2O) emissions from the use of fertilizers (Aneja, Schlesinger et al. 2009, US-EPA 2013a). Drift and volatilization of pesticides from soil and plant surfaces can adversely affect air quality via introduction of various chemicals (active and inert ingredients) into the atmosphere.

In 2015 APHIS issued 37 permits and acknowledged 447 notifications for environmental releases in 39 states, Puerto Rico, and the U.S. Virgin islands.[116] Authorized field trials for GE plants have ranged in size from .001 acres up to 100,000 acres. The median size of an approved field trial is approximately 5 acres, and average size about 20 acres. Collectively, authorized field trials comprise around 400,000 acres per year.

Pesticide volatilization and drift would adversely affect air quality in the immediate area of the field trial, as would emissions of NAAQS pollutants. Conservation tillage can reduce N_2O and CO, NOx, SOx, and PM emissions, although any reduction would provide marginal benefits to air quality due to the limited annual acreage employed for field trials (e.g., around 400,000 acres/year). Any emissions of NAAQS pollutants would contribute to regional air quality burdens, although again, due to the scale of field trials, would not be expected to significantly challenge regional NAAQS, or SIPs designed to achieve NAAQS.

In general, field trials of regulated GE organisms will result in emissions of NAAQS pollutants, and volatilization and drift of pesticides, as would occur with any commercial cropping system; GE or non-GE. For field trials, emissions would be rather limited, commensurate with the scale of the trial, which range from .001 to 100,000 acres, and average around 20 acres.

[116] Permit and notification request information for import, movement, and field release is publically available on the USDA funded Information Systems for Biotechnology website ISB (2015). *Information Systems for Biotechnology (ISB)*. USDA Cooperative State Research, Education, and Extension Service (CSREES), USDA Agricultural Research Service (ARS), and Agricultural Experiment Station at Virginia Tech. Retrieved December 19, 2016, from http://www.isb.vt.edu/Default.aspx..

4.2.3.1.4 Compliance, Enforcement, and Remediation

Under current regulations APHIS inspectors and compliance specialists perform targeted and random inspections to evaluate potential noncompliance incidents. All importations, movements, and environmental releases of regulated articles are subject to inspection by federal and/or state inspectors. APHIS evaluates field sites, facilities, equipment, records of developers, and potential incidents reported by permittees. APHIS works with state and other federal agencies, including the FDA, EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations. Enforcement of compliance with air emissions standards pursuant to regional NAAQS and SIPs would be under the authority of the EPA and state agencies.

In 2015, APHIS conducted 688 inspections. APHIS compliance inspection and enforcement activities would result in emissions of NAAQS via transport of inspectors to and from the sites of inspection. Where APHIS required remediation of a noncompliance incidence, and remediation required application of pesticide or tillage, there would be the potential for pesticide drift and volatilization, and emissions of NAAQS pollutants from tillage and similar activities involving internal combustion engines burning fossil fuels. As described for field trials, these actions are generally limited in scale (e.g., a few to several hundred acres), and would not significantly challenge SIPs or EPA NAAQS.

4.2.3.1.5 Determination of Regulatory Status

When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance with EPA, and other federal and state agency requirements. The vast majority of non-regulated GE organism are GE crop plants utilized for commercial agriculture. As described in section 3.5.3, commercial crop production can result in emission of air pollutants that can adversely affect the environment and human health, and challenge regional NAAQS.[117] Agricultural emission sources include smoke from agricultural burning (PM); soil particulates from tillage (PM); fossil fuel emissions from equipment used for tilling and harvest (CO, NOx, SOx, Pb); and drift and volatilization of pesticides.

APHIS regulations and determinations of regulatory status have no direct effects on air quality, although when APHIS has made a determination that a GE organism is not subject to regulation, GE organisms, namely crop plants, can be commercially cultivated at scales that adversely impact local and regional air quality. This is a fundamental tradeoff between provision of human and animal food, and fiber at scales sufficient to supply domestic demand, as well as international demand, and the inherent effects of crop production on air quality at commercial scales. The potential impacts on air quality are the same for GE and non-GE cropping systems (NAAQS pollutants, pesticide drift and volatilization), although there can be subtle differences in the overall emissions of certain NAAQS pollutants and pesticides, relative to the crop management practices employed by the grower.

Given the well-recognized emission sources associated with commercial crop production, the EPA and USDA Natural Resources Conservation Service (NRCS) have developed guidance to assist growers in implementing conservation measures that can reduce air emissions

[117] See EPA - Agricultural and Air Quality: https://www3.epa.gov/airquality/agriculture/

(USDA-EPA 2012). This guidance provides regional, state, and local regulatory agencies technical tools and information on how to manage agricultural air emissions using USDA approved measures, and satisfy SIP requirements. Specifically, these systems and activities aim to implement EPA recommended reasonably available control measures (RACM) and best available control measures (BACM) in areas that are not achieving NAAQS and SIP standards.

Tactics that can be used to minimize emissions in crop production include conservation tillage; cover crop and residue management; wind breaks; burn management; manure management; integrated pest management; nutrient management; chemigation and fertigation (inclusion of pesticides and fertilizers in irrigation systems); and conservation irrigation (USDA-NRCS 2006b, USDA-NRCS 2006a).

The EPA's Office of Pesticide Programs (OPP), which regulates the use of pesticides, has introduced initiatives to help pesticide applicators minimize off-target drift. The EPA's voluntary Drift Reduction Technology (DRT) Program was developed to encourage the manufacture, marketing, and use of spray technologies that reduce pesticide drift. EPA is also working with pesticide manufacturers through the registration and registration review programs on improvements to pesticide label instructions to reduce drift (e.g., see (US-EPA 2015g). In October of 2012 the EPA and USDA published guidance that further provides options for improving air quality on agricultural lands (USDA-NRCS 2012a). USDA and EPA recommended management practices are available to all growers, whether producing a GE or non-GE crop.

GE cropping systems can reduce or increase air emissions relative to the crop management practices employed by growers. To the extent GE HR crops facilitate use of conservation tillage practices there would be a commensurate reduction in NAAQS such as CO, NOx, SOx, and PM. Conservation tillage utilizes fewer passes over the field with a concomitant reduction in NAAQS emissions. Trends in adoption of conservation tillage practices would likely continue upward where there were adoption of HR crop varieties. Where there is the use of insect resistant GE crop varieties, there will be the increased potential for a reduction in insecticide use, and consequently, reductions in the introduction of insecticides into the air via drift and volatilization. This would likewise apply to disease resistant GE plants that facilitated reductions in fungicide use. GE crops engineered to use nitrogen more efficiently can potentially reduce NOx emission.

Where beneficial effects on air quality can derive from cultivation of certain GE crops, adverse effects can also occur. To the extent there is an increase in herbicide resistant weeds associated with cultivation of GE crops, and commensurate increase in use of herbicides, there would be an increase in drift and volatilization of these herbicides. Similarly, conventional tillage is often applied to combat resistant weed populations, and where practiced, would increase soil borne PM and vehicular NAAQS emissions.

Potential impacts to air quality associated with cultivation of non-regulated GE crop plants are not expected to be significantly affected by regulatory decisions made for GE organisms subject to 7 CFR part 340. Air quality would continue to be affected by GE and non-GE

cropping systems, along current trends, as described above, relative to the agronomic practices utilized in commercial crop production.

4.2.3.2 Preferred Alternative: Air Quality

4.2.3.2.1 Regulatory Scope

The Preferred Alternative would incorporate the noxious weed authority provided APHIS in the PPA; expand the range of organisms considered and potentially regulated using the revised definitions for "genetic engineering" and "GE organism"; remove the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures; and strengthen the compliance and enforcement program by clarifying APHIS authorities under the PPA and augmenting current approaches used to prevent or remediate potential risks to plant health. The EPA and states would continue to regulate air quality via NAAQS and SIPs, respectively.

4.2.3.2.2 Authorization of Interstate Movement and Importation

Under the Preferred Alternative APHIS would regulate GE organism only when the DNA sequence from the donor organism is sufficient to produce a gene product that is expected to adversely affect plant health. APHIS would no longer regulate an organism solely because the vector or other agent used in development of the GE organism was a plant pest. APHIS would regulate and require permits when it determines that the GE organism-trait combination causes it to pose a risk as a plant pest or noxious weed, as determined via a PPRA or WRA, or is a GE organism that has otherwise been determined by APHIS to pose a plant pest or noxious weed risk. This is a more efficient approach relative to procedure under current regulations, which is to regulate first, and determine risk later. Consequently, as a result of institution of a more efficient risk-based regulatory review process, it is expected that the total number of GE organisms regulated under the Preferred Alternative would likely decline, as the list of regulated organisms would be limited to those organisms that pose a plant pest or noxious weed risk. Hence, there would be a reduction in authorized movements and imports as fewer GE organisms would be subject to movement restrictions under 7 CFR part 340. However, overall, considering importations and movements of both regulated and non-regulated GE organisms, there could be a modest increase in interstate movement and importation as more GE organisms are developed for commercial purposes. Hence, if there were an increase in these activities, there would be an increase in NAAQS emissions as a result the fossil fuels used in transport of the GE organisms.

As described for the No Action Alternative; in 2015, APHIS issued permits or acknowledged notifications for 744 importations and 746 interstate movements, which is exemplary of the number of annual shipments that APHIS typically authorizes. APHIS anticipates regulating fewer GE organisms under the Preferred Alternative. Hence, air emissions as a result of permitted interstate movements and importations are expected to decline.

4.2.3.2.3 Authorization of Environmental Release

As with importations and interstate movement, the total annual acreage for APHIS authorized field releases, or the permitted field testing of regulated GE organisms, would likely decline as APHIS expects that fewer GE organisms would require permits under the

Preferred Alternative. However, considering both regulated and non-regulated GE organisms, overall annual acreage utilized for field testing of GE organisms would remain the same, or there may be an increase in field trials. An increase if field testing, this including both regulated and non-regulated GE organisms, could occur due to the fact that regulations would pose no undue burdens on innovation in the agricultural biotechnology sector, and more GE organisms may be developed and field tested for commercial purposes (e.g., insect and disease-resistant plants; plants developed for pharmaceutical, industrial, and phytoremediation purposes; microbial pesticides). Hence, developers would continue to field test non-regulated GE organisms, without APHIS oversight, and the sum total of acreage utilized for field trials for both regulated and non-regulated GE organisms could increase. It should be noted that the number of field trials of conventional organisms is likely to decrease as we assume that the amount of field testing remains relatively constant but the proportion of organisms that are field tested are increasingly GE. Where there were an increase in field testing of GE organisms, there would be an increase in NAAQS emissions but correspondingly, there would be a decrease in NAAQS emissions from fewer non GE field tests so the overall effect would be no net change.

Total annual acreage for field testing of GE organisms would likely increase along current trends, perhaps ranging around 400,000 to 500,000 acres on an annual basis This is a crude estimate, and actual acreage would be relative the rate of innovation and development in the plant biotechnology sector. For those GE organisms that APHIS determines are not likely to pose plant pest or noxious weed risks, and therefore not subject to regulation, those GE organism may be field tested in any U.S. state, commonwealth, or territory, subject to EPA, state, and county or local requirements.

Considering the above factors, under the Preferred Alternative, potential effects on air quality as a result of field testing of GE organism would be the same/similar as that described for the No Action Alternative.

4.2.3.2.4 Compliance, Enforcement, and Remediation

Under the Preferred Alternative APHIS would strengthen its compliance and enforcement program by augmenting the approaches currently used and clarifying its enforcement authority under the PPA. APHIS would require that the responsible person provide APHIS inspectors access to all relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other aspects related to the importation, interstate movement, and environmental release of organisms regulated under 7 CFR part 340. Enforcement of compliance with air emissions standards pursuant to regional NAAQS and state SIPS would be under the authority of the EPA and state agencies. The EPA and USDA, in cooperation with state agencies would continue to provide guidance to assist growers in complying with CAA regulations, as described under the No Action Alternative (USDA-EPA 2012).

As with the No Action Alternative, APHIS compliance inspection and enforcement activities would result in emissions of NAAQS via transport of inspectors to and from the sites of inspection. Where APHIS required remediation of a noncompliance incidence, and remediation required application of pesticide or tillage, there would be the potential for pesticide drift and volatilization, and PM and NAAQS emissions from these activities. These

types of remediation actions are generally limited in scale (e.g., a few to several hundred acres), and would not significantly challenge EPA NAAQS and SIPs.

4.2.3.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct plant pest risk assessments (PPRA) and/or a weed risk assessments (WRA) to inform the determination of whether a GE organism was subject to 7 CFR part 340 and required permitting. GE organisms would be listed on a regulatory status register on APHIS' website as regulated or not regulated. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk. If APHIS determined a GE organism was not subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340 regulation.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined unlikely to pose a plant pest or noxious weed risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

In regard to the acreage used for cultivation of non-regulated GE crops, which determines the magnitude of emissions, the Preferred Alternative would differ little from the No Action Alternative. As described for environmental releases, it is expected that the total number of GE organisms regulated under the Preferred Alternative would likely decline; that the list of regulated organisms would be limited to those organisms that posed a plant pest or noxious weed risk. This in turn would result in an increase in the rate of availability of GE organism for commercial uses, relative to EPA requirements, and voluntary FDA consultation, as applicable. If APHIS' process in determining the regulatory status of GE organisms is more efficient, and the rate of determinations of non-regulated status increases, this would not affect the areas and acreage of lands used for cultivation of commercial crops or forestry; no appreciable increase or decrease would be expected. Acreage used for commercial agriculture and tree plantations is determined by market demand for human and animal food, fiber, and wood products, and the areas of cultivation determined (apart from climate) by various federal and state laws and regulations, as well as local requirements (e.g., zoning, local ordnance). Certain GE crop plants may supplant conventionally bred crop plants in some areas where the grower found benefits from cultivation of the GE plant variety. This, however, would not significantly affect the areas or total acreage utilized for commercial crop production. The areas and total acreage used for commercial crop production would increase or decrease respondent to market demand, and relative to regulatory reviews, evaluations, and approvals by the EPA and APHIS, and FDA consultations, as appropriate.

Hence, the Preferred Alternative would differ little from the No Action Alternative in regard to the relationship between commercial crop production, and potential impacts on air quality. Air quality would continue to be affected by GE and non-GE cropping systems, along current

trends, relative to the agronomic practices utilized in commercial crop production. The potential beneficial and adverse effects on air quality that may derive from of cultivation of GE crops, specifically, would be the same as that described under the No Action Alternative.

The EPA and USDA, in cooperation with state agencies would continue to provide guidance to assist growers in complying with CAA regulations, as described under the No Action Alternative (USDA-EPA 2012). The USDA and EPA recommended management practices are available to all growers, whether producing a GE or non-GE crop. The EPA would continue to provide the Drift Reduction Technology (DRT) Program, which was developed to encourage the manufacture, marketing, and use of spray technologies that can reduce pesticide drift (e.g., see (US-EPA 2015g).

4.2.3.3 Alternative 3: Air Quality

4.2.3.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it incorporates noxious weed authority into 7 CFR part 340, utilizes the revised definitions for "genetic engineering" and "GE organism", and risk analyses would be conducted via the PPRA and WRA. However, it expands the scope of regulation to encompass potential economic impacts that can derive from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. Under this Alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms that could derive from the impacts of a GE crop on a non-GE crop (e.g., unintended presence as a result of pollen flow, volunteer GE plants). The WRA would include an economic effects analysis, and APHIS would distinguish those GE organisms that presented only potential economic impacts from those that presented plant pest and noxious weed risks.

If, after conducting a PPRA and/or WRA, APHIS determines that a GE organism is unlikely to pose a plant pest or noxious weed risk in the traditional sense (biotic effects), then it would not be regulated under 7 CFR part 340. However, if APHIS concludes that a GE organism is unlikely to pose a plant pest or noxious weed risk (biotic) but presented potential economic harms, then APHIS would regulate that product and require APHIS permitting for use. For the purposes of this dPEIS those with market impacts are termed mere presence noxious weeds (MPNW). All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. Hence, under Alternative 3 potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown. The EPA and states would continue to regulate air quality via NAAQS requirements (40 CFR part 50) and SIPs, respectively.

4.2.3.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative the notification process would be eliminated. The importation and interstate movement of regulated plant pests and noxious weeds would be conducted solely under APHIS permit. The importation and interstate movements of GE organisms that presented potential economic harms (MPNW) to non-GE crop producers would not require a permit for interstate movement or importation, although environmental release would. Consequently, relative to potential impacts of APHIS authorized interstate movements and importations on air quality; Alternative 3 is the same as or similar to that described for the Preferred Alternative, as the scope of GE organisms that would be permitted for transport, and permit requirements, would be the same.

4.2.3.3.3 Authorization of Environmental Release

Under Alternative 3 APHIS authorized environmental releases would include GE plants and other organisms that were field tested, and cultivated or otherwise used for commercial purposes. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have more stringent requirements than permits for cultivation of MPNW, as MPNW would not present a biotic risk as a plant pest or noxious weed. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, save for inclusion of MPNW.

While the number of regulated organisms would significantly increase under Alternative 3 due to inclusion of MPNW, and consequently, the number of APHIS permits required for environmental release (permitted planting), this would have little impact on the area or acreage utilized for agriculture or forestry – which is a proxy for the magnitude of potential air emissions.

All non-GE crop producers that preferred to receive protection conferred under the Preferred Alternative would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning map. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

One consideration relative to wide-scale permitting is that, where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of biotechnology crops may opt to cultivate conventional non-GE crops, or organic crops. If this were to occur, there could be seen an increase in use of conventional tillage practices in areas where conventional crops were chosen for cultivation in lieu of herbicide resistant biotechnology crops, and agricultural weeds were particularly problematic (see section 3.4.3). An increase in insecticide use could also occur where an insecticide-resistant (IR) biotechnology crop plant were abandoned for use of the non-IR crop plant in a conventional cropping system. Were this to occur, this Alternative could potentially result in an increase in insecticide drift and volatilization, and NAAQS emissions from equipment used in application of insecticides. The likelihood of some farmers opting to produce a particular non-GE plant utilizing a conventional or organic cropping system, as opposed to the GE plant variety as a result of APHIS regulation under Alternative 3, and the degree to

which this may occur, is indeterminate. Hence, potential changes in agronomic practices associated with such a shift in the choice of crop cultivation could adversely affect air emissions, relative to the magnitude and variety of current emissions.

Bearing these considerations in mind; as with the all the Alternatives considered, the EPA and USDA, in cooperation with state agencies would continue to provide guidance to assist growers in complying with CAA regulations (USDA-EPA 2012). The USDA and EPA recommended emissions reduction practices are available to all growers, whether producing a GE or non-GE crop. The EPA would continue to provide the Drift Reduction Technology (DRT) Program, which was developed to encourage the manufacture, marketing, and use of spray technologies that can reduce pesticide drift (e.g., see (US-EPA 2015g).

4.2.3.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative, however, these activities would be extended to MPNW, and would incur expanded responsibilities for developers, growers of GE crops, growers of non-GE crops, and APHIS. Enforcement of compliance with air emissions standards pursuant to regional NAAQS and SIPs would be under the authority of the EPA and state agencies. The EPA and USDA, in cooperation with state agencies would continue to provide guidance to assist growers in complying with CAA regulations (USDA-EPA 2012), as would be the case for all the Alternatives.

APHIS compliance inspection and enforcement activities would increase under Alternative 3, as a result of APHIS regulation of the majority of GE crops in commercial production, which would be in addition to APHIS regulation of GE organisms that would not be permitted for commercial uses. Hence, there would be an increase in emission of NAAQS pollutants from APHIS inspection and enforcement activities as a result of increased transport of APHIS inspectors, as well other federal and state officials, to and from sites of inspection and remediation. Where APHIS required remediation of a noncompliance incidence, and remediation required application of pesticide or tillage, there would be the potential for pesticide drift and volatilization, and NAAQS pollutant emissions from these activities.

4.2.3.3.5 Determination of Regulatory Status

Determination of regulatory oversight would be essentially the same as described for the Preferred Alternative. The petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and/or WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined was not a plant pest, noxious weed, or MPNW could be grown or otherwise utilized anywhere in

the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements (e.g., prescribed burning permits).

If the extensive permitting, monitoring, and reporting requirements prove to be burdensome for growers of GE crops, and some decide to produce non-GE crops, some increase in insecticide use could follow where GE IR crops were abandoned for their conventional counterparts. Where GE IR crops were replaced with conventional crops requiring chemical applications to combat crop damaging insects, there could be an increase in use of insecticides, and associated aerosolization and spray drift. Similarly, were some GE HR crops to be abandoned, a decrease in conservation tillage could follow, which would be accompanied by increase emissions of NAAQS pollutants and GHGs from agricultural systems. The likelihood of this occurring, or the degree to which it may occur, is indeterminate.

4.3 Biological Environment

4.3.1 Soil Biota

4.3.1.1 No Action Alternative: Soil Biota

4.3.1.1.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of regulated GE organisms that are, or are believed to be, plant pests under permit or notification procedure (USDA-APHIS 2011, USDA-APHIS 2012). Under current regulations APHIS considers the likelihood that a GE organism presents a plant pest risk, which is defined at 7 CFR part 340 as organisms that can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants. The primary purpose of 7 CFR part 340 regulations, promulgating the PPA, is to prevent the dissemination and establishment of organisms that can damage agricultural plants, and the production of food and fiber in the United States.

4.3.1.1.2 Authorization of Interstate Movement and Importation

APHIS authorized movements and importations of GE organisms must meet the notification performance standards and permit conditions prescribed that ensure confinement of the GE organism during shipping or movement (USDA-APHIS 2011, USDA-APHIS 2012). When requests for movement are received APHIS provides the necessary information to states for review and approval of import of a GE organism into the state. The majority of imports and movements are for basic and applied research purposes. For instance, during 2015, APHIS issued permits or acknowledged notifications for 744 importations and 746 interstate movements. Of the imports, 617 were requested by academic and private research institutions for import of *Drosophila* (fruit fly). For both import and interstate movements, around 1,025 authorizations were requested by universities or public research institutions (~ 69%).

Under 7 CFR part 340 APHIS regulates the movement and importation of any of the following GE organisms that are, or are believed to be, plant pests: insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied

with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

In addition to 7 CFR part 340 requirements, GE organisms imported into the United States are subject to the APHIS Plant Protection and Quarantine (PPQ) regulations at 7 CFR § 319.37 (covering importation of plants and seeds for planting) and 7 CFR § 319.56 (covering fruits and vegetables imported for non-propagative use). Hence, GE organisms would have to be authorized for importation under both part 340 and part 319 regulations.

When entities authorized to move or import GE organisms adhere to current notification and permit requirements the potential for inadvertent release of GE organisms is limited to instances of container failure or human error. Major incidents of noncompliance have involved shipment without proper identification. Accidental releases, such as spillage of seed or GE microorganisms are conceptually possible, and if such occurred would result in remediation actions at the site of release. APHIS authorizations of the movement or importation of GE organisms under current regulations have not had, nor are they expected to present any risks to, soil biota.

The trend in the number of requests for movement and importation are not expected to considerably change under the No Action Alternative as the types of GE organisms within the current 7 CFR part 340 regulatory scope will remain the same. However, there could be a marginal increase in requests, relative to innovation in the development of GE organisms both in the United States and abroad.

4.3.1.1.3 Authorization of Environmental Release

Field testing is part of standard research and development, and pre-market evaluation of the safety and utility of GE organisms. APHIS has authorized more than 18,400 permits and notifications for field testing of GE organisms. Most authorized field releases have involved major crop plants, and many of these have been GE plants developed for insect, viral, and fungal resistance.

To control and minimize GE plants or other organisms occurring beyond the area where it is intended to be tested, permits and notifications prescribe requirements for limiting regulated GE organisms to the field site and precluding persistence of the GE organism beyond termination of the field trial. Authorized field trials for GE plants have ranged in size from .001 acres up to 100,000 acres (these are noncontiguous acres, the sum total of multiple sites). The median size of field trial is approximately 5 acres, and average size about 20 acres. Field trials have been authorized in almost all U.S. states, commonwealths, and territories, a described in section 3.3.4. The areas and acreage of field trials is expected to continue along current trends.

Field Trials, GE Organisms, and Soil Biota

The vast majority of field trials are for GE crop plants and employ practices commonly used in the cultivation of commercial cropping systems such as tillage, herbicide and insecticide use, and irrigation. These practices can potentially affect soil biota in both beneficial and

detrimental ways, although developers field testing a GE plant, as growers of commercial crops, seek to sustain the fertility and health of soils to protect plant health and achieve desired yield. Fundamentally soil biota and crop cultivation are inherently linked. Plants are sources of energy and nutrients for soil biota, which in turn cycle soil organic matter (SOM), maintain nutrient availability and soil structure, transmit and prevent plant diseases, and degrade pesticides (Garbeva, van Veen et al. 2004, Gupta, Neate et al. 2007, Parikh and James 2012). The healthier populations of soil biota, the healthier plants and crop yields.

Soil biota range from the microscopic (e.g., bacteria, fungi, protozoa) to the macroscopic (e.g., arthropods and nematodes). There are estimated to be millions of organisms that inhabit soils, but only a fraction have been identified (e.g., 5% of fungi and 3% of nematodes) (Gupta, Neate et al. 2007). About 80 - 90% of soil biological activity is carried out by bacteria and fungi (Gupta, Neate et al. 2007). Soils in highly managed cropping systems can contain several dozen species of arthropods in a square mile, and in unmanaged environments, such as forests, there can be several thousand species per square mile. [118] Resistance to extreme changes in the soil environment increases as organisms decrease in size, which typically includes an increase in sheer number (Gupta, Neate et al. 2007). Hence, communities of macroscopic arthropods would be more sensitive to change than communities of bacteria and fungi.

Arthropods, which comprise a large and diverse number of soil species, are generally categorized by their functional roles in ecosystems, such as shredders, predators, herbivores, or fungal-feeders. Most soil-dwelling arthropods consume fungi, worms, or other arthropods. Through their functional roles arthropods aerate and mix soil, regulate the populations of other soil organisms, and help produce soil organic matter. Fundamentally, soil biota have critical roles in the cycling of vital plant nutrients, and consequently, maintaining the health of soil biota is a basic component of crop nutrient management programs. [119]

Sources of Impacts on Soil Biota

The primary sources of potential impacts on soil biota that would derive from field testing of GE plants would be from the use of pesticides (Locke and Zablotowicz 2004, Jänsch, Frampton, Römbke et al. 2006, Gupta, Neate et al. 2007), and tillage (Gupta, Neate et al. 2007, Roger-Estrade, Anger et al. 2010). Soil biota are typically tolerant of pesticides when they are applied at recommended rates, with only minor, transient effects on soil populations (Locke and Zablotowicz 2004). Pesticide use on GE plants during field trials is regulated by the EPA, and its use must adhere to EPA label requirements to optimize efficacy on target pests while limiting exposure to non-target biota. Tillage can introduce changes to the physical, chemical, and biological structural and functional relationships of soils that in turn affects soil fertility, both beneficially, and adversely (Gupta, Neate et al. 2007, Roger-Estrade, Anger et al. 2010). In no-till systems soil organic matter (SOM) is higher, fungi more prolific (beneficial), populations of nematodes, protozoa, and macro fauna more abundant, and residue decomposition and nutrient mineralization slower than that of tilled soils (Gupta, Neate et al. 2007, Horowitz, Ebel et al. 2010, Roger-Estrade, Anger et al. 2010).

[118] USDA-NRCS: http://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/soils/health/biology/?cid=nrcs142p2_053861

[119] For an overview see; http://www.extension.umn.edu/garden/fruit-vegetable/nutrient-cycling-and-ferti http://edis.ifas.ufl.edu/pdffiles/ss/ss63900.pdf

Under conventional tillage bacterial and viral populations increase, fungal populations decline, residue decomposition and nutrient mineralization is more rapid, SOM decreases, and nematode populations significantly decrease (Gupta, Neate et al. 2007, Horowitz, Ebel et al. 2010, Roger-Estrade, Anger et al. 2010).

In addition to pesticide inputs, the potential impact of GE plants themselves on soil microbial communities has also been of interest (e.g., see (Locke and Zablotowicz 2004, Lynch, Benedetti, Insam et al. 2004, Naranjo 2009, Turrini, Sbrana et al. 2015)). There have been some reports in the scientific literature that GE GR plants modify microbial communities due to glyphosate root exudation and altered plant physiology that results in exudation of carbohydrates and amino acids (Kremer and Means 2009, Turrini, Sbrana et al. 2015). Other reports have not observed such effects (Powell, Levy-Booth, Gulden et al. 2009, Duke, Lydon et al. 2012). Hence, to date, there is disparity in the scientific literature regarding the potential effects of GE HR crop plants on composition and diversity of soil biota (Duke, Lydon et al. 2012, Hannula, de Boer and van Veen 2014, Turrini, Sbrana et al. 2015).

There has been particular interest among the public and scientific community in regard to the effects of PIPs on soil biota. Since 2008, over 360 original research articles have been published examining the non-target effects of GE crops comprised of *Bacillus thuringiensis* (Bt) based PIPs on invertebrate organisms, mostly arthropods (Naranjo 2009, Turrini, Sbrana et al. 2015). The focus on GE Bt based crop plants derives from the fact that the Cry and Cyt proteins derived from *B. thuringiensis* comprise the vast majority of GE PIPs that have been field tested, and that are commercially produced. The insecticidal properties of *B. thuringiensis* have been known for over a century, and commercial Bt insecticides have been used to control insect pests in the United States since the 1960s (Ibrahim, Griko, Junker et al. 2010). There are numerous Bt based insecticides on the market, which are commonly applied as liquid sprays or dusts (US-EPA 1998). Bt based insecticides comprise around 90% of the biopesticide market (Naranjo 2009), and some of these products are approved for use in organic agriculture.[120] As a result of decades of common use Bt insecticides have been extensively evaluated for safety (Boisvert and Boisvert 2000, Federici 2003, Naranjo 2009), and widely used. However, the use of Cry and Cyt as PIPs in GE plants along with the continual, season-long expression of Cry and Cyt proteins in GE plants have raised concerns among the public and some scientists about their environmental effects (Naranjo 2009, Turrini, Sbrana et al. 2015).

The potential impact of current GE Bt crop plants on soil biota has been fairly well studied since the advent of these crop varieties in the later 1990s, and several reviews of the literature have been published (e.g., (Icoz and Stotzky 2008, Wolfenbarger, Naranjo, Lundgren et al. 2008, Carpenter 2011, Turrini, Sbrana et al. 2015)). In several papers, which spanned from molecular based laboratory studies to field studies, there have been some reports that Bt plants may affect soil communities, such as fungal populations and shifts in microbial community composition; however, adverse effects are not consistently observed, and differences in effects attributed to variances in geography, temperature, plant variety, soil

[120] USDA-NOP: Pesticide Residue Testing of Organic Produce; https://www.ams.usda.gov/sites/default/files/media/Pesticide%20Residue%20Testing_Org%20Produce_2010-11PilotStudy.pdf

type (nutrients), natural variation in soil community structure, and the difference between field and laboratory studies (Icoz and Stotzky 2008, Wolfenbarger, Naranjo et al. 2008, Carpenter 2011, Turrini, Sbrana et al. 2015). There have been some differences observed in the number and structure of soil microbial communities between Bt and non-Bt crops, although many of these observations were not statistically significant, were transient in nature, were not related to the inserted transgene, or were the result of altered lignin content (structural polymers in vascular plants) (Icoz and Stotzky 2008). To date, no outstanding adverse effects of Bt cotton, corn, and potato plants on the functional guilds of non-target arthropods have been described in the scientific literature (e.g., see reviews by (Wolfenbarger, Naranjo et al. 2008, Koch, Ward et al. 2015)).

In general, a considerable number of studies have been conducted investigating the potential adverse effects of GE Bt plants on soil biota. Scientific evidence that demonstrates GE Bt plants have substantively different effects on soil biota as compared to controls or conventionally bred crop plants, or affect soil communities in ways that exceeded natural variation, has not been clearly shown (Icoz and Stotzky 2008, Lancaster, Hollister et al. 2010, Carpenter 2011, Turrini, Sbrana et al. 2015). However, the lack of evidence that GE Bt plants adversely affect soil communities does not mean there may not be subtle effects (Icoz and Stotzky 2008, Turrini, Sbrana et al. 2015); for example, the difference between an adaptive and toxic response. Consequently, in light of the inconsistency in some of the findings reported in the scientific literature (Icoz and Stotzky 2008), assessment of the potential impacts of GE plants on soil biota will remain ongoing (Icoz and Stotzky 2008, Turrini, Sbrana et al. 2015).

PIP Oversight

In the field testing of GE plants comprised of a PIP, the EPA regulates and issues Experimental Use Permits (EUPs) for the field testing of PIPs - the insect or disease resistant gene and gene product – when test sites exceed 10 acres.[121] The regulations at 40 CFR part 172.4 contain the requirements for applications for EUPs. EPA regulations (40 CFR 172.2) provide that any person wishing to accumulate information necessary to register a pesticide under FIFRA may apply for an EUP. The EPA requires that a pesticide product, to include PIPs and GE microbial pesticides, undergo extensive chemical, toxicological, and field-testing before being registered as a pesticide. Some testing is done under field conditions to fully understand the pesticides properties, safety, and efficacy. Because testing undertaken as part of the registration process necessarily involves an unregistered product or is for a use not previously approved in the registration of the pesticide, the EPA sometimes must first authorize the distribution and sale for testing purposes by means of an EUP under FIFRA. For future field trials, the potential impacts of a particular type of PIP or other introduced trait on soil biota would be evaluated on a case-by-case basis as GE organisms were presented to EPA for permitting of field trials.

[121] Current and previously registered plant-incorporated protectant registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

4.3.1.1.4 Compliance, Enforcement, and Remediation

APHIS compliance and enforcement activities are to ensure confinement of the GE organism to the areas authorized for import, movement, or field testing. APHIS works with state and other federal agencies, including the FDA, EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations. Authorizations under the permitting and notification procedures require that noncompliance incidents be self-reported within designated time frames. Recordkeeping, reporting, and targeted and random inspections all work in concert to monitor the authorized environmental release of regulated GE organisms.

If an incident occurs, APHIS requires that authorized entities quickly comply with regulations to protect U.S. agriculture, the food supply, and the environment. Incidents with low potential impacts may require simple remedial actions, such as improving monitoring procedures. Serious incidents such as unauthorized releases may require destruction of filed test sites, quarantine of harvested crops, formal corrective action plans, or other long-term measures.

Remediation of noncompliance incidents can potentially adversely affect soil biota, although adverse impacts, if any, would be expected to be transient in nature. Serious incidents such as unauthorized or accidental releases may require destruction of field test sites or treatment of the area involving noncompliant GE plants with herbicides. For example, if there were dispersal of GE seed via a severe weather event, and a GE plant occurred outside an authorized area, or a volunteer plant presented after termination of the field trial, APHIS could order treatment of the area with a broad spectrum herbicide or mechanical removal to eradicate the GE plants. For certain incidences, remediation may involve actions like burning or burying unauthorized material. The effects of these types of remediation actions on soil biota would generally be transient in nature and lasting effects on soil communities once remediation was completed are considered unlikely. Any such remediation activities conducted would be done so in compliance with applicable federal and state laws and regulations.

4.3.1.1.5 Determination of Regulatory Status

When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance with EPA, and other federal, state, and county requirements. For GE organisms APHIS determines are not subject to regulation, the potential impacts on soil biota would be the same as those described above under environmental releases. APHIS generally evaluates potential impacts to soil biota via NEPA analyses, as required, when evaluating petitions for determination of non-regulated status. Hence, such impacts are evaluated on a case-by-case basis. Use of pesticides, to include GE PIPs and GE microbial pesticides, are regulated by the EPA.

The vast majority of GE organisms that APHIS has regulated, reviewed, and issued determinations of non-regulated status for are GE crop plants, and it is likely this trend will continue for the foreseeable future. Hence, agricultural lands are expected continue to comprise the dominant use of non-regulated GE organisms. If GE ornamentals or GE trees

were authorized for commercial or other uses, these would be cultivated in areas subject to federal and state laws and regulations, as well as county requirements.

4.3.1.2 Preferred Alternative: Soil Biota

4.3.1.2.1 Regulatory Scope

The Preferred Alternative would incorporate the noxious weed authority provided APHIS in the PPA; expand the range of organisms considered and potentially regulated using the revised definitions for "genetic engineering" and "GE organism"; remove the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures; and strengthen the compliance and enforcement program by clarifying APHIS authorities under the PPA and augmenting current approaches used to prevent or remediate potential risks to plant health.

4.3.1.2.2 Authorization of Interstate Movement and Importation

Movement and importation of GE organisms would be conducted solely under APHIS permit. APHIS would prescribe permit conditions, as applicable, designed to preclude unauthorized release. Shipping standards would be less prescriptive and more generally applicable, requiring they are handled in such a way to secure the shipment and maintain labeling and identity. Movements of regulated organisms would have to meet containment and handling requirements to prevent release into the environment. Specifics regarding labeling/marking and the methods of secure shipment would be prescribed as part of the permit conditions.

Conducted pursuant to APHIS requirements under the Preferred Alternative, movements and importations would present little risk to soils and soil biota. These activities would typically involve small quantities of GE material transported in secure shipping containers between clearly defined locations. When entities authorized to move or import GE organisms adhered to permit requirements the potential for inadvertent release of GE organisms would be limited to instances of accidents, unforeseen and severe weather events, or human error. There are no known noncompliance incidences that have impacted soil communities, nor are there are reasonably foreseeable scenarios where soils or soil biota would be adversely affected by APHIS authorized importation or interstate movement.

4.3.1.2.3 Authorization of Environmental Release

Under the Preferred Alternative APHIS would be considering a broader range of organisms that would include not only potential plant pests, but potentially noxious weeds, and other organisms subject to the definitions for "genetic engineering" and "GE organisms". The notification process (7 CFR § 340.3) and courtesy permits (§340.4(h)) would be eliminated, and all environmental releases conducted solely under permit. APHIS would prescribe permit conditions to prevent the unauthorized release of GE organisms from the field site and their persistence in the environment on termination of field trial. APHIS compliance and enforcement actions (discussed following) would also be revised under the Preferred Alternative. Collectively, the proposed revisions constitute a broadening of APHIS' oversight of the field testing of GE organisms, which was suggested by the USDA OIG (USDA-OIG 2015) and 2008 Food, Conservation, and Energy Act of 2008 (Farm Bill).

As a result of institution of a more efficient risk-based regulatory review process, the total number of GE organisms regulated under the Preferred Alternative would likely decline, as the list of regulated organisms would be limited to those organisms that pose a plant pest or noxious weed risk. While the total annual acreage for APHIS authorized field releases may decline under the Preferred Alternative, developers would continue to field test GE organisms that were not subject to part 340, and the total number of field tests for GE organisms, annually, would likely continue along current trends, perhaps increasing, relative to the rate of innovation in the agricultural biotechnology sector.

Potential impacts to soil biota as a result of APHIS authorized field trials under the Preferred Alternative would the same as that described for the No Action Alternative, in that any potential adverse effects would largely derive from use of chemical pesticides, PIPs, and GE microbial pesticides. However, under the Preferred Alternative, APHIS would be regulating a broader range of GE organism-trait combinations not captured under the current regulations. Hence, the Preferred Alternative could, conceptually, provide protections for soil communities not realized under the No Action Alternative. For example, for a novel GE organism-trait combination that were regulated under the proposed revisions to 340, APHIS would require data on the effects of that organism-trait combination prior to permitting a field trial if APHIS determined that the organism-trait combination may present a risk to soil biota.

Due to the relatively small scale and transient nature of field trials, the potential for field testing of GE organisms to significantly alter soil communities is considered negligible. As under the No Action Alternative, environmental releases of GE PIPs, GE microbial pesticides, and chemical pesticides, would be regulated by the EPA, and EUPs required for field testing of such GE organisms.

4.3.1.2.4 Compliance, Enforcement, and Remediation

To improve the clarity of the regulations, APHIS is proposing to consolidate all compliance and enforcement requirements in 7 CFR part 340 into a new § 340.5. In proposed 7 CFR part 340, APHIS would explicitly state its authority under the PPA to take remedial actions in the event that an incident requires such actions, and that it has the authority to order remedial action by others. APHIS would require that records for import or movement of a product of biotechnology be retained for at least 2 years, and records for environmental releases to be retained for at least 10 years after completion of all obligations required under a relevant permit or exemption. In the event of an investigation into the possible unauthorized environmental release of a regulated organism, or the escape of a regulated organism from a containment facility, an extended record of activities taken under the permit would provide APHIS the information necessary to assess compliance and determine whether enforcement and remediation actions may be needed. If an unauthorized or noncompliant release occurred and APHIS required remediation, any remediation actions would be transient in nature, localized to the site of release, and based on APHIS history in regulating movements and environmental releases, long-term adverse effects on soil biota considered unlikely. Use of pesticides for remediation would follow EPA and local requirements.

As detailed in Chapter 2 (section 2.2), failure to comply with the regulations could include denial of future permits; revocation of current permits; destruction, treatment, and removal of

regulated organisms; issuance of penalties; and a means to settle civil violations prior to the issuance of an administrative complaint. To the extent the proposed revisions help improve the management decisions of permit holders during field testing and transport of regulated organisms, and reduce instances of noncompliance, the potential for adverse impacts on soils and soil biota could be reduced, relative to the No Action Alternative.

4.3.1.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct plant pest risk assessments (PPRA) and/or a weed risk assessments (WRA) to inform the determination of whether a GE organism is subject to regulation and required a permit under 7 CFR part 340. GE organisms would be listed on a regulatory status register on APHIS' website as regulated or not regulated. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk. If APHIS determined a GE organism was not subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS.

Because most plants are not plant pests, nor present noxious weeds issues, it is anticipated that many of the GE plants currently regulated, and many of those GE plants that may be developed in the future, would not be regulated under the Preferred Alternative. When APHIS determined that a GE organism was not subject to 7 CFR part 340, that organism would still be subject to compliance with EPA, and other federal and state agency requirements, as well as county requirements.

Considering the regulatory scope is broader than the No Action Alternative, it is conceptually possible that certain novel GE plant-trait combinations that could potentially present a risk to soil biota may be captured under the Preferred Alternative; plant-trait combinations that would otherwise escape regulation under the current 7 CFR part 340 framework. In this respect, from a regulatory perspective, the Preferred Alternative could provide better protections for soil biota, and associated soil processes, were there any risk to be considered.

For those GE organisms APHIS issues determinations of non-regulated status, the potential impacts on soil biota (both beneficial and adverse, as described throughout this section) would not significantly differ from those described for the No Action Alternative. As required, APHIS would evaluate potential impacts to soil biota as part of NEPA review in assessment of a GE organism's regulatory status. Hence, such impacts would be evaluated on a case-by-case basis where NEPA review was necessary.

4.3.1.3 Alternative 3: Soil Biota

4.3.1.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it incorporates noxious weed authority, utilizes the revised definitions for "genetic engineering" and "GE organism", and risk analyses would be conducted via the PPRA and WRA. However, under this alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic from the mere presence of a GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. The WRA would include an economic effects analysis, and APHIS would distinguish those GE organism that presented only potential economic impacts from those that presented plant pest and noxious weed risks.

If, after conducting a PPRA and/or WRA, APHIS determines that a GE organism is unlikely to pose a plant pest or noxious weed risk in the traditional sense (biotic effects), then it would not be regulated under 7 CFR part 340. However, if APHIS concludes that a GE organism is unlikely to pose a plant pest or noxious weed risk (biotic) but presented potential economic harms, then APHIS would regulate that GE organism and require APHIS permitting for use. For the purposes of this dPEIS those with potential market impacts are termed mere presence noxious weeds (MPNW). All GE organisms that were determined to present a plant pest or noxious weed risk, or an economic risk (including all previously deregulated organisms), would be regulated. Hence, under Alternative 3 potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.3.1.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative the notification process would be eliminated. The importation and interstate movement of regulated plant pests and noxious weeds would be conducted solely under APHIS permit. The importation and interstate movements of GE organisms that presented potential economic harms (MPNW) to non-GE producers would not require a permit for interstate movement or importation, although environmental release would. Consequently, relative to potential impacts of APHIS authorized interstate movements and importations on soil biota; Alternative 3 is the same as or similar to that described for the Preferred Alternative, as the scope of GE organisms that would be permitted for transport, permit requirements, and compliance, enforcement, and remediation actions, would be the same. Where the Preferred Alternative and Alternative 3 provide broader regulatory scopes, movements and importations under all the alternatives considered would present negligible risk to soils and soil biota when conducted pursuant to APHIS permitting requirements.

4.3.1.3.3 Authorization of Environmental Release

Under Alternative 3 authorized environmental releases would include all regulated GE plants and other organisms that were field tested or utilized for commercial purposes. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have more stringent requirements than permits for commercial cultivation of MPNW, as MPNW would not present any biotic risk as plant pests or noxious weeds. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, save for inclusion of MPNW.

All non-GE crop producers would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations to APHIS on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

One consideration relative to wide-scale permitting is that, where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate a traditionally bred crop plant under a conventional or organic cropping system. If this were to occur, there could be seen an increase in insecticide use where an insect resistant GE crop plant were supplanted for use of the non-GE crop plant in a conventional cropping system. Similarly, if disease resistant GE crops were supplanted with a more vulnerable traditionally bred crop plant, there could be seen an increase in the use of fungicides and other chemical controls for suppression of plant pathogens. Were this to occur, this Alternative could potentially lead to agronomic practices that were less beneficial to soil communities. The likelihood of some growers opting to produce a particular non-GE crop plant utilizing a conventional cropping system, as opposed to the GE plant variety, and the degree to which any such shift in choice may occur, is indeterminate. Potential changes in agronomic practices associated with such a shift in the choice of crop cultivation could potentially adversely affect soils and soil biota, relative to the particular agronomic practices utilized in production of the non-GE crop.

Where a grower decided to cultivate a traditionally bred crop plant under a USDA certified organic cropping system, these cropping systems would be expected to have lesser adverse effects on soil communities. Organic systems commonly use soil conservation practices, cover crops, composting, organic mulches, green manures (crops grown specifically for soil improvement), and reduced synthetic chemical inputs relative to conventional systems. Organic systems also strive to retain field biodiversity that can help suppress plant pests and disease. However, conventional tillage is still practiced in some organic cropping systems, and heavy reliance on conventional tillage for pest, disease, and weed control could be detrimental to soil communities. The USDA National Organic Program assists certified organic farmers with implementing tillage practices that maintains or improves the physical, chemical, and biological condition of the soil and that minimize impacts to soils (NOP section §205.203).

While APHIS would regulate the commercial production of most GE crop plants, and field testing of all regulated organisms, these GE organisms would also be subject to compliance with EPA, and other federal, state, and county requirements. The use of pesticides on GE and

non-GE crops would be regulated by the EPA, under all the Alternatives considered. Likewise, the commercial cultivation of GE crop plants comprised of an EPA registered PIP, and use of GE microbial pesticides, would be regulated by the EPA. For GE plants developed for human or animal food purposes, the FDA recommends that developers of GE plant varieties intended for food use consult with the FDA about the safety and composition of the GE plant variety prior to its introduction into the food supply. Sponsors and developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006).

4.3.1.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative, however, these activities would be extended to MPNW, and would incur expanded responsibilities for developers, growers of GE crops, growers of non-GE crops, and APHIS. The extended oversight of MPNW would have no significant effect on soil biota. Any potential adverse effects would be the same as that described for the Preferred Alternative.

4.3.1.3.5 Determination of Regulatory Status

Determination of regulatory status would be the same as under the Preferred Alternative, save for inclusion of MPNW. The petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and/or WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production, and those that would be produced in the future. In general, there are few GE plants that would not be regulated under Alternative 3. Any GE plant or other organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Developers, or anyone else, would be able to consult with APHIS on the regulation of a GE organism as described under section 2.2 – Program Alternative 2.

As with the Preferred Alternative, it is possible certain GE plant-trait combinations that would not be subject to current regulations, and that may present a potential risk to soil biota, would be captured under Alternative 3 regulations due to broader scope of organisms considered. Hence, Alternative 3 potentially provides better protections for soil biota than the No Action Alternative, in the event a GE plant-trait combination may present risks to soil biota.

Any GE organism that APHIS determined was not a plant pest, noxious weed, or MPNW could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements. For non-regulated GE plants, the potential to affect soil biota, both beneficial and adverse, would be essentially the same as that described for the No Action Alternative, as these are likely to be herbicide resistant, and insect and disease resistant GE crop plants similar to those currently cultivated.

4.3.2 Invertebrates

APHIS regulations involve oversight of certain GE organisms that are developed to protect plants from invertebrate pests and pathogens; these are discussed in further detail in section 4.3.4. This section discusses potential effects on invertebrate community structures, in general.

4.3.2.1 No Action Alternative: Invertebrate Organisms

4.3.2.1.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of GE organisms that are considered plant pests under permit or notification (USDA-APHIS 2011, USDA-APHIS 2012). These activities may be authorized anywhere in the United States or U.S. territory, subject to other federal, state, and county or local requirements.

The majority of species in the animal kingdom, over 90%, are invertebrates. Common terrestrial invertebrate organisms include ants; bees and wasps; grasshoppers, crickets, and stick insects; butterflies and moths; cicadas and aphids; millipedes; snails and slugs; spiders; beetles; true flies and bugs; and worms. Common aquatic invertebrates include grass shrimp; worms; snails; mayflies; water fleas; copepods; and various mollusks.

Under 7 CFR part 340 APHIS regulates plant pests, many of which are invertebrates, and includes any living stage of insects, mites, nematodes, slugs, snails, protozoa, bacteria, fungi, or other invertebrate animals, or any organisms similar to or allied with any of the foregoing, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof.

4.3.2.1.2 Authorization of Interstate Movement and Importation

APHIS authorized movements and importations of GE organisms are required to adhere to notification performance standards and permit conditions that ensure confinement of the GE organism during shipping or movement (USDA-APHIS 2011, USDA-APHIS 2012). Over the years APHIS has authorized thousands of importations and interstate movements. During 2015 APHIS issued permits or acknowledged notifications for 744 importations and 746 interstate movements. Of the imports, 617 were requested by academic and private research institutions for import of Drosophila (fruit fly).[122] For both import and interstate movements in 2015, around 1,025 authorizations were requested by universities or public research institutions (~ 69%). Hence, the majority of imports and movements are for basic and applied research purposes.

Movements and importations under current regulations would present little risk to invertebrate populations. These activities typically involve small quantities of GE material transported in secure shipping containers between clearly defined locations. When entities

[122] Drosophila fruit flies are widely used in genetics and developmental biology research. In most instances, they do not contain genetic sequences from plant pests and are not listed as organisms that are or contain plant pests in current § 340.2. Therefore, they generally do not require permits for their movement under 7 CFR part 340. However, shipments labeled as "fruit flies, whether created through biotechnology or not, sometimes raise agricultural and environmental concerns because this common name also refers to regulated plant pests like the Mediterranean and oriental fruit flies.

authorized to move or import GE organisms adhere to current notification and permit requirements the potential for inadvertent release of GE organisms is limited to instances of container failure or human error. Accidental releases, such as spillage of GE seed are possible, and if they occurred would result in remedial actions at the site of release. These types of incidents would generally have no lasting effect on the area of release. If a noncompliance incidence occurred, any remediation actions would be transient in nature, and long term effects on invertebrate communities from such an incident are unlikely.

4.3.2.1.3 Authorization of Environmental Release

Field testing is part of standard research and development practices and pre-market evaluation of GE organisms. To date, APHIS has authorized more than 18,400 permits and notifications for field testing of GE organisms (the vast majority plants). In 2015 APHIS issued 37 permits or acknowledged 447 notifications for environmental release in 39 states, Puerto Rico, and U.S. Virgin islands.[123] As part of authorization for permits and notifications, APHIS requires applicants provide critical habitat analysis which is reviewed by APHIS and used in determination of approval of the environmental release (discussed further in Chapter 6). Critical habitat analyses identify areas that are essential to the conservation of a invertebrate species listed as threatened or endangered under the ESA, and that may require special management considerations or protection.

To control and minimize GE plants or other organisms occurring beyond the area where it is authorized to be tested, notification and permit criteria are designed to limit regulated organisms to the field site and preclude persistence of the GE organism beyond termination of the field trial. The median size of an approved field trial is approximately 5 acres, and average size about 20 acres. Currently, authorized field trials comprise, collectively, around 450,000 acres per year or less.

Field trials are commonly conducted for GE plants comprised of PIPs, which confer GE plant resistance to a target group of invertebrate pests. The most commonly used PIPs, and provided as an example, are those derived from naturally occurring soil bacteria *Bacillus thurigensis* (Bt), which synthesize crystal (Cry) and cytolytic (Cyt) proteins, also known as δ-endotoxins (Bravo, Gill et al. 2007). Cry proteins are specifically toxic to the insect orders Lepidoptera, Coleoptera, Hymenoptera, and Diptera, and also to nematodes; in contrast, Cyt toxins are mostly found in Bt strains active against Diptera (Bravo, Gill et al. 2007). Once ingested, the Cry and Cyt are solubilized in the midgut thereby releasing protoxins, which are cleaved by proteases that release the active toxin (Bravo, Gill et al. 2007, Pardo-López, Soberón and Bravo 2013). The active toxin binds to specific cell surface receptors on the midgut epithelium, enter the cell, cause cell swelling, rupture, and eventually death of the target invertebrate (Bravo, Gill et al. 2007, Pardo-López, Soberón et al. 2013). In addition to Bt based PIPs, GE microbial pesticides, such as bacteria, fungi, or viruses, and RNAi based

[123] Permit and notification request information for import, movement, and field release is publically available on the USDA funded Information Systems for Biotechnology website ISB (2015). *Information Systems for Biotechnology (ISB)*. USDA Cooperative State Research, Education, and Extension Service (CSREES), USDA Agricultural Research Service (ARS), and Agricultural Experiment Station at Virginia Tech. Retrieved December 19, 2016, from http://www.isb.vt.edu/Default.aspx..

PIPs, are increasingly explored and field tested as mechanisms to protect plants from insects and disease (Sherman, Munyikwa, Chan et al. 2015).

Bt derived PIPs are highly specific for their hosts (Bravo, Gill et al. 2007) and have gained worldwide importance as an alternative to chemical insecticides. The usefulness of certain Cry and Cyt proteins has spurred the search for new Bt isolates in order to identify and characterize new insecticidal proteins with different specificities (Palma, Muñoz, Berry et al. 2014). Bt also synthesizes other proteins, the sequences of which suggest insecticidal activity, and research and development of Bt based insecticides, to include PIPs, is expected to continue (Palma, Muñoz et al. 2014).

In areas where GE plants comprised of PIPs or GE microbial pesticides are field tested it is likely that many species of invertebrates that dwell in those areas will be exposed to these GE organisms. Invertebrate exposure to PIPs may occur through ingestion of pollen, leaf, root, nectar/sap, or plant detritus, and for some species, via inhalation. Invertebrate exposure in aquatic environments may occur as a result of pollen drift to these areas, and potentially through leaf or movement of other plant material off cultivated fields into lakes, streams, ponds, or estuaries. Exposure to GE microbial pesticides may occur through contact or inhalation.

The EPA regulates most PIPs and GE microbial pesticides under FIFRA, and publishes information on registered PIPs on its website.[124] The EPA issued new rules, commonly referred to as the PIP rules that clarify the relationship between plants and PIPs, and their regulatory status under FIFRA.[125] In these rules, the Agency has determined that, in regulating PIPs, the new protein and its genetic material are regulated by EPA; the plant itself is not regulated. The EPA also regulates GE microbial pesticides. These are either species of bacteria, fungi, viruses, protozoa, or algae, which have been modified to express pesticidal properties. To date, EPA has registered eight such products, which contain a modified microorganism and inert ingredients. A list of registered biopesticide active ingredients is published on the EPA website.[126] Because GE microbial products are subject to extensive regulation by EPA, APHIS entered into a memorandum of understanding (MOU) with EPA stating that APHIS will not exercise duplicative regulatory oversight of GE microbial products.

The EPA requires an experimental use permit (EUP) for field testing of GE organisms comprised of a PIP, and GE microbial pesticides (See 40 CFR part 172.2 – Experimental Use Permits). The EPA also regulates use of pesticides during field trials. Before a pesticide, to include GE PIPs and GE microbial pesticides, can be used commercially there must be sufficient data demonstrating that it will not pose unreasonable risks to human health or the

[124] EPA - Current and Previously Registered Section 3 Plant-Incorporated Protectant (PIP) Registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated

[125] EPA - Overview of Plant Incorporated Protectants: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants

[126] EPA - Biopesticide Active Ingredients: https://www.epa.gov/ingredients-used-pesticide-products/biopesticide-active-ingredients

environment. When assessing the potential risks of GE PIPS and microorganisms to non-target invertebrate species, the EPA requires extensive toxicological studies examining potential adverse effects on birds; mammals; freshwater and marine/estuarine fish and invertebrates; insects, including honey bees; non-target plants; and soil invertebrates.[127]

Risk assessments evaluating exposure of invertebrates to GE PIPs are typically based on expression levels of the PIP within plant tissues. Expression levels can differ among plant tissues, and over time, and the plant tissue with the most relevance to invertebrate diet is typically used to determine the dose, or dietary concentration, in non-target organism testing. Expression levels in pollen are often used, since many non-target insects consume pollen. Expression levels in leaf tissue are also considered as the leaf can be consumed by a variety of invertebrate species. Because there is some uncertainty as to the actual level of exposure (dose) given the varying diets among invertebrate species, a conservative approach is used to estimate invertebrate exposure, which utilizes the highest PIP expression levels measured among all tissues based on dry weight measurements. This helps reduce uncertainty regarding actual exposure in the field, and evaluation of toxicity thresholds (if any exist).

Under FIFRA, GE microbial products, as with all other pesticides, must be evaluated for their safety before any registration is granted by EPA (see 40 CFR part 158.2150). These studies require examination of pathogenicity to other organisms, and includes beneficial insects, aquatic invertebrates, estuarine and marine organisms (fish and invertebrates), plants, and honeybees (Wozniak, McClung et al. 2012). Other study data describes the environmental transport and fate of the GE microorganism in the area of application and its ability to persist; whether in soils, or as associated with an insect vector.

EPA regulation of pesticides and GE organisms with pesticidal properties would remain unchanged under the No Action Alternative, this includes issuance of EUPs. Any risks to invertebrates from field testing of GE organisms would largely derive from those with pesticidal properties; these are discussed subsequently in subsection 4.3.4 – Plant Pests and Disease. If APHIS determines that an environmental document must be prepared for a field release, APHIS may request additional information from applicants on the potential effects of the GE organism on non-target organisms and wildlife. As field releases are conducted over several seasons, applicants may also be requested to collect data that will assist the Agency in preparing future environmental documents. Information would typically consist of data relating to potential environmental effects, to include invertebrate populations.

4.3.2.1.4 Compliance, Enforcement, and Remediation

APHIS compliance and enforcement activities seek to ensure confinement of the GE organism to the areas authorized for import, movement, or field testing. While expected, compliance with regulatory requirements 100% of the time is not realistically achievable. Hence, monitoring is essential to ensuring that permit and notification requirements are being met, and appropriate remediation actions can be taken as necessary. Recordkeeping, reporting, and random and targeted inspections all work in concert to monitor field trials and movement of regulated GE organisms. APHIS works with state and other federal agencies,

[127] EPA - Introduction to Biotechnology Regulation for Pesticides: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides#non-target

including the FDA, EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations.

Remediation can be required if a noncompliance incident has occurred and APHIS determines that action must be taken to control or eradicate the GE organism. Remediation actions, such pesticide use (e.g., potential toxicity) or tillage (e.g., disturbance of habitat) could potentially affect invertebrate populations, although any adverse impacts would be temporally and spatially limited; no significant long-term impacts would be expected due to nature of such activities.

4.3.2.1.5 Determination of Regulatory Status

When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance with EPA, and other federal and state agency requirements. If any risk were subsequently identified, APHIS has the authority to revise its determination, and regulate that organism under part 340.

Individuals that petition APHIS for determinations of non-regulated status provide APHIS with information on the potential impacts of the GE organism to target and non-target invertebrate species. This is similar to or a subset of the information that would be submitted to the EPA. APHIS also considers EPA and FDA evaluations of the GE organism in regard to regulation.

As described for environmental releases above, all GE plants comprised of PIPs, and GE microbial pesticides, are regulated by the EPA under FIFRA (and some GE organisms under TSCA), as are the pesticides that may be used on GE plants used for commercial or experimental purposes. PIPs and similar genes/gene products are also evaluated by the OECD, European Union (EU), Australia, and other countries and international authorities. For example, the European Food Safety Authority (EFSA) assess any possible risks of GE organisms to human and animal health, and the environment, inclusive of potential adverse effects on invertebrate populations.[128] GE organisms can only be authorized in the EU if they have passed a rigorous safety assessment. The procedures for evaluation and authorization of GE organisms are described in Regulation (EC) No 1829/2003 and in Directive 2001/18/EC. APHIS could also consider these risk assessments where potentially harmful effects were identified.

Some stakeholders express concern that pesticide drift may injure non-target organisms, and that APHIS should consider the extent to which herbicide and insect resistant GE crop plants will be adopted. Pesticides are used on both commercial GE and conventional cropping systems. As described throughout this dPEIS, insect resistant GE crop plants can reduce the use of insecticides; there is no evidence that GE herbicide resistant crop plants necessitate increased herbicide use (NAS 2016b). However, the development of herbicide weed resistance (see 3.6.5) can potentially lead to an increased use of herbicides in some areas. Pesticide spray drift is a well-recognized concern in the application of pesticides. The EPA has several initiatives to help minimize pesticide drift, which includes the voluntary Pesticide

[128] http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32001L0018

Drift Reduction Technology (DRT) program that encourages the manufacture, marketing, and use of spray technologies and equipment scientifically verified to reduce pesticide drift.[129]

For invertebrate populations, the potential for adverse impacts is largely limited to GE plants comprised of PIPs, GE microbial pesticides, and chemical pesticides commonly used to control agricultural and forestry pests and disease. Invertebrate populations will always be affected, to some degree, by commercial scale agricultural production systems, GE and non-GE alike. While genetic engineering provides for the potential to introduce various traits into agricultural crop plants; only two traits - insect resistance and herbicide resistance - have been widely used. GE IR and HR plant varieties were grown on about 12% of the world's planted cropland in 2015. The most commonly grown, with one or both of the IR or HR traits were soybean (83% percent of land in soybean production), cotton (75% percent of land in cotton production), corn (29% percent), and canola (24%). A few other GE traits, such as virus resistant papaya and fungal resistant potato, are cultivated, disease resistant crops are produced on a relatively small number of acres worldwide.

To date, significant adverse effects on non-target invertebrate communities that are singularly attributed to the commercial use of GE IR and HR crop plants have not been identified (Naranjo 2009, Carpenter 2011, NAS 2016b). Wide-scale commercial production of these varieties of crop plants has taken place in the United States for around 20 years. In 2015, there were over 400 million acres plant to GE crops, worldwide. Over this time, no ecosystem level effects, such as disruption of populations, communities, and ecosystem goods and services, have been reported in the literature (Icoz and Stotzky 2008, Wolfenbarger, Naranjo et al. 2008, Naranjo 2009, NAS 2016b). A recent review by the National Academy of Sciences, examining the past 20 years of data on these GE crop types, found that overall, there is no evidence of cause-and-effect relationship between GE crops and environmental problems (NAS 2016b).

The potential for adverse effects on non-target invertebrate populations appears largely limited to current GE IR varieties, and the concerns primarily in regard to the development of PIP resistance among target insect populations. Consequently, insect resistance management has emerged as a basic practice in the production of GE IR crops. There remains some debate on the potential effect of herbicides (primarily glyphosate) on milkweed and monarch butterfly populations, although studies reported as of March 2016 have not shown that suppression of milkweed by glyphosate is the cause of monarch decline (NAS 2016b). Similarly, a recent review on the potential effects of GE Bt crop plants on honey bees concluded that evidence from many studies indicates that Bt pollen and nectar are not harmful to honey bees (Johnson 2015). As for potential beneficial effects, planting of GE Bt crop varieties tends to result in higher insect biodiversity than planting of similar varieties without the Bt trait that are treated with synthetic insecticides (NAS 2016b). In relation to the potential effects of GE crop plants on non-target invertebrate species, interest and debate

[129] EPA, What EPA is Doing to Reduce Pesticide Drift: https://www.epa.gov/reducing-pesticide-drift/what-epa-doing-reduce-pesticide-drift

among scientists and stakeholders will continue as new GE crops are developed and cultivated, both in the United States, and abroad (NAS 2016b).

Based on extant data (e.g., (Naranjo 2009, Carpenter 2011, NAS 2016b), and others), the current process and criteria for APHIS determinations of non-regulated status presents a very low risk to invertebrate populations. As part of its plant pest risk assessment (PPRA), APHIS evaluates the potential impacts of the GE organisms on non-target invertebrate organisms beneficial to agriculture.[130] As new GE crop plants are developed bearing herbicide resistant traits, insect and disease-resistance traits, and stress tolerance, and these are reviewed as to regulatory status, APHIS would evaluate potential effects on non-target invertebrate organisms on a case-by-case basis as petitions for non-regulated status are submitted for review.

4.3.2.2 Preferred Alternative: Invertebrate Organisms

4.3.2.2.1 Regulatory Scope

The Preferred Alternative broadens the scope of GE organism that could be considered under regulations by incorporating APHIS' noxious weed authority and providing new definitions for "genetic engineering" and "GE organism." APHIS would remove the notification procedure and authorize the importation, interstate movement, and environmental release of regulated GE organisms solely under permit. The compliance and enforcement program would be strengthened by augmenting current compliance requirements and clarifying the full range of authorities and penalties granted under the PPA.

4.3.2.2.2 Authorization of Interstate Movement and Importation

Movement and importation of GE organisms would be conducted solely under APHIS permit. APHIS would prescribe permit conditions, as applicable, designed to preclude unauthorized release. APHIS would use a performance-based approach for shipping of GE organisms and require they are handled in such a way to secure the shipment and maintain labeling and identity.

Conducted pursuant to APHIS requirements under the Preferred Alternative movements and importations would present little risk to invertebrate populations. When entities authorized to move or import GE organisms adhered to permit requirements the potential for inadvertent release of GE organisms would be limited to instances of accidents, unforeseen and severe weather events, or human error. There are no known noncompliance incidences that have impacts invertebrate species, nor are there are reasonably foreseeable scenarios where invertebrate populations could be adversely impacted. If an unauthorized or noncompliant release occurred and APHIS required remediation, any remediation actions would be transient in nature, localized to the site of release, and based on APHIS history in regulating movements and imports, long-term adverse effects highly unlikely.

[130] USDA-APHIS, Petitions for Determination of Non-regulated Status: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

4.3.2.2.3 Authorization of Environmental Release

Sources of potential impacts to invertebrate populations as a result of APHIS authorized field trials would be the same as that described for the No Action Alternative, these would largely be those associated with GE PIPs that target invertebrate populations, GE microbial pesticides, and chemical pesticides. To date, concerns have involved the effect of Bt based PIPs on non-target species (e.g., beneficial insects and pollinators), and the effects of chemical insecticides and herbicides used in conjunction with GE IR and HR crop plants on non-target species.

Under the Preferred Alternative, APHIS would have oversight of a broader range of GE organism-trait combinations not captured under the scope of current regulations. Hence, if the scope of regulatory capture is greater under the Preferred Alternative, and if there are GE organism-trait combinations that could potentially adversely impact non-target invertebrate organisms, APHIS would more likely to be able to review these under the Preferred Alternative, than under the current regulatory framework. If APHIS reviewed and identified certain GE organism-trait combinations that may present a potential risk to invertebrate populations, APHIS could regulate the field testing of that GE organism and require further information to address any questions raised in permit requests.

Due to the relatively small scale and transient nature of field trials anticipated under the Preferred Alternative, which would be similar to the No Action Alternative, the potential for field releases to significantly alter invertebrate communities is expected to be rather limited. As under the No Action Alternative, environmental releases of GE PIPs, GE microbial pesticides, and chemical pesticides, would be regulated by the EPA, and EUPs required for field testing of such GE organisms.

4.3.2.2.4 Compliance, Enforcement, and Remediation

Under the Preferred Alternative APHIS would strengthen its compliance and enforcement program by augmenting the approaches currently used to prevent or remediate potential risks to the environment, and clarifying its enforcement authority under the PPA, as outlined in section 2.2.4. To the extent the proposed revisions help improve the management decisions of permit holders during field testing and transport of regulated organisms, and reduce instances of noncompliance, the potential for adverse impacts on invertebrate communities could be reduced, relative to the No Action Alternative.

4.3.2.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct plant pest risk assessments (PPRA) and/or a weed risk assessments (WRA)) to inform the determination of whether a GE organism is subject to regulation and required a permit under 7 CFR part 340. As part of authorization for permits, APHIS would require applicants provide a Critical Habitat analysis,[131] which would be

[131] When a species is proposed for listing as endangered or threatened under the Endangered Species Act, the U.S. Fish and Wildlife Service (Service) must consider whether there are areas of habitat believed to be essential to the species' conservation. Those areas may be proposed for designation as critical habitat.

reviewed by APHIS and used in determination of approval of the environmental release (discussed further in Chapter 6).

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS.

Potentially, because APHIS' regulatory status review process would be refined for improved efficiency, there could be more GE crop plants available for commercial use, subject to EPA and other applicable federal, state, and county requirements. Consequently, it is possible there may be seen an increase in the adoption of certain GE crop varieties, namely stacked trait GE plants that are herbicide resistant, and insect and disease-resistant. However, because EPA regulations and regulatory review processes, as well FDA's voluntary consultation would remain unchanged, it is not expected that the rate of adoption of GE organisms for commercial purposes, namely GE crop plants, would significantly increase.

Relative to APHIS determinations of non-regulated status for a GE organism, the sources of potential impacts on non-target invertebrate species would be similar to the No Action Alternative and Alternative 3, in that the potential for any adverse effects would largely be those associated with GE organisms developed with pesticidal properties, such as Bt based PIPs, GE microbial pesticides, and chemical pesticides used with GE crop plants. As with all the alternatives, pesticides, to include GE PIPs and GE microbial pesticides, would be regulated by the EPA.

Relative to potential benefits; GE Bt crop varieties are well recognized as reducing the use of synthetic insecticides in those fields where Bt crops are cultivated, and in some cases, the use of Bt crop varieties has also been associated with a reduction in use of insecticides in nearby non-Bt crop varieties (NAS 2016b). Hence, where insect resistant GE crop varieties were adopted, there would be a potential decline in insecticide use, reducing exposure of invertebrates to such chemical inputs. In general, cultivation of GE Bt crop varieties tends to result in higher insect biodiversity than planting of similar crop varieties without the Bt trait that are treated with synthetic insecticides (NAS 2016b).

As described for environmental releases, because the scope of regulatory capture is greater, there may be certain GE organism-trait combinations regulated under the Preferred Alternative that would otherwise escape regulatory oversight under the current 7 CFR part 340 framework. This could, potentially, provide for reduction of risk to invertebrate organisms, if such risk where to be identified during a PPRA or WRA.

Of consideration are plants genetically engineered for pharmaceutical and industrial purposes (PMPI), which would require permitting under the Preferred Alternative only when APHIS determined such GE plants presented a plant pest or noxious weed risk. Consequently, APHIS would likely be regulating fewer GE P/I-producing plants under the Preferred Alternative, relative to the No Action Alternative, which presents a potential gap in federal oversight for small scale field tests of GE P/I-producing plants. While there are significant economic and public health benefits that can potentially be provided by plant made

pharmaceutical and industrial compounds, these may also present risks if such plants are consumed by invertebrates. Consequently, oversight of the field testing of GE P/I-producing plants is a salient concern. As discussed later in Section 4.8 – Federal, Tribal, and State Governance, APHIS is proposing several options to address this potential gap in oversight.

4.3.2.3 Alternative 3: Invertebrate Organisms

4.3.2.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it codifies noxious weed authority, utilizes the revised definitions for "genetic engineering" and "GE organism," and risk analyses would be conducted via the PPRA and WRA. However, under this Alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. The WRA would include an economic effects analysis, and APHIS would distinguish those GE organism that presented only potential economic impacts from those that presented plant pest and noxious weed risks.

If, after conducting a PPRA and/or WRA, APHIS determines that a GE organism is unlikely to pose a plant pest or noxious weed risk in the traditional sense (biotic effects), it would not be regulated under 7 CFR part 340. However, if APHIS concludes that while a GE organism is unlikely to pose a biotic plant pest or noxious weed risk but presented potential economic harms, then APHIS would regulate that product and require APHIS permitting for use. For the purposes of this dPEIS those with potential market impacts are termed mere presence noxious weeds (MPNW), described in subsection 2.2. All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated GE organisms), would be regulated. Hence, under Alternative 3 potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.3.2.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative the notification process would be eliminated. The importation and interstate movement of regulated plant pests and noxious weeds would be conducted solely under APHIS permit. The importation and interstate movements of GE organisms that presented potential economic harms (MPSW) to non-GE producers would not require a permit for interstate movement or importation, although environmental release would. Consequently, relative to potential impacts of APHIS authorized interstate movements and importations on invertebrate species; Alternative 3 is the same as or similar to that described for the Preferred Alternative, as the scope of GE organisms that would be permitted for transport, permit requirements, and compliance, enforcement, and remediation actions, would be the same.

4.3.2.3.3 Authorization of Environmental Release

Under Alternative 3 authorized environmental releases would include all regulated GE plants and other organisms that were field tested or utilized for commercial purposes. Potential impacts to invertebrate species would be the same as that described for the No Action and Preferred Alternative. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have more stringent requirements than permits for commercial cultivation of MPNW, as MPNW would not present any biotic risk as plant pests or noxious weeds. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, save for inclusion of MPNW. As with the No Action and Preferred Alternatives, APHIS would require applicants provide a Critical Habitat analysis, which would be reviewed by APHIS and used in determination of approval of the environmental release (discussed further in Chapter 6).

All non-GE crop producers wishing to receive protections under APHIS regulations would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning system on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

One consideration relative to wide-scale permitting is that, where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate a non-regulated traditionally bred crop plant under a conventional or organic cropping system. If this were to occur, an increase in insecticide and fungicide use could occur where an insect or disease resistant GE crop plant were supplanted for use of the non-GE crop plant in a conventional cropping system. Likewise, where a glyphosate-resistant crop were abandoned for the conventionally bred cultivar, there would be an increase in use of other herbicides, which may not be as environmentally benign. Were such shifts in crop cultivation to occur, this Alternative could potentially lead to agronomic practices that were less beneficial to invertebrate communities, largely in the way of increased inputs of synthetic pesticides.

The likelihood of some growers opting to produce a particular non-GE crop plant utilizing a conventional or organic cropping system, as opposed to the GE plant variety, and the degree to which any such shift in choice may occur, is indeterminate. Potential changes in agronomic practices associated with such a shift in the choice of crop cultivation could potentially adversely affect invertebrate communities, relative to the particular agronomic practices utilized in production of the non-GE crop plant under a conventional cropping system (e.g., increase in conventional tillage, increased use of insecticide). That said, the diversity and density of populations of invertebrate species in and around commercial crop fields, to include orchards, is substantially less than that found in an unmanaged environment. Hence, “adverse effects” are relative to the agroecosystem. Potential adverse effects would also extend to aquatic ecosystems, where pesticides inputs can have significant adverse impacts (subsection 4.2.2).

Bearing these considerations in mind, when APHIS determined that a GE organism is not subject to 7 CFR part 340, that organism would still be subject to compliance with EPA, and

other federal, state, and county requirements. Use of pesticides on GE and non-GE crops would be regulated by the EPA, as under the No Action and Preferred Alternatives. Likewise, commercial cultivation of GE crop plants comprised of an EPA registered PIP, and use of GE microbial pesticides in commercial cropping systems, would be regulated by the EPA. For GE plants developed for human or animal food purposes, the FDA recommends that developers of GE plant varieties intended for food use consult with the FDA about the safety and composition of the GE variety prior to its introduction into the food supply. Developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006).

4.3.2.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative, however, these activities would be extended to MPNW, and would incur expanded responsibilities for developers, growers of GE crops, growers of non-GE crops, and APHIS, as detailed in chapter 2 (section 2.3). The extended oversight of MPNW would have no significant effect on invertebrate populations.

4.3.2.3.5 Determination of Regulatory Status

Determination of regulatory oversight would essentially be the same as that described for the Preferred Alternative, save for inclusion of MPNW. The petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined did not pose a plant pest, noxious weed, or MPNW risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements. For those GE crop plants APHIS determined were not subject to regulation under Alternative 3, the potential impacts on invertebrate communities in and around commercial cropping systems, both beneficial and adverse, would be essentially the same as that those GE crop plants currently cultivated. Pesticide use, to include GE plants and other organisms with pesticidal properties, would be regulated by the EPA. However, as discussed above for environmental releases, if growers opt to produce conventional cultivars in lieu of the GE variety, there could be seen an increase in insecticide use, and potential for use less environmentally benign herbicides where dicamba, glufosinate, or glyphosate resistant crops where abandoned

4.3.3 Vertebrate Animals

4.3.3.1 No Action Alternative: Animal Communities

4.3.3.1.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of GE organisms that are considered plant pests under permit or notification (USDA-APHIS 2011, USDA-APHIS 2012). These activities may be authorized in any of the U.S. state, commonwealth, or territory.

4.3.3.1.2 Authorization of Interstate Movement and Importation

APHIS has specific requirements for securing the shipment of GE organisms (USDA-APHIS 2011, USDA-APHIS 2012), to include specifications for the types of containers (§ 340.8(b)), and marking and identity requirements (§ 340.7). As part of permit authorization, APHIS analyzes the potential effects of the permit request on federally listed threatened and endangered species (T&E) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act (ESA). To facilitate this analysis, permit applicants are asked to provide a preliminary Critical Habitat analysis which is reviewed by APHIS and used in the final analysis.

Authorization of the movement or importation of GE organisms generally presents little risk to vertebrate animals when conducted according to APHIS permit and notification confinement requirements. Shipments of GE organisms are conducted in sealed containers between defined locations and confinement requirements designed so that no interaction with the environment will occur. Where confinement is a basic component of notifications and permits, human error and container failure will inevitably occur at some point in time, consequently, mitigation measures are required to minimize potential adverse effects of unauthorized releases. Very few of these movements have resulted in incidents of noncompliance, such as shipment without proper identification. None have resulted in adverse impacts to vertebrate animals.

4.3.3.1.3 Authorization of Environmental Release

Under the No Action Alternative, APHIS authorizes environmental releases under permit or notification. For notifications, the notifier must meet eligibility requirements specified in 7 CFR part 340.3 (b)(4)(ii) and 7 CFR part 340.3 (6). GE organisms that are engineered with traits that are potentially toxic to non-target organisms likely to feed on the plant, and those that are engineered with sequences that are derived from animal pathogens are not eligible for notification, and require a permit. For permits, the applicant must submit the information listed in 7 CFR part 340.4. For GE organisms that may present unique environmental risks, to include to vertebrate animals, such as GE plants developed to produce a pharmaceutical or industrial product, APHIS requires additional information, standard operational procedure (SOPs), and personnel training (68 FR 11337-11340). The individual who is issued a permit must comply with permit conditions and any supplemental conditions required by APHIS.

Cropping systems used during field trials can be host to a variety of animal species. Vertebrate animals include mammals, birds, reptiles, and amphibians all of which may use

field tested crop plants and surrounding vegetation for food. Generally, disturbed habitats, highly managed environments such a crop fields, are low in biodiversity and support limited populations of vertebrate animals; namely rodents, deer, and birds that may feed on certain crop plants such corn, soybean, and orchard crops such as apples. As with movement and importation, APHIS requires those requesting authorization via notification or permit to identify whether the proposed release site and/or area to be monitored are within, or in close proximity, to designated critical habitat for a listed threatened or endangered species or within habitat proposed for designation under the Endangered Species Act (ESA) of 1973, as amended (see Chapter 6).

The potential effects of GE plants on vertebrate animals during field trials depends on the trait gene and gene product(s) expressed and the animals that are consuming the regulated GE plant. For instance, some plants developed to express pharmaceutical or industrial compounds may present unique concerns in regard to potential impacts on vertebrate animals, if the expressed protein is biologically active and consumed. Potential adverse effects on wildlife from authorized field trials is also dependent on the acreage utilized for the field trial, and duration of the field trial. These factors can contribute to the likelihood of wildlife interacting with the GE organism being field tested. When there is a potential for adverse effects on vertebrate wildlife that may interact with the field trial APHIS attempts to design permit conditions that restrict access to the field trial. Requirements for field testing of GE plants that produce pharmaceutical or industrial compounds are particularly stringent.

The type of pesticides that may be used in cultivation of the crop also require consideration. Before a pesticide can be used during an APHIS authorized field trial it must be registered by the EPA. Before a pesticide can be registered for use it must have undergone review for potential harm to humans, wildlife, plants, and surface water or groundwater.[132] Once registered, developers are required, by law, to use pesticides pursuant to EPA label requirements and other EPA use requirements, such as those issued under an EPA Experimental Use Permit (EUP). Other aspects of field testing relevant to vertebrate animals are discussed under the sections water resources (4.2.2), invertebrates (4.3.2), and biodiversity (4.3.7).

APHIS is unaware of any trait tested in a field trial that was harmful to vertebrate animals. To the extent individuals comply with current APHIS notification and permit requirements, EPA requirements for pesticide use, and ESA requirements, there would be little risk of harm to wildlife as a result of APHIS authorized field testing of GE organisms. Under the current regulatory review and authorization process there are no known adverse effects on animal communities that have resulted from authorized field trials, and the current authorization procedures considered protective of wildlife.

4.3.3.1.4 Compliance, Enforcement, and Remediation

APHIS compliance and enforcement activities are to ensure confinement of the GE organism to the areas authorized for import, movement, or field testing, and isolate environmental interaction of the regulated organism to the authorized site of release or route of transport.

[132] EPA - Data Requirements for Pesticide Registration: https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration

APHIS works with state departments of agriculture and other federal agencies, including the FDA, EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations.

APHIS performs targeted and random inspections of field tests to evaluate potential noncompliance incidents. APHIS also evaluates facilities, equipment, records, and potential incidents reported by those authorized to move of field release a GE organism. Authorizations under the permitting and notification procedures require that noncompliance incidents be reported to APHIS within designated time frames. Recordkeeping, reporting, and inspection all work in concert to monitor the authorized environmental release of regulated GE organisms. If there is an incident of noncompliance APHIS requires remedial actions as appropriate to the violation and informs other federal agencies of potential issues that may arise due to these incidents.

Remediation can be required if a violation has occurred, and based on an assessment of risk, it is determined that actions must be taken to control the GE organism. Due to the limited scale of field testing, as well transportation or shipping routes, the effects of remediation activities on wildlife would likely be limited in geographic scope, transient in nature, and have no lasting effect on animal communities once remediation actions were determined to be completed. Under current regulations APHIS expects that compliance, enforcement, and remediation actions to have continued beneficial impacts on vertebrate animal communities by limiting exposure to regulated GE organisms during field testing, and requirements for remediation of adverse impacts in the event any occur.

4.3.3.1.5 Determination of Regulatory Status

A person may petition APHIS to consider that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, should not be regulated under 7 CFR part 340. The petitioner is required to provide APHIS information and data that evidences the proposed organism is unlikely to present a greater plant pest risk than the unmodified organism. APHIS makes its determination based on the information submitted by the petitioner, a PPRA, and NEPA analysis as appropriate (e.g., EA or EIS). As part of the PPRA, APHIS evaluates the potential for the modified gene and gene product to change plant metabolism (alter its nutritional value), potential impacts on non-target organisms beneficial to agriculture, potential changes to cultivation practices, potential impacts on plants with which the GE organism can interbreed, and potential impacts that could derive from the transfer of genetic information to organisms with which the GE organism cannot interbreed. As part of its NEPA analysis, APHIS evaluates the potential impacts of the GE organism on vertebrate animal communities.

A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines, based on the PPRA, NEPA, and other relevant information that it is unlikely to post a plant pest risk. Once APHIS determines that a GE plant or other organism is not subject to 7 CFR part 340 it has no regulatory oversight of that GE organism, and it may be used anywhere in the 50 states or U.S. territories, subject to laws and regulations administered by the EPA, FDA, and other federal and state agencies; to include those agencies administering laws and regulations for the protections of fish and wildlife. If a GE organism were determined by APHIS not to be

subject to regulation, and it were later found to present potential plant pest or noxious weed risks, APHIS would have the authority to revise its determination, and regulate that GE organism under 7 CFR part 340.

The vast majority of GE organisms that have been regulated by APHIS, and been determined to be no longer subject to 7 CFR part 340, have been crop plants. Many, but not all of these, are commercially produced in the United States (see section 3.3). It is expected this trend will continue, and that the majority of future GE organisms APHIS will be evaluating and subject to 7 CFR part 340 will be GE plants developed for agricultural, forestry, pharmaceutical, industrial, and phytoremediation purposes. APHIS will likely continue to receive inquiries regarding GE microorganisms, as well as nematodes, and GE plants with traits such as drought tolerance, disease resistance, nutrient use efficiencies, and biofortified plants.

All commercial crop production, GE and non-GE alike, can potentially affect vertebrate animals through use of agricultural inputs such as pesticides (insecticides, fungicides, herbicides), fertilizers, and practices such as tillage. Exposure to pesticides can be harmful to wildlife, and non-point source runoff of these, sediments, and fertilizers can be damaging to water resources on which vertebrate communities depend. Before a pesticide can be sold on the market, the EPA determines the level of use that ensures it will not cause unreasonable harmful effects on wildlife or the environment, and specifies usage requirements of the pesticide label.[133]

Unfortunately, vertebrate wildlife are generally undesirable in cropping systems, to include organic systems, as crop damage (e.g., depredation) can cause significant losses in yield, on the order of hundreds of millions of dollars per year, and a widespread concern in the United States.[134] The USDA-WS works directly with crop producers, providing technical and management assistance to resolve wildlife conflicts that can threaten the Nation's agricultural resources. Many states, through Cooperative Extension Services, have wildlife damage management programs that likewise provide assistance in controlling nuisance wildlife.[135] The FDA issued a final rule in 2015, the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (80 FR 74353) focusing on five major potential routes of contamination including domesticated and wild animals. To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, the FDA established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption.[136]

Where the interests of agriculture and wildlife can be competing, after over 20 years of cultivation, there are no adverse impacts on vertebrate wildlife that have derived from commercial cultivation of GE crops. A recent review of the scientific literature by the

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[133] EPA - Factsheet on Ecological Risk Assessment for Pesticides: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/factsheet-ecological-risk-assessment-pesticides

[134] USDA-WS: https://www.aphis.usda.gov/wildlife_damage/informational_notebooks/2012/Protecting_Agriculture_combined.pdf

[135] For example, see Purdue Extension: https://www.extension.purdue.edu/extmedia/FNR/FNR-265-W.pdf

[136] FDA - FSMA Final Rule on Produce Safety: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

National Academy of Sciences found little evidence to connect GE crops with adverse agronomic or environmental problems (NAS 2016b).

The EPA, under FIFRA, regulates the registration, sale, and distribution of pesticides used in association with GE plants, including regulation of PIPs and GE microbial pesticides. The FDA, under the FFDCA, oversees the safety of human and animal food. Before pesticides can be used on a GE crop, or GE crops containing PIPs can be commercially produced, the EPA considers factors such as risks to vertebrate animals. The EPA requires certain tests to be conducted to identify such risks. These tests include mammalian toxicity testing of trait proteins or other gene products, comparison of trait proteins or other gene products to known toxins and allergens, and toxicity testing on birds, rodents, and fish.

In regard to production of commercial GE crops; crop production practices can somewhat vary among GE and non-GE cropping systems, and affect terrestrial and aquatic species directly or indirectly. The adoption of conservation tillage and no-till practices associated with the use of herbicide resistant crops is generally considered to benefit wildlife through improvements in water quality, availability of crop residues, and increased populations of invertebrates, which can serve as a food source for some wildlife, such rodents and birds.[137] Increased crop residue provides habitat for insects and other arthropods, consequently increasing this food source for insect predators. Insects are important food sources during the spring and summer brood season for many game birds and other birds because they provide a protein-rich diet to fast-growing young, as well as a nutrient-rich diet for migratory birds. In general, conservation tillage practices that leave greater amounts of crop residue can serve to increase the diversity and density of birds and mammals in the area of field crops. Areas where GE Bt crops are cultivated can have greater biodiversity than their non-GE counterpart, and reduce insecticide inputs, both of which can be of benefit to vertebrate wildlife.

The continued emergence of herbicide resistant weeds can indirectly affect vertebrate populations through the management practices used to control such weeds. GE GR crops contributed to this problem, and glyphosate resistance weeds will continue to be a problem. Herbicide use may increase in some areas, even where IWM is implemented, to control the spread of extant herbicide resistant weed populations. Some areas may see the adoption of conventional tillage practices where resistant weed populations are particular problematic. If conventional tillage rates increase as a means of weed suppression, increased soil erosion and indirect adverse impacts on fish and terrestrial vertebrates would be expected. More intensive tillage can reduce wildlife habitat and contribute to increased sedimentation and pollutants in runoff to nearby surface waters, affecting water quality, and vertebrate wildlife dependent on those waters, directly or indirectly. Management of weed resistance by developers and producers of GE crops is discussed in section 4.3.5.

[137] While there is a correlation between conservation tillage and GE HR crops, whether there is a causal affect that GE HR cropping system itself facilitates conservation tillage has not yet been determined.

4.3.3.2 Preferred Alternative: Vertebrate Animals

4.3.3.2.1 Regulatory Scope

The Preferred Alternative would incorporate the noxious weed authority provided APHIS in the PPA; expand the range of organisms that could be considered and potentially regulated using the terms and definitions for "genetic engineering" and "GE organism"; require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures; and strengthen APHIS' compliance and enforcement program by clarifying authorities under the PPA and augmenting current approaches used to prevent or remediate potential risks to plant pest and noxious weed risks.

4.3.3.2.2 Authorization of Interstate Movement and Importation

Under the Preferred Alternative APHIS would be considering a broader range of GE organisms that would include not only potential plant pests, but potentially noxious weeds, and other organisms subject to the definitions for "genetic engineering" and "GE organism." The notification process (7 CFR § 340.3) and courtesy permits (§340.4(h) would be eliminated, and all importations and interstate movement would be conducted solely under permit. Shipping standards would be less prescriptive and more generally applicable, requiring GE organisms be handled in such a way that their identity is maintained and that they are imported or moved in a secure shipment.[138]

As described for the No Action Alternative, authorization of the movement or importation of GE organisms, which occurs between distinct locations pursuant to APHIS containment requirements, is considered to present no to little risk to vertebrate animal communities. In the unlikely event there is an unauthorized release as a result of a noncompliance incident associated with importation or interstate movement, APHIS would immediately assess the event and take the appropriate actions necessary to minimize any potential impacts to wildlife. As appropriate, APHIS would consult with the EPA and/or USFWS on measures for minimizing potential adverse effects.

4.3.3.2.3 Authorization of Environmental Release

All environmental releases of GE organisms would be conducted solely under permit. APHIS would prescribe permit conditions as required to prevent the unauthorized release of the GE organism from the test site and its persistence in the environment, as well impose limits on the areas and acreage used for environmental release. APHIS compliance and enforcement actions (discussed following) would also be revised under the Preferred Alternative. Collectively, the proposed revisions institute a broadening of APHIS' oversight of the field testing of GE organisms, which were suggested by the USDA of OIG (USDA-OIG 2015) and 2008 Food, Conservation, and Energy Act of 2008 (Farm Bill).

Any potential impacts on vertebrate animals would the same as those described for the No Action Alternative. However, in the event an unusual risk was presented by a particular GE organism-trait combination, the Preferred Alternative is considered potentially more

[138] APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation".

protective of vertebrate animals than the No Action Alternative as a result of the broader range of GE organism-trait combinations that could be considered and regulated under 7 CFR part 340, refining of permitting procedure that provides for assigning protective measures, and more clearly defined compliance, enforcement, and remediation authority, as well as reporting requirements.

4.3.3.2.4 Compliance, Enforcement, and Remediation

Under the Preferred Alternative APHIS would strengthen its compliance and enforcement program by augmenting the approaches currently used and clarifying its enforcement authority under the PPA. APHIS inspectors would have well defined access to all relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other aspects related to the importation, interstate movement, and environmental release of regulated organisms. Failure to allow APHIS inspection prior to the issuance of a permit would be grounds for the denial of a permit application. Failure to allow inspection after permit issuance would be grounds for revocation of the permit. APHIS would require that records for import or movement of a GE organisms be retained for at least 2 years, and records for environmental releases to be retained for at least 10 years after completion of all obligations required under a relevant permit or exemption. In the event of an investigation into the possible unauthorized environmental release of a regulated organism, or the release of a regulated organism during shipping, an extended record of actions taken under permit would provide APHIS the information necessary to assess compliance and determine whether enforcement and remediation actions may be needed.

Considering the proposed revisions summarized above, and detailed in section 2.2.4, and that compliance and enforcement actions could potentially encompass a broader range of potential risks in terms of GE organism-trait combinations, the Preferred Alternative could be more protective of vertebrate animals than the No Action Alternative, largely in the way of reduction of noncompliance and remediation actions, which can disturb wildlife habitat.

4.3.3.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct a PPRA and/or a WRA to inform the determination of whether a GE organism is subject to regulation and required a permit under 7 CFR part 340. GE organisms would be listed on a regulatory status register on APHIS' website as regulated or not regulated. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk. If a GE organisms were determined by APHIS not to be subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined is unlikely to pose a plant pest or noxious weed risk could be grown or utilized anywhere in the

United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

The vast majority of GE organisms for which APHIS has, and is expected to continue to issue determinations of non-regulated status are GE plants, and most of these crop plants that will be used for food, fiber, and biofuels. Hence, as with No Action Alternative, potential adverse impacts on vertebrate animals would largely derive from altered habitat in agricultural fields, use of pesticides, and impairment of water quality through run-off agricultural inputs: sources of potential impact common to both GE and conventional commercial cropping systems.

Under the Preferred Alternative, EPA oversight of pesticides, to include GE PIPs and GE microbial pesticides would remain the same, as would FDA oversight of foods derived from GE plants, with the noted exceptions. Under the proposed revisions to 7 CFR part 340, PIP containing GE plants would not be regulated by APHIS unless they presented a plant pest or noxious weed risk. As EPA usually issues experimental use permits for pesticide field trials exceeding 10 acres, there is a potential gap in the federal oversight of field trials of PIPs under 10 acres under the Preferred Alternative.

Plants genetically engineered for pharmaceutical and industrial purposes (PMPI) would require permitting under the Preferred Alternative only when APHIS determined such GE plants presented a plant pest or noxious weed risk. Consequently, APHIS would likely be regulating fewer GE P/I-producing plants under the Preferred Alternative, relative to the No Action Alternative, which also presents a potential gap in federal oversight for small scale field tests of GE P/I-producing plants.

While there are significant economic and public health benefits that can potentially be provided by plant made pharmaceutical and industrial compounds, these may also present risks if such plants are consumed by wildlife, or are inadvertently introduced into the animal food supply. Consequently, oversight of the field testing of GE P/I-producing plants is a salient concern. As discussed later in Section 4.8 – Federal, Tribal, and State Governance, APHIS is proposing several options to address this potential gap in oversight.

4.3.3.3 Alternative 3: Vertebrate Animals

4.3.3.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it incorporates noxious weed authority, utilizes the revised definitions for “genetic engineering” and “GE organism,” and risk analyses would be conducted via the PPRA and WRA. However, it expands the scope of regulation to encompass potential economic impacts. Under this alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. The WRA would include an economic effects analysis, and

APHIS would distinguish those GE organism that presented only potential economic impacts from those that presented plant pest and noxious weed risks.

If, after conducting a PPRA and/or WRA, APHIS determines that a GE organism is unlikely to pose a plant pest or noxious weed risk in the traditional sense (biotic effects), then it would not be regulated under 7 CFR part 340. However, if APHIS concludes that a GE organism is unlikely to pose a plant pest or noxious weed risk (biotic) but presented potential economic harms, then APHIS would regulate that product and require APHIS permitting for use. For the purposes of this dPEIS those with potential market impacts are termed mere presence noxious weeds (MPNW). All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. Hence, under Alternative 3 potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.3.3.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative the importation and interstate movement of regulated organisms that presented a plant pest or noxious weed risk would be conducted solely under APHIS permit. The importation and interstate movements of regulated organisms that presented potential economic harms to non-GE producers would not require a permit for importation or interstate movement, although their environmental release would. Containment requirements would be the same as those prescribed under the Preferred Alternative, as well as the permitting and technical review criteria. Hence, the potential impacts to vertebrate animal communities as result of authorization of these activities would be the same as described for the Preferred Alternative.

4.3.3.3.3 Authorization of Environmental Release

Under Alternative 3 APHIS would function as a wide-scale permitting authority; permitting not only the field testing of regulated organisms, but the commercial production of all GE crop plants and other organisms that were determined to present a potential economic impact on non-GE crop producers. One of the basic principles of this approach would be issuance of permit conditions that minimized the likelihood of cross-pollination and commingling of non-GE crops with regulated GE organisms. This framework would support the coexistence of conventional, GE, and organic crop production. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have more stringent requirements than permits for commercial cultivation of MPNW, as MPNW would not present any biotic risk as plant pests or noxious weeds. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, save for inclusion of MPNW. Permits would require identification of critical habitat in the proposed area of environmental release for compliance with the ESA.

All non-GE crop producers wishing to receive protections under APHIS regulations would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary

national pinning system on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

As most regulated GE organisms are expected to continue to be crop plants, agricultural lands would comprise the dominant use of regulated and non-regulated GE organism, hence, potential impacts on vertebrate animals would largely be limited to these and surrounding areas. Regulated GE trees, ornamental plants, and GE plants developed for pharmaceutical and industrial purposes may also be authorized for field testing. In this respect, Alternative 3 and the No Action Alternative are similar.

As for commercial crops, APHIS would require buffer zones to isolate GE and non-GE crops where there were the potential for economic harms. Buffer zones would involve small areas of land and have little impact of vertebrate animal communities in and around commercial crop fields, other than perhaps provisions of habitat if the buffer zones were unmanaged areas.

One consideration relative to Alternative 3 is that where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate conventional non-GE crops, or organic crops. In contrast to the Preferred Alternative, if the regulatory burden under 7 CFR part 340 and other factors (market price of crop commodity) facilitate growers choosing to cultivate non-GE crop varieties; conventionally bred crop varieties, to include organic production, could supplant some of the current acreage of GE crops. The overall area and acreage of U.S. cropland would remain the same/similar, as would the communities of vertebrate animal communities in and around current cropland. Where insect resistant GE crop plants were supplanted with the conventionally bred variety, there could be seen an increase in the use of insecticides to control plant pests. In this event, there could be seen some localized adverse effects in the way of increased risk of exposure of wildlife to synthetic chemical inputs. Whether any such shifts in grower choice as to cultivation of a GE or non-GE variety, and production under a conventional or organic system, would occur, is indeterminate. It is considered as a possible outcome of regulation under Alternative 3, although the likelihood of such an outcome is uncertain. The market price of the crop commodity, which can shift rather markedly, would be a determining factor in grower choice.

Where a grower decided to cultivate a traditionally bred crop plant under a USDA certified organic cropping system, these cropping systems would be expected to present lesser risks to vertebrate animals via reductions in use of synthetic chemicals for pest and disease control. Organic systems commonly use soil conservation practices, cover crops, composting, organic mulches, green manures (crops grown specifically for soil improvement), and reduced synthetic chemical inputs relative to conventional systems. Organic systems also strive to retain field biodiversity. All of these factors are beneficial to wildlife. However, conventional tillage is still practiced in some organic cropping systems, and heavy reliance on conventional tillage for pest, disease, and weed control could be detrimental to water quality. The USDA National Organic Program assists certified organic farmers with implementing tillage practices that maintains or improves the physical, chemical, and biological condition of the soil and that minimize erosion and run-off. As do conventional

and GE cropping systems, many commercial organic cropping systems may also require wildlife damage management, if the grower so decides to reduce losses to wildlife.

Bearing these considerations in mind, significant differences among the No Action, Preferred Alternative, and Alternative 3 – relative to potential effects of GE crop production on vertebrate wildlife – are not expected, with the noted exception discussed below. There could be seen, as described, a marginal increase in insecticide use, although this use would be regulated by the EPA under FIFRA. There could also be seen some degree of increase in organic crop production, considered more benign relative to potential effects on vertebrate animals. Such shifts in crop production are however, speculative.

There are differences in how GE P/I-producing plants will be regulated under the Preferred Alternative and Alternative 3, which are discussed in Section 4.8 – Federal, Tribal, and State Governance. Under Alternative 3, the majority of GE P/I-producing plants are expected to be regulated by APHIS, by virtue of expansion of noxious weed authority. Under the Preferred Alternative it is expected few such GE plants would be regulated under 7 CFR part 340, however, other regulatory options are being explored (discussed in Section 4.8 – Federal, Tribal, and State Governance). The regulatory oversight of these are of some concern, as such plants can present risks if consumed by wildlife, or are inadvertently introduced into the animal food supply. Under Alternative 3, APHIS would retain federal oversight of GE P/I-producing plants.

Under all the Alternatives considered the USDA would continue to provide for various programs that support wildlife diversity and sustainability, such as the Conservation Reserve Program (CRP),[139] and the USDA funded Sustainable Agriculture Research & Education (SARE) program.

4.3.3.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative, however, these activities would be extended to MPNW, and would incur expanded responsibilities for developers, growers of GE crops, growers of non-GE crops, and APHIS. These activities would specifically address preventing and remediating economic harms through commingling of GE and non-GE crops, and as such, would have little to no effect on wildlife.

Both this and the Preferred Alternative would strengthen APHIS' compliance program. This, in conjunction with broader scope of GE organisms considered under regulations, and potentially regulated, could provide better protections for wildlife during field testing of organism regulated under Alternative 3. This would be derive from APHIS oversight of GE organisms that may present novel risks to wildlife in the way future plant-trait combinations, organisms not captured under the scope of the No Action Alternative.

4.3.3.3.5 Determination of Regulatory Status

Determination of regulatory oversight would essentially be the same as described for the Preferred Alternative, save for evaluation of MPNW. The petition process (7 CFR § 340.6)

[139] USDA-Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation

would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and/or WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production, and those that would enter production in the future. Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. If a GE organisms were determined by APHIS not to be subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340 regulation.

Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined was not a plant pest, noxious weed, or MPNW could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

The vast majority of GE organism that APHIS has regulated, reviewed, and issued determinations of non-regulated status for have been plants – it's expected this trend will continue. In general, the vast majority of GE organisms developed for agricultural, pharmaceutical, industrial, forestry and phytoremediation purposes would be regulated under Alternative 3. It is expected that an increase in development of GE plants with stress tolerance and disease resistance would continue. There is also expected to be seen a greater variety of stacked-trait crop plants. Increases in GE ornamental plants are unlikely relative to current trends due to cost of regulation under the Alternative 3. APHIS could also see more GE microorganisms, although most these are developed for pesticidal purposes, which are regulated by the EPA under FIFRA.

The rate of innovation – development of GE organisms for various commercial purposes – could possibly be less than that under the Preferred Alternative due to cost and burden of regulatory compliance under Alternative 3. In general, it expected that certain GE plant-trait varieties, such as disease resistant varieties, will continue to be developed, the overall number of GE organisms developed, or the rate of development, however, may decline under Alternative 3.

Comprehensive regulation, and APHIS determinations of regulatory status under Alternative 3, would have little effect on the relationship between agricultural crop production and wildlife. The choices available to growers in terms of agronomic inputs and tillage practices, and GE and non-GE plants available for cultivation under conventional, GE, or organic production systems - these options would not change. Hence, the potential effects of regulated and non-regulated GE organisms on wildlife is essentially the same as the Preferred Alternative, bearing in mind potential shifts in grower choice in cultivation of a GE or non-GE crop.

4.3.4 Plant Pests and Disease

4.3.4.1 No Action Alternative: Plant Pests and Disease

4.3.4.1.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of regulated GE organisms that are, or are believed to be, plant pests under permit or notification procedure (USDA-APHIS 2011, USDA-APHIS 2012). Under current regulations APHIS considers the likelihood that a GE organism presents a plant pest risk, which is defined at 7 CFR part 340 as organisms that can which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants. The primary purpose of 7 CFR part 340 regulations, promulgating the PPA, is to prevent the dissemination and establishment of organisms that can damage agricultural plants, and the production food and fiber in the United States.

4.3.4.1.2 Authorization of Interstate Movement and Importation

APHIS authorized movements and importations of GE organisms must meet the notification performance standards and permit conditions prescribed that ensure confinement of the GE organism during shipping or movement (USDA-APHIS 2011, USDA-APHIS 2012). When requests for movement are received APHIS provides the necessary information to states for review and approval of import of a GE organism into the state.

Under 7 CFR part 340 APHIS regulates the movement and importation of any of the following GE organisms that are, or are believed to be, plant pests: insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

During 2015 APHIS issued permits or acknowledged notifications for 744 importations and 746 interstate movements. Of the imports, 617 were requested by academic and private research institutions for import of Drosophila (fruit fly). For both import and interstate movements, around 1,025 authorizations were requested by universities or public research institutions (~ 69%). Hence, the majority of imports and movements are for basic and applied research purposes.

In addition to APHIS-BRS 7 CFR part 340 requirements, GE organisms imported into the United States are subject to the APHIS Plant Protection and Quarantine (PPQ) regulations at 7 CFR parts 319–37 (covering importation of plants and seeds for planting) and 7 CFR parts 319–56 (covering fruits and vegetables imported for non-propagative use). Hence, GE organisms would have to be authorized for importation under both APHIS-BRS and APHIS-PPQ regulations.

When entities authorized to move or import GE organisms adhere to current notification and permit requirements the potential for inadvertent release of GE organisms is limited to

instances of container failure or human error. Major incidents of noncompliance have involved shipment without proper identification. Accidental releases, such as spillage of seed are possible, and would result in remediation actions at the site of release, and other sites if potentially affected. APHIS authorizations of the movement or importation of GE organisms under current regulations have not had, nor are they expected to have, any adverse effects on plant pests and diseases in the United States.

The trend in the number of requests for movement and importation are not expected to considerably change under the No Action Alternative as the types of GE organisms within the current 7 CFR part 340 regulatory scope will remain the same. However, there could be a marginal increase in requests, relative to innovation in the development of GE organisms both in the United States and abroad.

4.3.4.1.3 Authorization of Environmental Release

Field testing is part of standard research and development, and pre-market evaluation of the safety and utility of GE organisms. APHIS has authorized more than 18,400 permits and notifications for field testing of GE organisms. Most authorized field releases have involved major crop plants, and many of these have been GE plants developed for insect, viral, and fungal resistance. APHIS has authorized the field testing of over 220 GE plants developed for bacterial resistance, 1,190 for fungal resistance, 1,425 for virus resistance, and 4,800 for insect resistance.

To control and minimize GE plants or other organisms occurring beyond the area where it is intended to be tested, authorized notifications and permits are designed to limit regulated GE organisms to the field site and preclude persistence of the GE organism beyond termination of the field trial. Authorized field trials for GE plants have ranged in size from .001 acres up to 100,000 acres. The median size of an approved field trial is approximately 5 acres, and average size about 20 acres. Field trials have been authorized in almost all U.S. states, commonwealths, and territories, as described in section 3.3.4. The areas and acreage of field trials is expected to continue along current trends.

Environmental considerations for regulators when field testing GE pest and disease resistant plants are no different than those for commercial-scale production; these are for PIPs to affect non-target organisms. GE plants developed for insect or disease resistance are comprised of PIPs that target a specific group of insects or pathogen (e.g., corn rootworm, corn borer, plum pox virus). These have largely involved Cry and Cyt based PIPs for insect resistance, although APHIS has also authorized the field testing of, and subsequently deregulated, GE papaya resistant to ringspot virus (PRSV), potato resistant to the pathogenic effects of the fungus *Phytophthora infestans*, plum resistant to plum pox virus (a virus that may also infect various stone fruits such as peaches, apricots, nectarines, almonds, and cherries), and squash resistant to two viruses – the Watermelon Mosaic Virus 2 (WMV2) and Zucchini Yellow Mosaic Virus (ZYMV). GE microbial pesticides are also field tested (Wozniak 2002).

Regulation of Field Testing

APHIS regulates the field testing of insect and disease resistant GE plants, and certain GE microorganisms developed for pest and disease control (Wozniak 2002). The EPA regulates PIPs, the insect or disease resistant gene and gene product; the plant itself is not regulated by the EPA.[140]

The EPA requires that a pesticide product, to include PIPs, undergoes extensive chemical, toxicological, and field-testing before being registered as a pesticide, this includes effects on non-target populations.[141] Some testing is done under field conditions to fully understand the pesticide's properties, safety, and efficacy. Because testing undertaken as part of the registration process necessarily involves an unregistered product or is for a use not previously approved in the registration of the pesticide, the EPA sometimes must first authorize the distribution and sale for testing purposes by means of an experimental use permit (EUP) under FIFRA. The regulations at 40 CFR 172.4 contain the requirements for applications for EUPs. EPA regulations (40 CFR 172.2) provide that any person wishing to accumulate information necessary to register a pesticide under FIFRA may apply for an EUP. Applicants applying for an EUP are required to submit to the EPA data from prior testing on the GE organism on the potential toxicity and effects in or on target organisms and the potential toxicity and effects in or on non-target plants, animals, and insects at or near the field site. EUPs are time-limited and require reporting of results as well as any adverse events (6(a)2 of FIFRA). EUPs may only be used to collect data required for FIFRA Section 3 registration.

The data requirements for an EUP involving GE plants comprised of PIPs, and microbial pesticides, are discussed at 40 CFR Part 174 (Procedures and Requirements for Plant-Incorporated Protectants), and the specific tests described in part 158 (Data Requirements for Pesticides). In general, the data requirements for an EUP and Section 3 registration are similar, however, due the limited temporal and spatial scale of field tests, EUPs do not require the same level of non-target organism testing as when full commercial registration is approved through registration procedures (Wozniak 2002). Evaluation of potential non-target effects are commonly conducted as part of the EUP.

4.3.4.1.4 Compliance, Enforcement, and Remediation

APHIS compliance and enforcement activities are to help ensure that regulated GE organisms developed for pest and disease resistance are confined to the areas authorized for import, movement, or field testing. APHIS works with state departments of agriculture and other federal agencies, including the EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations. Monitoring is essential to ensuring that regulatory requirements for these activities are met. Under current regulations APHIS performs targeted and random inspections of field tests to evaluate potential noncompliance incidents. APHIS also evaluates facilities, equipment, records, and potential incidents reported by those

[140] Current and previously registered plant-incorporated protectant registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

[141] EPA - White Paper on Tier-Based Testing for the Effects of Proteinaceous Insecticidal Plant-Incorporated Protectants on Non-Target Arthropods for Regulatory Risk Assessments: https://www.epa.gov/sites/production/files/2015-09/documents/tier-based-testing.pdf

authorized to move or field test a GE organism. Authorizations under the permitting and notification procedures require that noncompliance incidents be self-reported within designated time frames. Recordkeeping, reporting, and inspection all work in concert to monitor the authorized environmental release of regulated GE organisms.

If an incident occurs, APHIS requires that authorized entities quickly comply with regulations to protect U.S. agriculture, the food supply, and the environment. Incidents with low potential impacts may require simple remedial actions, such as correcting clerical errors or improving monitoring procedures. Serious incidents such as unauthorized or accidental releases may require destruction of field test sites, quarantine of harvested crops, formal corrective action plans, or other long-term measures.

4.3.4.1.5 Determination of Regulatory Status

Under the No Action Alternative APHIS conducts a PPRA in response to petitions for determinations of non-regulated status. The PPRA includes assessment of the potential for GE organism to result in the introduction or spread of a damaging pest or disease to other plants; (2) result in the introduction, spread, and/or creation of a new disease; and/or (3) result in a significant exacerbation of a pest or disease for which APHIS has a control program.

As part of the decision-making process regarding a GE organism's regulatory status APHIS conducts the relevant environmental analyses in accordance with the National Environmental Policy Act (NEPA) to provide the Agency information on any potential environmental impacts associated with the petition request. This would include potential effects of the GE organism on plant pests and diseases, and the potential effect of a PIP on non-target organisms.

If it is determined that a GE organism is not subject to the PPA and 7 CFR part 340 regulation, APHIS has no authority over how a GE organism may be used, or whether it may be used. For example, APHIS would have no authority over the adoption of a particular GE plant, the cultivation of that plant as an agricultural commodity, or the agronomic practices used in commercial production of that plant. When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance EPA, and other federal and state agency requirements. In regard to GE organisms that contain PIPs, or are microbial pesticides, these are regulated by the EPA as described under environmental releases. Since 1995, the EPA has registered numerous PIPs,[142] which include GE plants such potato, corn, cotton, soybean, and plum. GE microbial pesticides regulated by the EPA include bacteria, fungi, viruses, protozoa, and algae.

Before making a regulatory decision about a pesticide, which includes GE plant PIPs and GE microbial pesticides, the EPA requires data on a various subjects to ensure that the product meets federal safety standards. For all pesticide products, the EPA requires testing of product composition and chemical properties, human health effects, environmental effects on non-

[142] EPA - Current and Previously Registered Section 3 Plant-Incorporated Protectant (PIP) Registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

target pests, and the fate of the pesticide in the environment. Data requirements for EPA PIP registration (40 CFR part 158) include product characterization; human health effects (e.g., toxicity, allergenicity); ecological effects (e.g., non-target species effects, environmental fate and persistence); and gene flow. Specifically for GE plant PIPs and GE microbial pesticides, the EPA examines the following types of information and data: mammalian toxicity testing (human health risks); comparison of introduced genes and gene products to known toxins and allergens; toxicity testing on birds, fish, earthworms, and representative insects such as bees, ladybird beetles, and lacewings; toxicity testing on insects related to target insect pests; and the length of time required for the new proteins to degrade in the environment.[143] GE plant PIPs and microbial pesticides that pass EPA's evaluation under FIFRA are granted a license or "registration" that permits their sale and use according to the requirements set by EPA to protect human health and the environment.

Growers in different regions of the United States are faced with different types of pests and disease. Consequently, growers will adopt certain GE crop plants developed for insect and/or disease resistance, and employ different management practices, depending on what pests and diseases are present or emerging. There are several insecticidal proteins derived from Bt, crystal (Cry) and cytolytic (Cyt), each of which is toxic to different orders of insect (Palma, Muñoz et al. 2014). Target insects include corn rootworm (Coleoptera), flies and midges (Diptera), corn borer (Lepidoptera), and many others, as described in section 3.6.3. Owing to the agricultural and environmental benefits that have been provided, insect and disease resistant crop plants are widely cultivated in a variety of commercial crops (corn, soybean, cotton), and their use expected to continue, if not increase.

Environmental considerations regarding the use of GE organisms developed for pest and disease control are for PIPs to affect non-target organisms, or for pests or disease to become resistant to the PIP or GE microbial pesticide.

Insect Resistance

Where insect and disease resistant GE crop plants are well recognized as providing agricultural and environmental benefits while meeting market demand for food and fiber, there are concerns among the EPA, developers, and producers regarding the development of resistance to PIPs among target pest populations. Target insect pests can become resistant to the PIP, a natural process that would occur over time as a result of the PIP selecting for populations that were not susceptible to the effects of the PIP. The issue is not specific nor unique to the GE plant or PIP; this is inherent to virtually any substance to which a target population is exposed (e.g., antibiotic resistance among bacteria). Resistance naturally occurs among plant pests and pathogens in response to any selection pressure on a given population. Insects can develop resistance to chemical or biological agents, a gene already present the crop species, or a gene introduced by recombinant DNA techniques or other biotechnologies (Webber 1995). Microbial insecticides, likewise, can select for resistant populations. More than 500 insects and mite species are recognized as having acquired resistance to a number of chemical insecticides, as well that of related conventional biopesticides such as microbial Bt sprays.(McGaughey and Whalon 1992, Webber 1995). Consequently, the development

[143] EPA - Overview of Plant Incorporated Protectants: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants#assessment

(selection for) of target insect populations with resistance to Bt toxins is a concern. Where resistance occurs, the efficacy and utility of the GE plant or organism is reduced. Hence, for insect and disease resistant GE plants to be of long-term value to commercial crop production, they have to be used in a sustainable manner (NAS 2016b).

For example, in some areas of the country corn rootworm is becoming resistant to single trait Bt products. The extensive use of Bt based crops for insect control, which began being used in the mid 1990s, is contributing to the development of corn rootworm resistance. This is fundamentally a crop management issue common to all pesticides used on crops, as it is with herbicides and weeds. Where an insect pest is resistant to the Cry and Cyt δ-endotoxins; other pesticides, as well as non-chemical crop management practices, would necessarily need to be employed.

In response to the potential for development of PIP resistant populations, industry and the EPA are instituting measures to curtail further development of resistant populations.[144] Currently, these primarily involve implementation of recommended insect resistance management practices. [145] The EPA requires companies supplying GE Bt seed to implement an Integrated Pest Management (IPM) program for corn rootworm management, and work with growers to implement IPMs. IPM practices that are required by EPA include rotation to an alternate non-corn rootworm host crop; planting of pyramided (stacked-trait) Bt corn; rotating crops to an alternate PIP; and planting of non-Bt corn rootworm protected corn with a soil-applied insecticide at planting. The EPA also requires the planting of refuges for GE Bt crops comprising EPA registered PIPs. Refuges are areas within or close to a field test site where non-GE plants of the same GE plant species are planted. Refuges encourage the interbreeding of resistant and nonresistant insects, reducing the likelihood of pesticide-resistant offspring. In general, Insect Resistance Management (IRM) plans and refuges are recommended for all Bt crops. Farmers are required to implement IRM plans for all Bt crops grown in the United States in order to reduce the probability that insects susceptible to Bt will develop resistance. [146]

A Center for Science in the Public Interest (CSPI) report in 2009 found that compliance with refuge size and distance requirements has not been consistent, with compliance for refuge size ranging from greater than 90% during the 2003 to 2005 year period, to 74% in 2008.147 Corn rootworm refuge distance compliance percentages fell from 82% percent to 63% over the same time frame. Compliance has since improved[148] but remains an ongoing concern. Hence, compliance programs are important to assist/encourage growers to comply with EPA

[144] EPA - Framework to Delay Corn Rootworm Resistance: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/framework-delay-corn-rootworm-resistance

[145] EPA - Insect Resistance Management Fact Sheet for Bacillus thuringiensis (Bt) Corn Products: https://www3.epa.gov/pesticides/biopesticides/pips/bt_corn_refuge_2006.htm

[146] Insect Resistance Management Plans - The Farmers' Perspective: http://www.agbioforum.org/v10n1/v10n1a04-alexander.htm

[147] Iowa State University Extension - Compliance or Complacency: Corn Producers and Bt Refuge; http://crops.extension.iastate.edu/cropnews/2010/04/compliance-or-complacency-corn-producers-and-bt-refuge

[148] NCGA: http://www.ncga.com/news-and-resources/news-stories/article/2015/02/refuge-compliance-report-shows-increased-compliance-in-2014

IRM and industry stewardship requirements (Tabashnik, Brevault et al. 2013). Groups like the National Corn Growers Association (NCGA) are promoting compliance education programs, and there are industry efforts to address this problem, namely through education and outreach.

Overall, the National Academy of Sciences (NAS) concluded in a recent review that the high dose/refuge strategy for delaying evolution of resistance to Bt based PIPs appears to be successful, but deployment of GE Bt crops with intermediate levels of Bt PIPs and small refuges has sometimes resulted in the evolution of insect pest resistance, which can erode the benefits of GE Bt crops (NAS 2016b). Consequently, the NAS recommends that development and utilization of GE PIP varieties without a high dose PIP should be discouraged, and use of appropriate refuges should be incentivized (NAS 2016b).

Relative to Potential Effects on Non-target Species

The Cry and Cyt proteins (δ-endotoxins) produced by *B. thuringiensis*, those proteins expressed in Bt crop plants, have been used to control insect pests in United States since the 1960s (US-EPA 1998). There are around 180 products on the market, which are commonly applied as liquid sprays or dusts. Some of these products are approved for use in organic agriculture. Hence, Bt based pesticides are not new, and studies on the toxicity of Bt to humans and wildlife have been conducted since adoption of the insecticide in the1960s (Heimpel 1967). The potential impact of Bt crops, specifically, on non-target organisms has been fairly well studied. Since 2008, over 360 research articles have been published on the non-target effects of Bt crops on invertebrate organisms (Naranjo 2009). Note that the findings from these studies are also discussed in section 0 – Invertebrates, and 4.3.1 – Soil Biota, and 4.3.7 – Biodiversity.

In general, GE Bt plants appear to have little adverse effects on soil biota such as earthworms and soil microflora (Saxena and Stotzky 2001, Baumgarte and Tebbe 2005, Icoz and Stotzky 2008, Zeilinger, Andow, Zwahlen et al. 2010, Carpenter 2011, Turrini, Sbrana et al. 2015).

The potential non-target impacts of insect resistant Bt crops on above-ground invertebrates have been extensively studied. Several reviews of the literature have been published, concluding that adverse effects of GE Bt plants on non-target populations appear to be minimal, if effects were observed (Wolfenbarger, Naranjo et al. 2008, Naranjo 2009, Carpenter 2011). There have been some effects of Cry and Cyt proteins on non-target organism reported in the literature, namely soil microbial communities, although effects are not consistently observed and differences in effects attributed to variances in geography, temperature, plant variety, and soil type (Wolfenbarger, Naranjo et al. 2008). For example, a two year field study examined how four different genotypic lines of GE corn may alter the structure of arthropod food webs relative to non-GE corn (control) that is widely used in commercial agriculture. The GE corn studied produced either Bt toxins, conferred glyphosate resistance or a combination of the two traits. The findings from these studies suggest that at least in short-term, GE Bt crop plants have no adverse effects on arthropod biota of agricultural landscapes (Szenasi, Palinkas, Zalai et al. 2014). Overall, no uniform effects of Bt cotton, corn, and potato on the functional guilds of non-target arthropods have been detected (Wolfenbarger, Naranjo et al. 2008).

There was some concern that Bt crops were adversely impacting monarch butterfly (*Danaus plexippus*) populations. A two year collaborative research effort by scientists in the United States and Canada concluded that the impact of Bt corn pollen from current commercial hybrids on monarch butterfly populations is negligible (Sears, Hellmich, Stanley-Horn et al. 2001). There has also been some concern that that the widespread planting of GE crop plants could harm honey bee populations. A meta-analysis of 25 studies investigating the potential effects of Bt Cry proteins on honey bee mortality found that Bt Cry proteins used in GE crops for control of lepidopteran and coleopteran pests have no adverse effects on the survival of either honey bee larvae or adults in laboratory settings (Duan, Marvier, Huesing et al. 2008).

Indirect effects on the natural predators, parasites, and pathogens of target insects such as European corn borer, could conceptually occur, as populations of predators, parasites, and pathogens of target insects would decline as their host populations decline. While at face value this would be a logical assumption, a 2010 National Research Council report on the relationship between GE crops and farm sustainability in the United States noted that generalist predator populations tended to be unchanged or were actually more abundant in fields where Bt crops were cultivated, relative to the non-Bt crop (NRC 2010a). This observation was likewise reported in a more recent review by Lu et al. (2012). Examining data spanning from 1990 to 2010, across 36 sites in six provinces of Northern China, there was observed a marked increase in populations of three types of generalist predators (ladybirds, lacewings and spiders) and a decrease in aphid pests was associated with the cultivation of Bt cotton. The increase in generalist predator populations is attributed to reductions in insecticide use with Bt based crops (Brookes and Barfoot 2010, NRC 2010a, Lu, Wu, Jiang et al. 2012). Lu et al. also suggest that the increased generalist predator populations observed in Bt cropping systems, relative to the non-GE crop plant, may provide for biocontrol in neighboring crops (e.g., corn, peanut, and soybean) (Lu, Wu et al. 2012).

In general, scientific evidence to date supports the conclusion that Cry and Cyt proteins are highly selective for insect pests of the orders the orders Coleoptera, Diptera, and Lepidoptera, and have not been found to significantly affect populations of beneficial insects such as bees, lady beetles, green lacewing, spiders, or parasitic wasps (e.g., review by (Naranjo 2009). Bt is essentially non-toxic or pathogenic to birds, rodents, fish, and shrimp, and the potential for adverse impacts of Bt corn pollen on monarch butterfly populations is considered negligible (Sears, Hellmich et al. 2001, USDA-ARS 2015). Similarly, adverse effects of GE Bt crop plants on honey bee larvae or adults have not been observed in laboratory or mesocosm studies (Duan, Marvier et al. 2008, Hendriksma, Kuting, Hartel et al. 2013).

There has been some concern among stakeholders regarding the use of newer RNAi based mechanisms to protect plants from insects and disease, and the potential effects of such PIPs on human and environmental health (Sherman, Munyikwa et al. 2015). As with any emerging technology, the potential range of future RNAi based PIP products, their regulation, and public acceptance of the technology will continue to evolve (Sherman, Munyikwa et al. 2015). The current framework for the risk assessment of RNAi based PIPs is found in the EPA's white paper on use of RNAi technology as a pesticide (US-EPA 2013b,

US-EPA 2014b). The EPA convened a Scientific Advisory Panel Meeting (SAP)149 meeting in 2014 (US-EPA 2014b). Regarding the potential ecological impacts of RNAi constructs, the Panel agreed with concerns raised by the EPA on the inadequacies of the current environmental fate and non-target effects testing frameworks for RNAi based PIPs, as well as those exogenously applied. The Panel recommended an exposure-based model to reduce the uncertainties in the ecological risk assessment of RNAi PIPs and RNAi based non-PIP products. It was decided that this approach would identify non-target organisms that might be exposed, and the spectrum of non-target organisms that would need to be tested for effects (US-EPA 2014b).

While the science indicates that current PIP based GE crop plants present minimal risk to non-target populations, the potential for future PIP based crops to have adverse effects on non-target organisms will remain an ongoing consideration among the scientific and regulatory communities, both in the United States and abroad, as new PIPs emerge, and PIPs are incorporated into plants as stacked-traits (or pyramided), and at different levels of expression. Likewise, regulatory process and procedure to ensure sufficient evaluation of the human and ecological risks of such PIPs will continue to evolve (US-EPA 2013b, US-EPA 2014b, Sherman, Munyikwa et al. 2015).

Environmental Benefits

While the potential for adverse effects on non-target species exists, insect and disease resistant GE cropping systems, for the most part, are considered more environmentally benign than cropping systems utilizing traditional chemical pesticides (Gatehouse, Ferry, Edwards et al. 2011, Brookes and Barfoot 2013a)}, and highly effective in controlling target plant pests and diseases that can significantly impair crop yields. In general, based on data over the years 1995 through 2014, there has been a pronounced reduction in pesticide used on GE Bt-crops; approximately by 41.7% (Klümper and Qaim 2014). For both GE IR and HR crops, pesticide use was found to be reduced by 37% (Klümper and Qaim 2014). Cultivation of GE Bt crops can also suppress area wide plant pest populations, which benefits crops in nearby fields, to include non-GE cropping systems, and reduces the need for insecticide use in nearby cropping systems(Carpenter 2011). While the environmental benefits conferred by such reductions in pesticide use are more obvious, such reductions likewise reduce exposure of farmworkers to pesticides, and incidences of pesticide poisoning (Kouser and Qaim 2011). A further benefit that has been realized since adoption of these varieties of GE crop plants is that they can also improve food safety by reducing post-harvest infection of grains by fungi, thereby lowering levels of mycotoxins in human and animal food commodities. Mycotoxins, namely fumonisin and aflatoxin, can be a significant contaminants of food (Wu 2006), and are known to have adverse health effects in animals, and likewise a human health risk (Abbas, Cartwright, Xie et al. 2006, Wild and Gong 2010).

[149] The FIFRA SAP is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act and established under the provisions of FIFRA as amended by the Food Quality Protection Act (FQPA) of 1996.

4.3.4.2 Preferred Alternative: Plant Pests and Disease

4.3.4.2.1 Regulatory Scope

The PPA provides APHIS two authorities that could be used in regulating GE organisms: plant pest authority (the basis of current 7 CFR part 340 regulations) and noxious weed authority. The term ‘‘noxious weed’’ is defined as “any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.”

The Preferred Alternative broadens the scope of GE organism that could be considered under regulations by clarifying APHIS’ noxious weed authority under the PPA (7 U.S.C. §7701(7)) and providing new terms and definitions for “genetic engineering” and “GE organism.” Hence, the proposed revisions are, in part, intended to broaden APHIS’s regulatory scope by explicit inclusion of APHIS’ noxious weed authority, and redefining the types organisms that may be subject to regulation.

APHIS would remove the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures, and strengthen its compliance and enforcement program by clarifying the full range of authorities and penalties granted under the PPA.

Fundamentally, the proposed revisions to 7 CFR part 340 address how APHIS implements its statutory authority under the PPA, and implements APHIS’ new weed risk assessment (WRA) tool for GE plants, described in Chapter 2 under the Preferred Alternative. Under the Preferred Alternative APHIS’ approach would be to analyze plant pest and noxious weed risks first (as opposed to conduct of a PPRA in response to petition under current regulations), and publish on APHIS’ website via a regulatory status register which GE organisms presented a potential plant pest or noxious weed risk, and which were determined unlikely to present a risk.

For noxious weeds, interpretation of harm to agricultural interests could extend to certain GE organisms that are unlikely to present a plant pest risk under the PPA, but did present a risk as a noxious weed. For instance, this could include certain biotechnology derived plants such as trees, and those developed for production of pharmaceutical and industrial products, which may be species that are fast growing, prolific, and hardy. Where the scope of GE organisms considered and potentially regulated is broadened, the purpose of the PPA, and APHIS implementing regulations, is the protection of agricultural production, the environment, and economy of the United States. By extension, the proposed revisions to7 CFR part 340, including explicit incorporation of noxious weed authority, are to serve the same purpose.

4.3.4.2.2 Authorization of Interstate Movement and Importation

APHIS is proposing to eliminate the notification process and all importations and interstate movements of regulated organism would be conducted solely under APHIS permit. APHIS would use a performance-based approach for shipping of GE organisms (section 2.2.3.1) and require they be handled in such a way that their identity is maintained and that they are

imported or moved in a secure shipment.[150] Movements of regulated organisms, those determined by APHIS via the PPRA and/or WRA to be a plant pest or noxious weed risk, would have to meet all containment requirements defined within the new regulations and shipped in such a way that there is no release into the environment. Specifics regarding labeling and the methods of secure shipment would be included as permit conditions.

All locations where regulated organisms are received, stored, distributed, or released into the environment would have to be identified within a permit if movement occurs. This includes but is not limited to greenhouses; laboratories; growth chambers; field trial locations; production, propagation, sale, distribution, and manufacturing locations.

Under this Alternative APHIS regulation of interstate movement and importation would encompass a broader range of organisms subject to the terms and definitions for "genetic engineering" and "GE organism," in addition to noxious weeds, which is considered to provide better protection of agricultural plant health. Movement and importation would be conducted by authorized permit only, which would allow for issuing of specific containment requirements where there were particular concern in regard to GE organism being moved. Consequently, as with the No Action Alternative, the Preferred Alternative provides for issuing of any requirements necessary to protect against the potential release and dissemination of regulated GE organisms that could adversely affect agricultural production in the United States.

4.3.4.2.3 Authorization of Environmental Release

In 2005 and 2015 the USDA's Office of Inspector General (OIG) conducted audits of APHIS' current regulatory program for GE organisms. The OIG suggested that APHIS revise the regulations to minimize the risk of inadvertent dissemination of regulated articles from an authorized field site, and encouraged APHIS to revise the regulations to provide broader oversight of environmental releases (USDA-OIG 2015).

As part of implementing these recommendation field trials of GE organisms under the Preferred Alternative would be conducted solely under APHIS authorized permits. As with the No Action Alternative, APHIS would prescribe permit conditions designed to prevent the unauthorized release of the GE organism from the field site and its persistence in the environment on conclusion of the field trial. As a result of the broader range of GE organisms considered, and potentially regulated under part 340; release of regulated organism only under conditional permit; and revisions to compliance and enforcement activities (described following); the Preferred Alternative could potentially provide better protections than the No Action Alternative in oversight of authorized field releases. As described under the No Action Alternative, APHIS would regulate the field testing of insect and disease resistant GE plants, and certain microorganisms developed for pest and disease prevention. The EPA would continue regulation of PIPs, and issuance of Experimental Use Permits (EUPs) for field testing of PIPs.

[150] APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation".

The singular environmental concern in field testing of insect and disease resistant GE plants, and microbial pesticides, is in regard to potential impacts on non-target species. These potential impacts would be the same as described under the No Action Alternative. Authorization of release only under permit, which could prescribe specific conditions for protection of non-target organisms, is potentially more protective than current authorizations under notification procedure.

4.3.4.2.4 Compliance, Enforcement, and Remediation

The Preferred Alternative would strengthen the compliance and enforcement program by augmenting the approaches currently used. The proposed revisions to APHIS compliance and enforcement activities would implement the USDA OIG recommendations described above.

APHIS would clarify what locations and regulated organisms may be subject to inspection and expand reporting requirements. Responsible persons would be required to provide APHIS inspectors access to any relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other articles related to the importation, interstate movement, and environmental release of organisms regulated under 7 CFR part 340.

As described in section 2.2, APHIS would revise requirements for the establishment and maintenance of records, and provision of APHIS inspectors with all required records upon request. APHIS proposes to require that certain records would have to be retained for periods of up to 10 years after completion of obligations required under permit or exemption. Record keeping requirements would facilitate compliance, and implementation of remedial measures and penalties in the event of an unauthorized release, such as the persistence of a regulated organism at the field site.

The purpose of many of the GE organisms field tested, a primary goal in the development of GE organisms, is for protection against plant pests and disease. The GE organisms themselves, those field tested to date have, and are expected to continue to, present negligible risk to plant health. Issues of development of resistance to PIPs have been discussed above under the No Action Alternative. Due to temporal and spatial limits of field testing, development of insect resistance to PIPs in the areas of field tests is not a significant concern.

4.3.4.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct plant pest risk assessments (PPRA) and/or a weed risk assessments (WRA) to inform the determination of whether a GE organism is subject to regulation and required a permit under 7 CFR part 340. The PPRA includes assessment of the potential for GE organism to result in the introduction or spread of a damaging pest or disease to other plants; (2) result in the introduction, spread, and/or creation of a new disease; and/or (3) result in a significant exacerbation of a pest or disease for which APHIS has a control program. As part of the decision-making process regarding a GE organism's regulatory status APHIS conducts the relevant environmental analyses in accordance with the National Environmental Policy Act (NEPA) to provide the Agency information on any

potential environmental impacts associated with the petition request. This would include potential effects of the GE organism on plant pests and diseases, and the effect of PIPs on non-target organisms.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under Section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined is unlikely to pose a plant pest or noxious weed risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

As with current regulations, if it is determined that a GE organism is not subject to 7 CFR part 340, APHIS would have no authority over how a GE organism may be used, or whether it may be used. For example, APHIS would have no authority over the adoption of insect and disease resistant GE crop plants, the cultivation of that plant as an agricultural commodity, or the agronomic practices used in commercial production of that GE plant. When APHIS determined that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance EPA, and other federal and state agency requirements. In regard to GE organisms that contain PIPs, or are microbial pesticides, these would continue to be regulated by the EPA, as described under the No Action Alternative and throughout this dPEIS.

However, the Preferred Alternative differs from the No Action Alternative in that, as a result of a more efficient process for determination of regulatory status (see section 2.2.2.3), there will be an increase in the number of GE organisms evaluated for plant pest and noxious weed risk. Because most GE plants developed for agricultural purposes are not plant pests, nor are they likely to present noxious weed risks, it is expected that most GE plants APHIS reviews via the PPRA and WRA would not be subject to regulation as plant pests or noxious weeds. Consequently, more non-regulated GE crop plants will be available for commercial uses, relative to review and approval by the EPA and the FDA's voluntary consultation process, as applicable, and if adopted for commercial production would supplant current acreage for conventional crops. This would include, likely, a greater variety of insect and disease resistant GE crop plants, particularly disease-resistant varieties, and stacked-trait varieties resistant to both a particular insect pest, and disease. Under the Preferred Alternative, there may also be seen an increase in insect and disease resistant ornamental plants, given that the regulatory burden on development and commercialization would be reduced, for certain species of ornamentals.

Where insect and disease-resistant GE crops were adopted and less insecticide and fungicide were used, there would be a commensurate decrease in the risk of exposure of humans and wildlife to insecticides and fungicides. In general, the environmental, human health, and economic benefits conferred through cultivation of insect and disease-resistant GE crops would continue where these varieties of crops were cultivated. Conceptually, where there were effective utilization of insect and disease-resistant GE crop plants, there would likely be seen a reduction in pest and disease populations in the areas where these crops are cultivated, by virtue of suppression of reproduction of target insect pests and pathogens. Hence, this

would indirectly benefit neighboring cropping systems, GE and non-GE alike, where the crop were subject to damage by the plant pest or pathogen populations suppressed. These benefits would be in the way of reduced crop damage, which can increase product quality and yield, and a reduction in the overall use of synthetic pesticides for control of plant pests and disease.

Where GE IR crops are used, IPM/IRM plans will be required to cultivate these crops to reduce the potential for development of resistance to the PIPs utilized in the GE plant varieties, and help ensure the long-term viability of such GE crop varieties (NAS 2016b).

There are no reasonably foreseeable adverse outcomes on agricultural plant pests and diseases that could derive from APHIS procedure for determination of regulatory status under the Preferred Alternative. To the contrary, this Alternative regulatory framework is considered more supportive and protective of agricultural plant health than the framework under existing part 340 regulations, as it broadens the scope of plant pest and noxious weed risks that can be considered under regulations, and potentially regulated, while reducing oversight of GE organisms that present no such risks.

4.3.4.3 Alternative 3: Plant Pests and Disease

4.3.4.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it codifies noxious weed authority, utilizes the revised definitions for “genetic engineering” and “GE organism,” and risk analyses would be conducted via the PPRA and WRA. However, under this Alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. The WRA would include an economic effects analysis, and APHIS would distinguish those GE organism that presented only potential economic impacts from those that presented plant pest and noxious weed risks. Hence, under Alternative 3 potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.3.4.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative, the notification process would be eliminated. The importation and interstate movement of regulated plant pests and noxious weeds would be conducted solely under APHIS permit. The importation and interstate movements of GE organisms that presented potential economic harms (MPNW) to non-GE crop producers would not require a permit for interstate movement or importation, although environmental release (permitted planted) would. Relative to APHIS oversight of importation and interstate movements of regulated organisms, and plant pest and disease considerations, Alternative 3 and the Preferred Alternative are functionally the same. The extension of noxious weed

authority to include potential economic harms would have no effect on APHIS oversight of plant pets and diseases in the United States.

4.3.4.3.3 Authorization of Environmental Release

Under Alternative 3, authorized environmental release of GE organisms would include regulated crop plants grown for both field testing and commercial purposes. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have more stringent requirements than permits for commercial cultivation of MPNW, as MPNW would not present any plant pest or noxious weed risks in a biological sense. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, save for inclusion of MPNW.

The number of regulated organisms would significantly increase under Alternative 3 due to inclusion of MPNW, and consequently, the number of APHIS permits required for environmental release (permitted planting). APHIS would require buffer zones to isolate GE and non-GE crops where there were the potential for economic harms, however, buffer zones would involve small areas of land and have little bearing on the overall acreage, or the area of lands allocated to crop production. To some extent, the required buffer zones could serve as biological refuge areas, similar to those required by the EPA for reduction in the potential development of insect resistance to Bt based and similar GE crops.

All non-GE crop producers wishing to receive protections under APHIS regulations would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning system on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

One consideration relative to wide-scale permitting by APHIS is that, where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate conventional non-GE crops, or organic crops. If this were to occur, there could be seen a decrease in utilization of certain insect and or disease resistant GE crops. In such instance, an increase in insecticide use could follow where a GE IR crop plant were abandoned for use of the non-GE crop plant in a conventional cropping system. Similar, where GE HR crop plants where supplanted with their conventional counterparts there would likely be seen a shift in herbicide use. For example, where glufosinate, glyphosate, and dicamba resistant GE crop plants were supplanted with non-GE crop plants, there would likely be seen shifts in the use of these herbicides. The choice of herbicide would depend on the nature and diversity of weed species present in a given cropping system, to include herbicide resistant weeds.

The likelihood of some growers opting to produce a particular non-GE plant utilizing a conventional or organic cropping system, as opposed to the insect or disease resistant GE plant variety as a result of APHIS regulation under Alternative 3, and the degree to which it may occur, is indeterminate. The choice in whether to cultivate a GE or non-GE variety of a crop plant would depend on how farmers interpreted regulatory requirements as burdensome; the market price of a given commodity, and seed cost, which affects the profitability of a

given crop; the species of crop plant; and the prevalence and nature of extant pests and diseases in the area of crop production. Any potential changes in insecticide use would be relative to shifts in grower preference for cultivation of a GE IR crop plant, or the non-GE variety.

It is expected that an increase in development of GE crop plants with stress tolerance (e.g, drought) and insect and disease-resistance would continue. This would include a greater variety of stacked-trait GE crop plants. Increases in insect and disease-resistant GE ornamental plants are unlikely relative to current trends due to the cost of regulation under the Alternative 3. There could be seen more GE microbial biocides as these can be highly useful. However, the rate of innovation – development of GE organisms for various commercial purposes – could possibly be less than that under the Preferred Alternative due to the cost and burden of regulatory compliance under Alternative 3. In general, it expected that certain GE plant-trait varieties, such as disease resistant varieties, will continue to be developed. The overall number of GE organisms developed, or the rate of development, however, may decline under Alternative 3. The potential outcomes of comprehensive regulation of GE plants on the relationship between agricultural crop production and management of plant pests and diseases are based on various factors, discussed following, and difficult to predict with high degree of certainty. On one hand, the choices available to growers in terms of agronomic inputs and management practices used in the control of pests and diseases, and GE and non-GE plants available for cultivation under conventional, GE, or organic production systems - these options may not significantly change. On the other hand, if, due to regulatory compliance costs, and burden of compliance requirements, it becomes economically unfeasible or difficult to produce GE crops, certain biotechnology companies may decide to allocate their resources to more profitable ventures, or reduce efforts on research and development in the agricultural sector. In these instances, the choices among insect and disease resistant GE crop plants may not significantly expand, as efforts in development and/or innovation across the agricultural biotechnology sector may wane. It is expected that some growers will likely choose to produce non-GE, versus GE varieties, due to regulatory compliance costs (monetary and non-monetary).

A further consideration is that, to the extent regulation under Alternative 3 may result in grower preference for conventionally bred crop plants that are more susceptible to plant pests and disease, there could be seen an increase in use of insecticides, and possibly fungicides, for control of pests and disease. The use of synthetic chemical pesticides would not allay issues with the potential for development of insect and pathogen resistance; the potential for development of resistance exist wherever pesticides are used, be they chemical or PIP based. Where certain soil borne pests and diseases were pernicious, increased tillage would also be a possibility, as tillage is commonly used to suppress soil borne plant pests and pathogens. Consequently, where insect and disease-resistant GE crop plants were supplanted for their conventionally bred counterparts, there could be seen less environmentally friendly crop management practices employed.

This does not necessarily imply effective pest and disease management are singularly dependent on GE crop varieties; insect and disease-resistant GE plant varieties provide one method, among a suite of practices available (e.g., biocontrol, increased biodiversity, crop rotation, IPM practices) to manage plant pests and diseases. That said, there are no

commercially available chemical pesticides that provide the combined specificity and efficacy in protection against pests and disease, as do current insect and disease resistant GE plants. For many chemical pesticides there may be equivalent efficacy, but specificity for target pests and disease would be lacking, and their use would come at an environmental cost; any increased input of synthetic chemicals into the environment brings with it inherent, well-recognized risks. Agricultural biotechnology has provided methods of insect pest and disease control that have a high degree of both efficacy and specificity, which are likely to improve with time. The tailoring of chemical pesticides that have the specificity provided through plant biotechnologies has not been achieved, and development of such products in the future remains to be seen. While it is true there are non-biotech alternatives to plant pest and disease management (chemical pesticides, tillage, crop rotation, cover crops or mulches, or using crops with allelopathic potential in the rotation, biological controls), these methods generally lack the specificity, and the human and environmental safety, plant biotechnologies provide in targeting specific plant pest insects and pathogens or creating crops resistant to wide spectrum herbicides. Ideally, plant biotechnologies are conjoined with cultural practices and biological controls for the sustained suppression of plant pests and disease, and preservation of the efficacy of the PIP or other mechanism conferring pest or disease resistance.

In general, the potential environmental benefits of insect and disease-resistant GE crop plants, relative to more traditional chemical methods of pest and disease control, can be rather significant. For example, in 2011, the global reductions in insecticide use (active ingredient) as a result of GE IR corn was reported to be 6.9 million kg/15.2 million lbs (or an 86% reduction), and for GE IR cotton 17 million kg/37.5 million lbs (a 37% reduction) (Brookes and Barfoot 2013b). Cumulatively, since 1996, there has been a 50 million kg/110.2 million lb reduction in corn insecticide active ingredient use and a 189 million kg/417.6 million lb reduction in cotton insecticide active ingredient use (Brookes and Barfoot 2013b). Various estimates are provided in the literature, although, overall, there are fewer synthetic insecticides used on GE IR crops, relative to their conventionally bred counterparts (NAS 2016b).

While insect and disease-resistant cultivars can be traditionally bred, this process can require much more time for development, and introduces traits undesirable in the plant. Traditional breeding in agriculture is commonly accepted to include mutagenic techniques such as X-ray or chemical mutagenesis, which lack the precision of more modern methods for gene transfer or genome editing. It can take more than 10 years to generate cultivars using such techniques, cultivars which can carry with them a large number of affected genes (Ricroch 2014). Hence, there can be less specificity in traditionally bred plants than that which can be achieved with more modern biotechnologies, where only one or a few genes are modified or introduced to provide a desired trait; and insect and disease resistant cultivars developed in a more timely manner. How Alternative 3 influences growers choice in cultivation of GE or non-GE crops could affect how agricultural plant pests and diseases are managed, and the efficiency by which food and fiber are produced in the United States. Where the cost and burden of regulatory compliance leads to growers supplanting insect and disease resistant GE cropping systems with a non-GE cultivar, there will be an increase in the use of chemical pesticides for control of pests and disease. It also possible that the incidence of pest and disease damage to crops (namely corn, soybean, cotton) may increase, relative to the incidence among current

crops. Hence, the abandonment of insect and disease resistant GE crops would carry with it a loss of the environmental and economic benefits that have been afforded by those varieties currently in production. While the benefits vary by GE crop trait and geographic region, a recent review found that, since adoption of GE crops in 1995, chemical pesticide cost, as part of crop production, has been reduced by 37% (Klümper and Qaim 2014). Similar findings on the benefits of insect-resistant GE crops have been reported by Brooks and Barfoot (e.g., (Brookes and Barfoot 2010, Brookes and Barfoot 2013b, Brookes and Barfoot 2015)). The most recent analysis found that biotechnology has made significant contributions to increasing global production levels of major crops. During the years 1996 - 2011, average yield gains for GE IR corn ranged from around 5% (U.S.) to 23.7% (Honduras), and for cotton 9.9% (U.S.) to 33% (India) (Brookes and Barfoot 2015).

In general, GE Bt crop plants in production from 1996 to 2015 have, in many locations, contributed to a statistically significant reductions in the gap between actual and potential yield, when target insect pests caused substantial damage to non-GE crop varieties, and synthetic chemicals did not provide control of insect pests (NAS 2016b). Similarly, the use of Bt crop varieties has been found to reduce application of synthetic insecticides in GE Bt crops, and in some cases, the use of Bt crop varieties has been associated with a reduction in use of insecticides in nearby non-GE crop fields due to area wide suppression of insect pests (NAS 2016b).

Hence, while there are a variety of tools available for the management of plant pests and disease, GE crop plants can provide one of the more effective, specific, and non-chemical (environmentally friendly) methods for doing so. To the extent Alternative 3 may deter the use insect and disease resistant GE crop plants, and alter the non-chemical management options available to growers in controlling plant pests and diseases, this Alternative could, indirectly, result in increased agricultural plant health and environmental risks, relative to the No Action and Preferred Alternative.

4.3.4.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative, however, these activities would be extended to MPNW, and would incur expanded responsibilities for APHIS, developers, growers of GE crops, and growers of non-GE crops. APHIS would include revised requirements in the regulations for the establishment and maintenance of records and provision of APHIS inspectors with all required records upon request. Biotechnology developers would be required to track and record the plantings, acreage, and location of their GE plant products being grown as well as implement a GE plant volunteer management program. Records required to be maintained would include the locations and acreage where the regulated organism was planted during field testing and copies of contracts between the responsible person and all of his/her agents as well as copies of other records (e.g., emails, telephone records). Maintenance of these types of records conjoined with inspections would facilitate preventing non-compliance incidents, and remediation of unauthorized releases of a regulated organism in the event they occur. Regulations under this and the Preferred Alternative are designed to strengthen APHIS' compliance program, and consequently expected to provide better protection of agricultural plant health than the No Action Alternative.

4.3.4.3.5 Determination of Regulatory Status

The process and criteria for determination of regulatory oversight would be the same as described for the Preferred Alternative, save for the inclusion of MPNW. The petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production. As described under environmental releases above, the potential outcomes of APHIS determinations of regulatory status would be quite different under Alternative 3, potentially affecting how plant pests and disease are managed in agricultural production systems.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined is unlikely to pose a plant pest or noxious weed risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

4.3.5 Agricultural Weeds and Noxious Weeds

This section describes potential impacts on weed management: Common agricultural weeds, the development of herbicide resistant weed populations, and noxious weeds.

4.3.5.1 No Action Alternative: Agricultural Weeds and Noxious Weeds

4.3.5.1.1 Regulatory Scope

APHIS would authorize the movement, importation, and environmental release of regulated GE organisms under current permit or notification procedure (USDA-APHIS 2011, USDA-APHIS 2012). While APHIS' noxious weed authority under federal law is mentioned in current 7 CFR part 340 regulations, it is not clearly described. One, current regulations reference APHIS authority under the Federal Noxious Weed Act (FNWA; 7 U.S.C. 2801 et seq.), which was superseded in 2000 by the Plant Protection Act (Pub.L. 106–224). Two, current regulations state regulated articles are eligible for notification if they are not listed as noxious weeds in regulations at 7 CFR part 360 under the FNWA (7 U.S.C. 2809), and, when being considered for release into the environment, the regulated article is not considered by APHIS to be a weed in the area of environmental release. The PPA of 2000, superseding the FNWA, provides APHIS broader authority over noxious weeds than the FNWA, and preventing the dissemination of noxious weeds in the United States (in addition to plant pests). APHIS revised 7 CFR part 360 regulations to implement the provisions of the PPA of 2000, however, this authority is not clearly conveyed in current 7 CFR part 340.

Noxious weeds are particular category of weed that can be especially problematic to agriculture. Noxious weed is legal term that differentiates weeds deemed noxious from

commonly occurring agricultural weeds.[151] Legally, a noxious weed is any plant designated by a federal, state or county government as injurious to humans, agricultural or horticultural crops, livestock, wildlife, or ecosystems. Most noxious weeds have been intentionally or unintentionally introduced into ecosystems in which they are not native. However, some noxious weeds are native to the environment in which they are problematic. Noxious weeds cannot be imported or moved under the notification procedure, these plants require an APHIS authorized permit for these activities.

4.3.5.1.2 Authorization of Interstate Movement and Importation

Permit and notification authorizations prescribe container requirements for GE plants, plant parts, and seed designed to confine these materials during shipment. Movements occur between a defined point of origin and destination. When APHIS notification and permit requirements are followed there is a very low likelihood of release of GE organisms - for GE organisms to potentially affect the weediness of agricultural weeds, noxious weeds, or other plants. There have been no impacts on agricultural weeds, noxious weeds, or herbicide resistant weeds as a result of APHIS regulation of these activities, and none would be expected.

Unauthorized release of GE organisms could occur if there is accidental spillage of seed, intact plant, or other material, as result of container failure during transport. Human error could also result in the mislabeling of shipping containers and unauthorized seed being planted in areas where it was not permitted. Both conditions comprise an unauthorized release. Risks from unauthorized release include the potential for spread of the GE plant if it is invasive, or the creation of more harmful weeds if the GE plant crossbred with a wild plant and conferred a fitness advantage (discussed in subsection 4.3.6 below). This could occur (1) if unauthorized seed germinated, or the GE plant or plant material were to propagate outside of authorized areas, sexually compatible weed species were present in the area, gene flow from the GE plant to such sexually compatible species were to occur, and such gene flow imparted enhanced weediness characteristic to the hybrid plant, or (2) there was establishment of a GE plant beyond an authorized area, and the GE plant became invasive in agricultural fields. For a GE plant to affect the weediness of agricultural or noxious weeds, all of these conditions would have to be met. Hence, there is low probability that a GE organism would present concerns in affecting the weediness of agricultural or noxious weeds when imported or moved interstate pursuant to APHIS notification and permit requirements.

In the event of an unauthorized release during movement due to container failure or human error, seeds or plants would be physically removed from the environment. In the rarer cases where plants have established, GE plants may be treated with herbicides as a means of eradication. Such remedial measures would be transient in nature and isolated to the area of unauthorized release. Consequently, there would be limited herbicide use, applied per EPA requirements, and negligible risks that herbicide resistant weeds would be selected from repeated herbicide exposure.

[151] See The Plant Protection Act (PPA) (part of Pub.L. 106–224).

In the unlikely event there is a noncompliance incident associated with importations and interstate movements, APHIS assesses the event and takes the appropriate actions necessary to prevent dissemination of the GE organism into the environment. APHIS would consult with the EPA as appropriate in remediation of unauthorized/accidental releases to include herbicide use and potential impacts on development of herbicide weed resistance.

4.3.5.1.3 Authorization of Environmental Release

Under current regulations, authorized environmental releases have prescribed permit conditions and notification performance standards designed to prevent the interaction of the GE organism with plants outside of the field site. Most release sites are small, of limited acreage, and authorized field tests are for a single growing season. However, permits may extend for several years in some cases. The median size of an approved field trial is approximately 5 acres, average size about 20 acres, and cumulative annual acreage utilized for field testing, over the last several years, around 400,000 acres.

Agricultural weeds are common in and around field test sites, and noxious weeds may be present as well. Control of weed growth during field trials is the same as with commercial crop production; through use of herbicides and tillage, and perhaps crop rotation and cover crops for field trials that may extend for several years. It is well recognized that the singular, long-term use of an herbicide can promote the development of resistant weeds. This is not unique to GE plants themselves; herbicide resistance has routinely occurred with non-GE conventional crops and herbicides since the introduction of herbicides in the1950s.

Use of herbicides during field trials can potentially select for weed species that have innate resistance to the herbicide (shift in weed populations), and the testing of any GE plant has the potential consequence of increasing populations of weeds resistant to the particular herbicide utilized during field testing, where the field test may extend for a year or more, or rather, span several life cycles of weed populations. While the potential exists wherever herbicides are used, the likelihood of selecting for herbicide resistant weed populations during field trials is quite low due to the spatial and temporal constraints place on field trials, and intensity with which weeds are managed during field trials.

In order to effectively reduce the potential for development of resistant populations developers field testing GE plants must implement an integrated weed management (IWM) program that utilizes all available weed control tactics, and reduces the repeated use of herbicides with a single mode of action. APHIS recommends best management practices (BMPs) to help prevent the development of herbicide resistant weed populations as part of authorization for the field testing of GE plants.[152] Herbicides used during field trials are regulated by the EPA and must be registered with the Agency prior to use. Developers are required, by law, to use herbicides pursuant to EPA label requirements and other EPA requirements issued for use. The EPA label contains information on weed resistance management consistent with the Weed Science Society of America's (WSSA) Best

[152] APHIS Recommendations for Best Management Practices for Authorized Field Trials of Regulated Herbicide Resistant Crops: https://www.aphis.usda.gov/brs/aphisdocs/aphis_bmp_recs_hr_crops.pdf

Management Practices for weed resistance management.[153] The EPA may also require a weed resistance management plan as part of authorization of use. It is expected that herbicides will be judiciously used during field trials per APHIS and WSSA recommendations, and EPA requirements.

4.3.5.1.4 Compliance, Enforcement, and Remediation

During the course of movement or field testing of a GE organism those authorized under permit or notification are required to keep records and report to APHIS breaches of permit or notification requirements. APHIS also conducts targeted and random periodic inspections to confirm that permit conditions or notification performance standards are being met. If there is an incident of noncompliance APHIS requires remedial actions as appropriate to the violation.

To the extent individuals comply with current APHIS notification and permit requirements, EPA requirements for herbicide use, and well recognized industry standards for management of development of herbicide resistant weeds (e.g., WSSA), the development of resistant weed populations as a result of field trials is expected to be limited, to the extent that it can be. Field trials a generally limited in terms temporal and spatial scale, typically occurring for 1 year, and generally comprising around 5 to 50 acres. These factors limit the potential for development of resistant weed populations. However, some field trials are conducted over several years, and comprise up to 50,000 acres. For field trials of this nature, the risk of development of resistant weed populations is greater, as there may be several cycles of seeding and reproduction in weed populations over the duration of the trial. APHIS works with the EPA and other federal agencies to facilitate compliance with regulations as well as WSSA to develop strategic approaches to the management of weeds and weed resistance to herbicides. In the event a resistant line of weeds were discovered in a regulated field trial, company personnel and EPA would be notified of the occurrence and a remediation plan enacted to minimize the spread of that weed population.

4.3.5.1.5 Determination of Regulatory Status

A person may petition APHIS to consider whether a particular regulated article is unlikely to pose a plant pest risk, and, therefore, should not be regulated under 7 CFR part 340. The petitioner is required to provide APHIS information and data that evidences the proposed GE organism is unlikely to present a greater plant pest risk than the unmodified organism. APHIS makes its determination based on the information submitted, a PPRA, and NEPA analysis as appropriate. As part of the PPRA, APHIS evaluates the potential for enhanced weediness in GE organisms, and the potential impacts of GE organisms on the weediness of other plants with which the GE organism can interbreed. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk. Once APHIS determines that a GE plant is not subject to 7 CFR part 340 it has no regulatory oversight of that GE plant and it may be cultivated anywhere in the 50 states or U.S. territories.

[153] WSSA - Reducing the Risks of Herbicide Resistance, Best Management Practices and Recommendations: http://wssa.net/2012/04/wssa-endorses-strategies-to-reduce-the-threat-of-herbicide-resistance-to-agricultural-productivity/

Some stakeholders have expressed concern regarding the potential impact of GE herbicide resistant crop systems on sustainable weed control. The use of herbicides on crop plants, GE and non-GE alike, and the potential for development of resistant weed biotypes is well recognized by weed scientists, growers, and the biotechnology industry. As discussed in section 3.4.4, the implementation of IWM programs appropriate to the crop and area of cultivation are required to prevent or allay the development of resistant weed populations where that GE plant is used with herbicides.

There are two avenues of thought in addressing the development of herbicide resistant weeds. Some stakeholders are critical of GE crops in particular, asserting use herbicides on herbicide resistant crop plants facilitates overuse and perpetuation of weed management systems they believe should not be allowed to occur. This position derives from the repeated and singular use of glyphosate on GE glyphosate resistant crops, which led to selection for weeds with resistance to glyphosate. Others stakeholders assert, factually so, that the potential for development of herbicide resistance is a problem for all crops on which herbicides are used, not just GE crop plants, and that with proper management of weeds, development of resistant weed populations can be minimized. Fundamentally, it is in the best interest of the crop producer to avoid practices that select for resistant weed populations, as this reduces yield, increases costs to the grower, and requires greater effort to control in the event such populations emerge. Likewise, it is in the best interest of the manufacturer of the herbicide to ensure weed resistance management practices are properly implemented, as the market share of their herbicide will be significantly reduced where weeds resistant to their product develop.

While glyphosate resistance is a well-recognized example, resistant weed populations have been developing since the advent herbicide use in the 1950s, and their prevalence has been sharply increasing since the 1970s. As of 2016, there were around 156 resistant weed species in the United States as described in section 3.4.4.2. Development of resistance has occurred most frequently with ALS inhibitors (i.e., imidazolinone and imazethapyr); ACCase inhibitors (i.e., phenylpyrazoline); triazine based photosynthesis II inhibitors (i.e., atrazine); synthetic auxins (i.e, dicamaba, 2,4-D); bipyridilium based photosynthesis I inhibitors such as paraquat; glycines, which include glyphosate; various ureas and amides that inhibit the photosynthesis II process; and dinitroaniline based microtubule inhibitors such as trifluralin (see Figure 3-19).

In commercial crop production, the problem with development of herbicide resistant weeds has been addressed in part by the adoption of stacked-trait varieties of GE crop plants. These varieties allow use of multiple herbicides with varying modes of action, which reduces selection pressure for resistant weed biotypes. GE crop varieties incorporating two or more herbicide resistant traits are now common. Stacked-trait varieties comprised less than 1% of planted acres in 2000, and as of 2014 comprised 76% of planted acres, in part due to the development of herbicide resistant weeds and need for their management. Stacked-trait varieties may be useful in managing agricultural weeds, and allaying development of weed resistance to herbicides, but they will not prevent it (NAS 2016b); prevention will require collective integration of cultural, biological, and limited chemical controls. Specialists in weed science and the biotechnology industry understand the necessity for use of an IWM system to manage weeds and control the development of resistance weed biotypes. IWM

includes timely herbicide applications, use of herbicides with multiple modes of action, crop rotation, cover crops, various tillage practices, and weed surveillance. To assist growers in managing weeds individual states track the weeds prevalent in their area and the most effective means for their management, and provide this information to growers typically through state agricultural extension services which work with USDA.

For conventional and GE commercial cropping systems herbicides are a fundamental input for the control of weeds. They have allowed growers to reduce the time, effort, and the cost of managing weeds in meeting domestic and international market demand for human and animal food, and fiber. Herbicide use will not significantly change for large scale commercial cropping systems, and such use will be controversial where there is the continued development of herbicide resistant weeds.

Management of extant herbicide resistant weeds, and their development, will remain a fundamental practice in commercial agriculture for the foreseeable future; this applies equally to GE and conventional cropping systems, to include conventional crops marketed as "non-GMO". Reliance of growers solely upon herbicides for weed management will result in development of resistant weed populations. Effective, long-term weed management will require implementation of IWM programs that wisely integrate chemical, physical, biological, and cultural methods to control weeds and allay selection for resistant populations.

There are numerous efforts underway to increase grower compliance with recommended best management practices to control weeds and allay development of resistant populations. These include efforts by university extensions and the Weed Science Society of America to educate growers, financial incentives by biotech developers for the purchase of alternative herbicide chemistries, and enhanced oversight by EPA on herbicide management through the inclusion of stewardship requirements on herbicide registration.

4.3.5.2 Preferred Alternative: Agricultural Weeds and Noxious Weeds

4.3.5.2.1 Regulatory Scope

The PPA provides APHIS two authorities that could be used in regulating GE organisms: plant pest authority (the basis of current 7 CFR part 340 regulations) and noxious weed authority. The term ''noxious weed'' is defined in the PPA as "any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment."

The Preferred Alternative broadens the scope of GE organism that could be considered under regulations by incorporating APHIS' noxious weed authority under the PPA (7 U.S.C. §7701(7)) and providing new terms and definitions for "genetic engineering" and "GE organism." Hence, the proposed revisions are, in part, intended to broaden APHIS's regulatory scope by explicit inclusion of APHIS' noxious weed authority, and re-defining the types organisms that may be subject to regulation.

APHIS would remove the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures, and strengthen its compliance and enforcement program by incorporating the full range of authorities and penalties granted under the PPA.

The proposed revisions to 7 CFR part 340 address how APHIS implements its statutory authority under the PPA, and implements APHIS' new weed risk assessment tool. Under the Preferred Alternative, APHIS' would analyze plant pest and noxious weed risks prior to issuing permits, and then publish the risk assessment findings on a regulatory status register maintained on APHIS' website. The regulatory status register will be publicly available, and identify which GE organisms presented a potential plant pest or noxious weed risk, and which were determined unlikely to present a risk.

Some GE organisms may be found unlikely to present a plant pest risk under the PPA, but may present a risk as a noxious weed. Because the scope of GE organisms considered and potentially regulated is expanded under the Preferred Alternative, and a broader range of GE plant-trait combinations that may present a noxious weed risk can be identified and regulated, the Preferred Alternative provides greater oversight of potential risks to resources protected under the noxious weed authority of the PPA.

4.3.5.2.2 Authorization of Interstate Movement and Importation

Under the Preferred Alternative the notification process would be eliminated and all importations and interstate movements of regulated organisms would be conducted solely under APHIS permit. APHIS would use a performance-based approach for shipping of GE organisms and require they be handled in such a way that their identity is maintained and that they are imported or moved in a secure shipment.[154] Movements of regulated organisms, those determined by APHIS via the PPRA and/or WRA to pose a plant pest or noxious weed risk, would have to meet all containment requirements defined within the new regulations and shipped in such a way that there is no release into the environment. Specifics regarding labeling and the methods of secure shipment would be included as permit conditions.

All locations where regulated organisms are received, stored, distributed, or released into the environment would have to be identified within a permit if movement occurs. This includes but is not limited to greenhouses; laboratories; growth chambers; field trial locations; production, propagation, sale, distribution, and manufacturing locations.

Under this Alternative APHIS regulation of interstate movement and importation would encompass, explicitly, those GE organisms that APHIS determined to pose noxious weed risks, in addition to plant pest risks. Movement and importation would be conducted under authorized permit only, which would allow for issuing of requirements tailored to address specific concerns in regard to the potential weediness of the GE plant, and/or its effect on the weediness of other plants. Consequently, the Preferred Alternative is considered more protective of agricultural and environmental interests by implementing controls that serve to

[154] APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation".

prevent the unintended release and dissemination of GE organisms that may present noxious weed risks.

4.3.5.2.3 Authorization of Environmental Release

In 2005 and 2015, the USDA's Office of Inspector General (OIG) conducted audits of APHIS' current regulatory program for GE organisms. The OIG suggested that APHIS revise the regulations to minimize the risk of inadvertent dissemination of regulated articles from an authorized field site, and encouraged APHIS to revise the regulations to make explicit APHIS' evaluation of GE organisms for noxious weed risk (USDA-OIG 2015).

As part of implementing these recommendations, field trials of GE organisms under the Preferred Alternative would be conducted solely under APHIS authorized permits. APHIS would prescribe permit conditions designed to prevent the unauthorized release of the GE organism from the field site and its persistence in the environment on conclusion of the field trial. As a result of the broader range of GE organisms considered under regulations; release of regulated organisms only under conditional permit; and revisions to compliance and enforcement activities (described following); the Preferred Alternative could potentially provide better protections than the No Action Alternative in oversight GE plants that presented a potential weed risk.

Where the scope of regulated organisms permitted for field testing would be expanded, inclusive of potentially noxious weeds, this would not translate to reductions in the risk of development of herbicide resistant weeds during field testing: the risks for development of herbicide resistant weed populations would be the same under all alternatives. APHIS would recommend the same BMPs for management of development of herbicide resistant weed populations as described under the No Action Alternative.[155] Likewise, herbicides used during APHIS authorized field trials would be subject to the same EPA requirements described under the No Action Alternative. Weed management practices, and management of development of herbicide resistant weed populations, would be the same under both the Preferred Alternative and No Action Alternative.

4.3.5.2.4 Compliance, Enforcement, and Remediation

The Preferred Alternative would strengthen the compliance and enforcement program by augmenting the approaches currently used. The proposed revisions to APHIS compliance and enforcement activities would implement the USDA OIG recommendations described above.

APHIS would clarify what locations and regulated organisms may be subject to inspection and expand reporting requirements. Responsible persons would be required to provide APHIS inspectors access to any relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other articles related to the importation, interstate movement, and environmental release of organisms regulated under 7 CFR part 340.

[155] APHIS Recommendations for Best Management Practices for Authorized Field Trials of Regulated Herbicide-Resistant Crops: https://www.aphis.usda.gov/brs/aphisdocs/aphis_bmp_recs_hr_crops.pdf

APHIS would revise requirements for the establishment and maintenance of records, and provision of APHIS inspectors with all required records upon request. APHIS would require that certain records would have to be retained for a period of up to 10 years after completion of obligations required under permit or exemption. Record keeping requirements would facilitate compliance, and implementation of remedial measures and penalties in the event of an unauthorized release, such as the persistence of a regulated organism at the field site.

Incorporating the noxious weed authority under of the PPA, APHIS would apply remediation measures to destroy or otherwise dispose of any plant APHIS deemed a noxious weed, or order the owner to treat or destroy noxious weeds. This applies to noncompliance incidents that may occur during the importation, movement, or field release of GE plants that presented a weed risk.

With clarification of oversight of GE organisms that may present a noxious weed risk, and those that would fall under the new definitions for "genetic engineering" and "GE organisms," compliance, enforcement, and remediation actions would encompass a broader range GE plants that presented potential noxious weed concerns.

4.3.5.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would regularly conduct plant pest risk assessments (PPRA) and/or a weed risk assessments (WRA) to inform the determination of whether a GE organism is subject to regulation and required a permit under 7 CFR part 340. As part of the WRA APHIS would evaluate the potential weediness of a GE plant, and the potential effect of a GE organism on the weediness of other plants, prior to making a determination that the organism was or was not subject to regulation. APHIS would also conduct NEPA analyses as appropriate, on a case-by-case basis, which would further evaluate the potential impacts of a GE organism on weeds, and development of herbicide weed resistance. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined was not a plant pest or noxious weed risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

The explicit inclusion of noxious weed authority, expanded scope of organisms evaluated and potentially regulated using the terms and definitions for "genetic engineering" and "GE organism," conduct of an upfront WRA that assesses the risks for weediness, and review pursuant to NEPA as required, provides a regulatory review framework that would make it unlikely that any GE organisms determined not to be subject to regulation would have any adverse effects on issues regarding agricultural weeds.

Herbicides used in the cultivation of any crop plant, whether the plant was derived from conventional breeding or methods utilizing biotechnology, will always present potential risks for selection of resistant weed populations, as described under the No Action Alternative and in section 3.4.4.2. As with the No Action Alternative, the USDA announced measures to help farmers diversify weed control efforts on in October, 2014.[156] These efforts are intended to prevent further development of herbicide resistant weeds, and span across the USDA's Natural Resource Conservation Service (NRCS), USDA's Office of Pest Management Policy – which will work with the EPA to address issues with herbicide weed resistance, and USDA's partnering with the Weed Science Society of America (WSSA) for funding and education initiatives.

In regard to the management of agricultural weeds and development of herbicide resistant weeds; the potential beneficial and adverse consequences of APHIS determinations that a GE organism is not subject to regulation are not expected to significantly differ from the No Action Alternative. The stewardship and IWM practices implemented by developers and growers of commercial crops will remain the same, along current trends. Adoption of regulations under the Preferred Alternative would have no effect on weed management practices, or current efforts to manage and reduce development of herbicide resistant weeds. The use of GE herbicide resistant cropping systems is likely to be similar under the both the No Action and Preferred Alternatives. In these respects, there is no difference between the Preferred and No Action Alternative.

However, considering the broader scope of GE organisms potentially evaluated under this Alternative, and potentially regulated, there could be seen regulation of certain GE organism that otherwise would not be regulated under the current 7 CFR part 340 regulations. These would include those GE plants that may present noxious weed risks. In these instances, certain GE organisms that are beyond the scope of current regulations may be determined to be subject to regulation under the Preferred Alternative, and would not be utilized for commerce or grown anywhere in the United States without APHIS authorization. Hence, to the extent regulations under the Preferred Alternative reduces the environmental introduction of GE organisms that could present risks as noxious weeds, there could be seen environmental protections not realized under the No Action Alternative.

Although the scope of organisms potentially regulated under the Preferred Alternative would be broader, there would likely be an increase in the number and variety of GE organisms that would not be regulated by APHIS, and available for commercial uses. These would largely be GE crop plants, particularly those plant-trait combinations that are similar to or the same as those APHIS has previously reviewed and determined not to be subject to regulation. For instance, it is anticipated that many of the herbicide resistant, and insect and disease resistant plant-trait combinations that APHIS will be evaluating for plant pest and/or noxious weed risk, will not be subject to regulation under 7 CFR part 340. This would be the case for both the No Action and Preferred Alternative, however, under the Preferred Alternative, APHIS' PPRA and WRA review process would be more efficient, and regulatory decisions issued in a more timely manner. Hence, where in the long-term there would be little difference in terms of the variety and number of GE organisms APHIS determined not to be subject to 7

[156] USDA: http://www.usda.gov/wps/portal/usda/usdahome?contentid=2014/10/0227.xml&contentidonly=true.

CFR part 340, under the Preferred Alternative, it is likely that in the short-term, there would be more GE crop plants available for commercial uses in as far as they were not subject to APHIS regulation. Those GE organisms APHIS found were not subject to 7 CFR part 340 would however remain subject to review and approval per EPA requirements, as well as state and county requirements, as under the No Action Alternative.

If a GE organism were determined by APHIS not to be subject to regulation, and it were later found to present potential plant pest or noxious weed risks, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340.

4.3.5.3 Alternative 3: Agricultural Weeds and Noxious Weeds

4.3.5.3.1 Regulatory Scope

Under Alternative 3, APHIS would substantially increase regulatory oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it incorporates noxious weed authority, utilizes the revised definitions for "genetic engineering" and "GE organism," and risk analyses would be conducted via the PPRA and WRA. However, under this Alternative APHIS would interpret the noxious weed authority to include potential economic harms from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. The WRA would include an economic effects analysis, and APHIS would distinguish those GE organisms that presented only potential economic impacts from those that presented plant pest and noxious weed risks (biotic). All GE organisms APHIS determined to present a plant pest or noxious weed risks, or presented potential economic harms as a noxious weed (including all previously deregulated organisms), would be regulated under 7 CFR part 340. The only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing not only the importation, movement, and field testing of GE organisms, but the production of many of the commercial GE crops currently grown, and that will be grown.

4.3.5.3.2 Authorization of Interstate Movement and Importation

The importation and interstate movement of regulated organisms that presented a plant pest or noxious weed risk would be conducted solely under APHIS permit. The importation and interstate movements of regulated organisms that presented only potential economic harms (that were unlikely to present a biotic risk) would not require a permit for importation or interstate movement, although their environmental release, including commercial production, would.

As with the Preferred Alternative, Alternative 3 would potentially provide better protections during the shipment/movement of regulated organism than the No Action Alternative due to the expanded scope of GE organisms APHIS would evaluate under regulations, potentially regulate, and revisions to permitting and compliance programs (described following). However, from a practical standpoint, there would be little difference among the Alternatives considered, as interstate movement and importation generally present negligible risk in regard to issues concerning agricultural and noxious weeds.

4.3.5.3.3 Authorization of Environmental Release

Under Alternative 3, APHIS would function as a wide-scale permitting authority; permitting not only the field testing of regulated organisms, but the commercial production of all GE crops produced in the United States that were determined to present a potential economic impact on non-GE crop producers. This framework in essence would support the coexistence of conventional, GE, and organic crop production. All mere presence noxious weeds (MPNW) regulated by APHIS and desired for use in commerce would require a permit for cultivation. Plant biotechnology developers and growers of regulated organisms would be required to track and record the location and acreage of the MPNW being grown and implement a GE plant volunteer management program. The records would be required to be made available to APHIS upon request.

All non-GE crop producers wishing to receive protections under APHIS regulations would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national map-based pinning system on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

Field testing of regulated organisms would be conducted solely under permit with prescribed confinement conditions as required. Permits for field testing of regulated organisms that present risks as plant pests or noxious weeds would have more stringent requirements than those that presented only potential an economic harms.

Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting of field testing and commercial production would largely be the same. MPNW would require a different kind of permit under Alternative 3, with conditions that aimed to facilitate coexistence. APHIS would provide the same recommendations to developers and growers for the management of agricultural weeds and development of weed resistance, as describe under the No Action and Preferred Alternatives.[157]

Environmental release permits for MPNW would not be required to meet the same standards as regulated organisms that were determined to pose a plant pest or biological noxious weed risk, because GE organisms categorized as MPNW would present negligible risks as a plant pest or noxious weed. Hence, their allowance for permitted use as a commercial crop. Alternative 3, like the Preferred Alternative, would provide better protection than the No Action Alternative as a result of inclusion of noxious weed authority and evaluation, and potential regulation, of a broader range of GE organisms under the new terms and definitions. These protections would be in the way of oversight of GE plants with potential weedy properties, or the potential to enhance the weediness of wild relatives through gene flow, and conferring of a fitness trait.

As discussed in the above section on plant pests and disease; the potential outcomes of comprehensive regulation of GE plants on the relationship between agricultural crop

[157] APHIS Recommendations for Best Management Practices for Authorized Field Trials of Regulated Herbicide-Resistant Crops: http://www.aphis.usda.gov/brs/aphisdocs/aphis_bmp_recs_hr_crops.pdf

production, weed management, and herbicide resistant weed management will be based on several factors, discussed below, and difficult to predict with high degree of certainty. On one hand, the choices available to growers in terms of weed management practices in the production of GE and non-GE crop plants under conventional, GE, or organic production systems - these options may change because the regulatory compliance costs of producing GE crops is expected to increase under Alternative 3. If due to regulatory compliance costs, and burden of compliance requirements, it becomes economically unfeasible or difficult to produce GE crops, certain biotechnology companies may decide to allocate their resources to more profitable ventures, or reduce efforts on research and development in the agricultural sector. In these instances, efforts in development and/or innovation in production of new varieties of GE HR crop plants may see a decline, as well as commercial cultivation of GE HR crop plants. Where there was a reduction in use of current varieties of GE HR crops, there could be seen a decrease in the likelihood for selection of glyphosate, 2,4-D, and dicamba resistant weeds. In turn, there would be seen an increase in usage of other herbicides, those herbicides not commonly used in GE HR cropping systems, and likewise and an increase in selection pressure for these herbicides. As with all the Alternatives, where herbicide resistant weeds are problematic, there may be seen an increase in tillage. In terms of management of agricultural weeds and selection for resistant weed populations, there may be seen differences under Alternative 3 if GE HR crops become a less attractive option.

If the extensive permitting, monitoring, and reporting requirements prove to be burdensome for growers of GE crops, some growers may decide to cultivate conventional non-GE crops. Such a shift in choice of the variety of crop cultivated would have no significant effect on the prevalence of agricultural weeds, but it could affect the choice of herbicides used in cultivation of a crop, and in turn the propensity for selection of weed resistance to a particular herbicide or management technique. Shifts in herbicide use, or rather the particular type of herbicide used (mode of action) could occur, relative to the growers preference in controlling the particular agricultural weeds extant in their cropping system. How this would affect the potential development of resistant weed populations is indeterminate. Certain herbicides are more prone for selection of resistant weed biotypes, some less. Development of weed resistance to herbicides that are ALS enzyme inhibitors is the most common type of resistance that occurs. Development of populations resistant to synthetic auxins (i.e, dicamba, 2,4-D) on the other hand, has been observed to be far less over the years. The relatively low incidence observed in the selection of populations resistant to auxinic herbicides has been attributed to the presence of rare alleles imparting resistance in weed populations, and the complex mode of action of auxinic herbicides (Mithila, Hall, Johnson et al. 2011). For herbicides with longer residual activity (e.g., ALS inhibitors), selection pressure will be higher because more weeds are exposed over time. For those with shorter or no residual activity (e.g., benzothiadiazines, nitriles), selection pressure will be lower. However, where herbicides with shorter or no residual activity are repeatedly used in the same location over a single growing season, selection pressure can be just as high as herbicides with long residual activities.

Depending on shifts in herbicide use, there could also be seen an increase in use of less environmentally benign herbicides. For example, glyphosate[158] and dicamba[159], which are used in association with GE HR crops, have relatively low toxicity. Where the use of these is replaced with more toxic herbicides with longer residual activity, there will be a commensurate increase in environmental risks.

Any shift in grower preference for cultivation of conventional crops over GE crops as a result of regulatory burden on the grower, and associated shift in herbicide use, will be the choice of the grower. Consequently, any shifts in the propensity for development of herbicide resistant weeds will be relative to the mode of action of the herbicide chosen, the weed species present, and the IWM practices employed by the grower. Whether it is GE or non-GE conventional crop, the requirement for implementation of an effective IWM program is the same. The weed species present will not change, only grower decisions in the management of them.

As described under the No Action and Preferred Alternative, the USDA announced measures to help farmers diversify weed control efforts on in October, 2014,[160] and APHIS would provide developers guidance for managing the potential development of weed resistance during cultivation of GE plants; be for field testing or commercial production. These efforts are intended to prevent further development of herbicide resistant weeds, and span across the USDA's Natural Resource Conservation Service (NRCS), USDA's Office of Pest Management Policy – which will work with the EPA to address issues with herbicide weed resistance, and USDA's partnering with the Weed Science Society of America (WSSA) for funding and education initiatives.

4.3.5.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative, however, these activities would be extended to MPNW, and would incur expanded responsibilities for developers, growers of GE crops, growers of non-GE crops, and APHIS. These activities would specifically address preventing and remediating economic harms through commingling of GE and non-GE crops, and as such, discussed under the socioeconomics impacts section below.

Both this and the Preferred Alternative would strengthen APHIS' compliance program. This, in conjunction with broader scope of GE organisms that would be considered under regulations, and potentially regulated, could provide better protections in regard to oversight of GE plants that may present noxious concerns. APHIS oversight and approach to management of herbicide weed resistance under regulated activities would be the same among the No Action, Preferred Alternative, and Alternative 3.

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[158] EPA - Glyphosate: https://www.epa.gov/ingredients-used-pesticide-products/glyphosate

[159] Reregistration Eligibility Decision for Dicamba and Associated Salts: https://archive.epa.gov/pesticides/reregistration/web/pdf/dicamba_red.pdf

[160] USDA New Release No. 0227.14: http://www.usda.gov/wps/portal/usda/usdahome?contentid=2014/10/0227.xml&contentidonly=true.

4.3.5.3.5 Determination of Regulatory Status

As with the Preferred Alternative, the petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and WRA. Determinations of regulatory status would be the same of for the Preferred Alternative, with the exception of inclusion GE organisms as MPNW. As part of the risk analyses APHIS would evaluate the potential weediness of a GE organisms prior to making a determination that the organisms was or was not subject to regulation. APHIS would also conduct NEPA analyses as appropriate, on a case-by-case basis, which would further evaluate the potential impacts of a GE organism on the human environment, to include agricultural weeds and development of herbicide weed resistance. Regulated organisms would include those that presented a plant pests or/and noxious weed risk (biotic) and those that presented potential economic harms as noxious weeds.

The potential beneficial and adverse consequences of APHIS determinations that a GE organism is not subject to regulation, and subsequent effect of GE plants on the use of herbicides and management of agricultural weeds are not expected to significantly differ from the No Action or Preferred Alternative. However, as with the Preferred Alternative, considering the broader scope of GE organisms evaluated and potentially regulated, there could be seen regulation of certain GE organism that otherwise would not be regulated under the current 7 CFR part 340: These would be in the way of GE organisms that presented a noxious weed risk (from a biotic perspective). In these instances, certain GE organisms that are beyond the scope of current regulations may be determined subject to regulation under Alternative 3, and would not be utilized for commerce or grown anywhere in the United States without APHIS authorization. To the extent the regulatory framework proposed under Alternative 3 reduces such risks, there could be seen environmental protections not realized under the No Action Alternative.

If APHIS determined a GE organism was not subject to regulation, and it were later found to present potential plant pest or noxious weed risks, or cause other agricultural harms, APHIS would have the authority to change its determination and regulate that GE organism under 7 CFR part 340.

4.3.6 Gene Flow and Weediness

This section describes the relationship potential gene flow from GE to non-GE organisms, and the weediness of GE plants. Weediness in this subsection refers to the potential weediness of the GE plant by virtue of the GE plant-trait combination, and its ability to confer weediness to other plants via gene flow. Management of agricultural weeds and development of herbicide resistant weeds is discussed separately, above.

4.3.6.1 No Action Alternative: Gene Flow and Weediness

4.3.6.1.1 Regulatory Scope

Current regulations provide APHIS oversight of potential gene flow and weediness during the importation, interstate movement, and environmental release of regulated GE organisms, which includes GE plants, microorganisms, insects, fungi, viruses, and any organism that is, or is believed to be, a plant pest.

4.3.6.1.2 Authorization of Interstate Movement and Importation

APHIS currently handles requests involving the importation and movement of GE organisms on a case-by-case basis. When notification performance standards, and in the case permits, permit conditions are followed, the unintended release of GE organism during import or movement is of low probability. Such unintended releases would be limited to rare instances of container failure and human error. When conducted according to APHIS requirements these activities are considered to present low risk for gene flow to wild relative species and commercial crops (USDA-APHIS 2011, USDA-APHIS 2012).

Unauthorized and unintended releases can occur, however, and the occurrence of GE organisms outside authorized areas would be presented in the event of such releases. Major incidences of noncompliance, such as shipping without proper identification, have been of low incidence and when they have occurred remedial actions taken to limit dispersal and preclude persistence of the GE organism in the environment. Based on the outcomes of 20 years of APHIS regulation of the importation and movement of GE organisms, the current regulatory program is considered effective in preventing unauthorized releases during movement and importation, and consequently gene flow between GE and wild relative species, gene flow to commercial crops, and establishment of a GE organism in the wild. If APHIS adopts the No Action Alternative the risk of adverse impacts to crops, wild relative species, and other biota from authorized import and movement of regulated GE organisms is expected to continue to be minimal, given the low likelihood of exposure of plants and other biota to GE organisms during the conduct of these activities.

4.3.6.1.3 Authorization of Environmental Release

Field testing of GE organisms will always present some degree of risk in regard to gene flow. As with authorization for imports and movements, when current notification performance standards and permit conditions are followed the unintended release and dissemination of GE organism during field testing would be of low probability.

Potential Risks of Gene Flow during Environmental Release

Sexually compatible plant species can hybridize and for GE plants this can be a concern. The likelihood and success of gene flow from GE plants is dependent on numerous factors described in section 0, such as presence of sexually compatible species; the species of GE plant or other organisms field tested; the GE trait; outcrossing rate for plants; pollen type; pollen and seed dispersal pathways; seed dormancy characteristics; management practices used in cultivation of GE plants; and environmental conditions and events where the GE plant is used.

For plants, the particular species of GE plant and occurrence and proximity of sexually compatible species is the primary factor in evaluating the risk of gene flow, as discussed in Section 3.4.2. For example, the crops of corn, soybean, and cotton do not have wild relatives of concern in the United States. One exception is cotton, which has wild or feral cotton relatives in Hawaii, Florida, Puerto Rico, and the US Virgin Islands (Mendelsohn, Kough et al. 2003). Consequently, the EPA restricts the sale or distribution of Bt cotton in these areas. For human and animal food crops, the potential for gene flow to wild relatives in the United States is limited to species of wheat, rice, sorghum, rapeseed/canola, sunflower, sugarbeet,

and squash. Among these, sorghum, wheat, and sunflower remain under 7 CFR part 340 regulation. Apart from food crops, GE creeping bentrgrass, developed for use on golf courses, and GE eucalyptus, developed for commercial forestry purposes, also have wild relative species in the United States. Both remain regulated under 7 CFR part 340, although petitions have been submitted requesting non-regulated status. If these GE plant species are grown in proximity to their wild relatives, or GE seed of these species is inadvertently introduced in the area of their wild relatives, gene flow from the GE plant variety to wild relative species could potentially occur. Because trees have not been domesticated to the extent of cultivated crop plants, and various species are ubiquitous in the environment, they present a greater risk of gene flow. Similarly, there is a greater risk for gene flow among species of grasses, which are likewise ubiquitous.

Microorganism such as bacteria and fungi, and arthropods and other invertebrates present unique concerns due to their mobility and modes of transfer of genetic material. In arthropods, reproduction is usually sexual, although in many species produce eggs that develop without fertilization. The reproduction of fungi is both sexual and asexual, although the majority of fungi reproduce asexually. The EPA regulates products containing certain GE eukaryotic microorganisms, prokaryotic microorganisms, and viruses as "substances," and has established a registration process for their use as microbial pesticides under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq., FIFRA). The EPA also issues outdoor experimental use permits under FIFRA to allow persons to release these organisms into the environment on a limited basis in order to obtain information necessary to apply to have products containing the organisms registered as microbial pesticides. EPA outdoor experimental use permits for microorganisms currently registered by the EPA as microbial pesticide products having outdoor uses are not regulated under part 340. Because both permitted and registered products are already subject to extensive regulation by EPA, APHIS entered into a memorandum of understanding (MOU) with the EPA stating that APHIS will not exercise duplicative regulatory oversight of the products.

Potential for Weediness and Invasiveness

One of the more commonly expressed concerns among stakeholders is that GE plants may escape areas of field testing or cultivation and persist in the environment as weeds or invasive species. In this context "weedy" refers to plants that are growing where they are not wanted, typically in managed environments. "Invasive" refers to species that tend to spread aggressively, typically of concern in unmanaged environments. For most GE crop plants, their potential for evolving as an invasive or weedy plant is considered quite limited, as discussed in section 3.4.2. For certain GE grasses and trees, and to some extent ornamentals, the risks are higher. These risks are summarized following.

As a result of centuries of selective breeding most crop plants lack weedy and invasive characteristics and have a low propensity for persistence when not managed in an agricultural setting. After over 20 years of field testing and commercial cultivation there have been no known instances where traits introduced into GE plants altered their domesticated nature and led to the development of weediness or invasiveness. Fundamentally, most cropped plants require human cultivation (Warwick and Stewart 2005). A few species, such as cranberry, are essentially undomesticated. Warwick and Stewart (2005) provide a good review of the world's most important food crops, related sexually compatible weeds, and weed

geographical distribution, and the reader is referred to this publication for more detailed discussion (Warwick and Stewart 2005).

In general, the multiple factors governing weed evolution, whether as crop-turned-weed on its own or development of weediness via hybridization with related weeds or wild species, render the occurrence of crop plants as weeds rare in nature; most domesticated plants stay domesticated. While all domesticated crop plants have the capacity to occur as feral populations and present problems as weeds or invasive species, by virtue of the fact that they are plants, this has been rarely observed over centuries of cultivation (Warwick and Stewart 2005, Ellstrand, Heredia et al. 2010). As summarized in section 3.4.1.4 there are few examples of domesticated crop plants directly evolving into competitive weedy or invasive plants. One study examining domesticated plants, those that have been cultivated for at least 1000 years, found only 13 examples of weedy plants that descended from crop progenitors (Ellstrand, Heredia et al. 2010). As further detailed in section 3.4.1.4, the domesticated nature of most crop plants rather limits the likelihood of crop species colonizing outside areas of cultivation, and evolution into weeds.

GE crop plants, being derived from domesticated crop plants are comprised of the same domesticated genome, the introduced trait gene(s) being the exception.[161] Consequently, a GE crop plant, inherently, is no more likely to develop invasive or weedy characteristics than the non-GE variety, save for the potential contribution of the introduced transgene or transgenes to development of weedy or invasive characteristics.

Traits that may confer a fitness advantage to GE plants are those that provide insect and disease-resistance, stress tolerance, and those that provide an enhanced agronomic characteristic such as increased photosynthetic efficiency. For GE plants possessing these types of traits there may be an increased potential for weediness or invasiveness in areas where the GE plant escaped or hybridized with wild relatives, and all other factors selected for the GE plant or GE plant/wild-relative hybrid. Abiotic stress tolerance would be fitness enhancing when it increased reproductive and vegetative growth, and the competitive ability of plants under selection pressure. In theory, such increased fitness under stress conditions could confer persistence or volunteer potential in agricultural settings and invasiveness in natural habitats (Häggman, Raybould et al. 2013).

The potential weediness and invasiveness of GE trees require considerations beyond those of crop plants because they are long lived perennials (as opposed to annual crop plants), and the potential range of pollen distribution can be substantial; on the order of miles. For field testing of GE trees, confinement of trait genes is a primary concern. Confinement techniques that may be employed include isolation to areas where no sexually compatible wild or commercial tress occur, deflowering of trees, removal before flowering, and application of GE terminator and sterility techniques. Grasses likewise are perennials with ample sexually compatible wild relatives, and GE varieties require considerations beyond those of crop plants when authorization of field testing is requested.

[161] For example, the genome of domesticated corn (*Zea mays*) contains around 2.3-billion base-pairs and 32,000 protein-coding genes, spread across 10 chromosomes. Modern methods of genetic engineering modify a small subset of the 2.3-billion base-pair sequence, with negligible effect on domesticated traits.

Whether the transgene confers a fitness advantage to the GE plant or hybrids that yields weedy or invasive characteristics depends on myriad factors, which were summarized in section 3.4. In brief, it is not only the particular trait conferred by the transgene, but the interaction of the GE plant's entire genome with the biotic an abiotic environment (global gene expression) that includes such factors as: the particular role or function of the plant species in ecosystem dynamics; the fecundity and overall vigor of the particular GE plant species or hybrid progeny; the particular selection pressures present such as herbicide use, insects pests, disease causing pathogens, herbivory, the presence or absence of human activities and intervention; nutrient requirements and soil nutrient availability; stressors such as too little or too much water; and the frequency and duration of selection pressures and stressors. Over the course of many generations, with continuous natural selection from insect pests, diseases, environmental stressors, and other factors the GE plant or hybrids derived from it could conceptually outcompete other plant populations lacking certain traits, and become weedy or invasive.

Fundamentally, the weediness or invasiveness of a plant is a function of global gene expression, and less so a function of the expression of a single gene. The process of natural selection in a given environment would need to be in favor the GE plant or hybrid progeny through basic factors such as reproduction, heredity, variation in the fitness of the cadre of organisms involved in natural selection, and variation in individual characteristics among members of the population.

Years of cultivation and plant breeding have resulted in a substantial and growing body of knowledge regarding the potential weediness and invasiveness of both domesticated and wild plants grown throughout the United States, the likelihood of hybridization between crops and their wild relatives, and fitness and fertility of potential hybrids (i.e., (Stewart, Tranel, Horvath et al. 2009, Warwick, Beckie et al. 2009, Ellstrand, Heredia et al. 2010, Ellstrand 2014) and others). Consequently, the potential risk for weediness or invasiveness of a GE plant possessing one or more transgenes can be reasonably estimated by evaluating the plant species into which the gene(s) was introduced, and the fitness potentially conferred by the introduced trait gene(s). From this information management strategies can be adopted to control potential avenues of gene flow for traits that might increase the weediness of GE plants or their wild relatives, and establishment of the GE plant as weedy or invasive. In such instances, confinement and reproductive isolation or prevention requirements may be required in order to field test such GE plants. Fundamentally, minimizing the amount and frequency of transgene flow to unmanaged ecosystems is the most direct way to minimize the risk for development of weediness or invasiveness for traits that may confer a fitness advantage to wild populations.

APHIS anticipates that as plant biotechnologies continue to advance, developers will propose field tests of GE plants with traits such as drought and salt tolerance, nutrient efficiencies, disease resistance, and enhanced photosynthetic activity. Such traits, either singly or in combination, could contribute to potential weedy or invasive characteristics in a GE plant or GE plant/wild-relative hybrid. The development of stacked-trait GE plant varieties is increasingly more common, which would require additional scrutiny in determination of their potential for weediness or invasiveness.

APHIS Approach under Current Regulations

All of the factors described above are considered when evaluating authorization of environmental release of GE organisms, and particular conditions applied to permits depending on the type and nature of the GE organisms being field tested (USDA-APHIS 2011, USDA-APHIS 2012).

Under current regulations two general approaches are used to manage potential gene flow: containment of the transgene to the authorized field site and mitigation of potential impacts where a trait gene escapes containment. APHIS issues performance standards and permit conditions designed to prevent gene flow and confine the regulated GE organism to the area of testing during an environmental release. The purpose of performance standards and permit conditions is to prevent populations of the GE organisms from establishing outside of the area authorized, prevent the GE organism from persisting in the area after testing has concluded, and prevent gene flow from the GE organism to sexually compatible wild relative species or commercial crops during the release. Most authorized releases are for small sites and for a single growing season. Certain authorized releases of GE organisms, however, may occur on the same site over several years. The median size of authorized field trials is around 5 acres, and average size 20 acres. The larger the size and density of the GE plant test site, the greater the pollen and seed pool size, and risk for gene flow to sexually compatible species outside the test site.

APHIS Authorization Review Criteria

In making a regulatory determination for a permit request or notification, APHIS makes such a determination based on whether the actions under authorized permit or notification are unlikely to result in the introduction or dissemination of a plant pest. This determination takes into account various risk factors including, among other things, a low risk that the GE organism or its progeny can persist in the environment, reproduce, and establish without human assistance. Other risk factors that would support an ‘‘unlikely’’ determination would be minimal availability of suitable hosts or habitats for the GE organism, limited or no presence of sexually compatible species with which the GE organism can breed, and low risk that the organism may cause damage to plants and plant products.

Regarding the risk of introduction or dissemination of the GE organism as a plant pest, an ‘‘unlikely’’ determination takes into consideration both the low risk that the organism or its progeny can persist, reproduce, establish, and spread without human assistance, and any mitigation measures placed upon the GE organism that restrict its movement and make its unauthorized introduction or dissemination unlikely. Fundamentally, the key to prevention of gene flow and potential establishment of GE plants as weeds/invasive plants during authorized field testing is confinement. Assumption of confinement 100% of the time is not reasonable, nor realistically achievable, hence, mitigation measures must be in place to remedy instances where accidental release of a transgene occurs. APHIS evaluates design protocols and sets permit conditions to ensure adequate isolation between GE and non-GE plants to limit pollen or seed flow between them, either through dispersal (by wind, water, insects, or animals) or during planting and harvesting. Likewise, based on seed dormancy, seedbank, and ability to persist as volunteers special conditions may be prescribed as required to prevent gene flow between GE and non-GE plants.

Notifications, described in section 1.3.2.1- Notification Procedure, are part of a streamlined application process intended to simplify the process for applicants and increase the efficiency with which APHIS evaluates GE plants which meet certain eligibility criteria. It is not applicable to non-plant organisms. Field testing under notifications requires developers to design field tests in such a way as to that meet performance standards to ensure that GE plants do not persist or spread. For non-plant organisms, and GE plants that do not meet the eligibility criteria for a notification, a more prescriptive APHIS permit is required which dictates specific conditions. In either case, measures must be taken to prevent persistence and spread of the GE plant or other organism. These may include:

- geographic isolation of the field test from other crops;
- temporal (time of planting) separation of the field test from plants of the same species to prevent simultaneous availability of viable transgenic pollen and receptive flowers outside the test plot;
- physical barriers to gene flow (e.g., bagging flowers);
- biological barriers to gene flow (e.g., male sterility);
- requirement for dedicated planters and harvesters and APHIS-approved cleaning protocols for other equipment;
- post-harvest monitoring to remove volunteer plants;
- proper disposal of transgenic material;
- mandatory, APHIS approved personnel training; and
- dedicated storage facilities.

Measures for containment of plants developed for pharmaceutical, industrial, or phytoremediation purposes, and GE trees and grasses, may include additional confinement requirements.

The scope of the No Action Alternative provides for the prevention and management of gene flow, and mitigation of impacts to plant populations in both managed and unmanaged settings. Potential impacts to non-GE plant populations will be limited for authorized field releases. Permit conditions and performance standards are designed to minimize interactions of the GE organism with the environment outside of the defined activity. Most field release are also limited in space and time, so any direct and indirect impacts of these activities to non-GE plants are typically transient in nature and localized.

As to persistence of field tested GE plants beyond the conditions of permit requirements: For perennial plants, site inspections may be different than that of annual plants depending on the biology of the species. Generally, sites are inspected prior to planting/release and during planting/release. The field release is usually inspected during the period when volunteer plants usually emerge or when flowering is expected each year. Harvest and post-harvest inspections are performed in the year in which these activities occur. Site inspections for volunteer monitoring occur in year one or year two following the harvest of the regulated plants to ensure they do not persist in the environment.

Notification and permit authorization procedures under the current regulatory scheme have been effective in limiting gene flow when APHIS requirements for field testing are met. One exception was during the field testing of glyphosate resistant creeping bentgrass where gene flow up to 13 miles from the test site was recorded (Watrud, Lee, Fairbrother et al. 2004). Since that time, APHIS has increased the stringency of permit requirements for field testing grasses and no longer allows them to be field tested under the notification procedure. When APHIS requirements are not met there will be an increased probability of unintended releases during the field testing of a GE organism. Consequently, the risk for gene flow and weed development largely lays in the degree of compliance, or lack thereof, with the current regulatory framework. The potential impacts and remediation requirements of an unauthorized release are assessed on a case-by-case basis, in the event such occurs.

However, where notification and permit authorization procedures under the current regulatory scheme have been effective, as discussed above, in 2015 the USDA's OIG audit found that the use of current performance standards in APHIS' notification process allowed for a broad spectrum of methods to meet the required performance standards, particularly regarding how the authorized release would be contained to the field site, but Agency practices did not require responsible persons to provide written protocols to APHIS detailing the exact methods that person would use to meet the standards. The OIG suggested APHIS revise the regulations to minimize the risk of inadvertent dissemination of regulated articles from an authorized field site. The OIG also suggested that APHIS develop risk-based criteria for conducting inspections and exercising oversight of field tests for the release of GE organisms, and suggested that we provide more explicit guidance regarding how to terminate a field test and document this termination. Hence, APHIS has proposed revisions to regulations, discussed subsequently under the Preferred Alternative.

Where gene flow will always be of concern in regard to authorization of field releases; it is, in practical terms, more of an economic than environmental issue (e.g., see (Van Deynze 2011)). In part this is because the vast majority of GE plant-trait combinations field tested have not been weedy and the predominant crop plants tested (i.e., corn, soybean, and cotton) do not have wild relatives in most of the United States. Consequently, this aspect of potential gene flow is discussed in further detail below in section 4.6 – Socioeconomic Impacts.

4.3.6.1.4 Compliance, Enforcement, and Remediation

APHIS conducts random and targeted onsite inspections to ensure compliance with regulations. APHIS may make several inspections during the growing season coinciding with critical production times (i.e., pre-planting, flowering, harvesting) and post-harvest onsite inspections to ensure that equipment is cleaned properly and that no volunteers remain. APHIS also requires it be orally notified immediately upon discovery of any accidental or unauthorized release of a regulated article, and in writing within 24 hours in the event.

If a regulated GE plant does establish outside of the authorized area of release a compliance investigation would be initiated and remedial measures applied as necessary. The consequences of an unauthorized release are likely to be local, limited to the area where the unauthorized release occurred, and will vary depending on the species of GE plant, the trait, and the sexually compatible relative species in the area.

If there were an unauthorized release during field testing APHIS could order treatment of the area with herbicide(s) or manual/mechanical removal of the plants. Some actions associated with remediation might result in impacts on non-GE plants and other biota and habitats in the area of the action. These may include the damaging or killing wild plants through the use of herbicides or plowing, and disturbance of habitat for various animal and plant species. These disturbances would be local and temporary.

To the extent individuals comply with current APHIS notification and permit requirements the probability of gene flow and establishment of GE organisms outside an authorized field site is considered very low. APHIS works with state departments of agriculture, the FDA, EPA, the Department of Justice, and other federal agencies as necessary to ensure compliance with APHIS regulations. APHIS enforces compliance with regulations under the authority of the PPA, which provides substantial penalties for serious infractions, including the possibility of criminal prosecution.

As discussed above, APHIS's OIG suggested APHIS could implement better controls to monitor field trial locations and revise record keeping and reporting requirements to track authorized field releases, which could further strengthen APHIS' compliance and enforcement program (USDA-OIG 2015).

4.3.6.1.5 Determination of Regulatory Status

Under the No Action Alternative APHIS conducts a PPRA in response to petitions for determinations of non-regulated status. The PPRA includes assessment of the potential weediness of the GE organism, potential impacts on the weediness of other plants with which the GE organism can breed, and potential impacts from transfer of genetic information to both sexually compatible species and species with which the organism cannot interbreed (e.g., see (USDA-APHIS 2015a)).

As part of the decision-making process regarding a GE organism's regulatory status APHIS conducts the relevant environmental analyses in accordance with the National Environmental Policy Act (NEPA) to provide the Agency information on any potential environmental impacts associated with the petition request. This may include potential effects on federally listed threatened and endangered species, species proposed for listing, and their designated or proposed critical habitats. If the PPRA concludes the GE organism is unlikely to pose a plant pest risk, and considering NEPA analyses and other relevant information, APHIS may approve petitions and issue a determination of non-regulated status for a GE organism.

APHIS also provides under current regulations an "Am I Regulated" (AIR) consultative process. If an individual is unsure whether a GE organism meets the definition of a regulated article as described in 7 CFR part 340, they may seek a determination from APHIS-BRS by sending a letter of inquiry, and providing required information to APHIS.[162] If it is determined that a GE organism is not subject to 7 CFR part 340 regulation, APHIS will inform the inquirer that it will not require a permit for the interstate movement, importation,

[162] USDA-APHIS: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

or environmental release of the organisms. That organism may still be subject to other regulations such as 7 CFR part 360, or oversight by EPA

As with the potential impacts described for environmental releases, one of the principle concerns among some stakeholders regarding commercial use of non-regulated GE plants (e.g., agricultural or forestry products) is gene flow. As part of the PPRA, APHIS evaluates the potential for gene flow, hybridization and gene introgression between the GE plant and other plants with which it can breed. APHIS also evaluates horizontal gene transfer – the potential for gene flow to other organisms without sexual reproduction, and whether such an event could lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants. If APHIS determines the GE plant (or other organisms) is unlikely to pose a plant pest risk, and that gene flow is also unlikely, APHIS may determine the plant or other organism is not subject to regulation.

If a GE organism is determined not subject to APHIS regulation, it may be subject to laws and regulations administered by the EPA, and other federal and state agencies. The EPA, under FIFRA, regulates the registration, sale, and distribution of pesticides used in association with the GE plant, including regulation of PIPs and GE microbial pesticides. The FDA, under FFDCA, oversees the safety of GE plant products used for human or animal food.

The vast majority of GE organism that have been deregulated by APHIS have been crop plants. Many, but not all of these, are commercially produced in the United States (see section 3.3). It is expected that the majority of future GE organisms APHIS will be evaluating and subject to 7 CFR part 340 will be GE plants and trees developed for agricultural and forestry purposes. APHIS will likely see different plant species, new plant-trait combinations, and more GE microorganisms, as well as nematodes. APHIS will also see new varieties of GE plants developed for pharmaceutical and industrial purposes. As plant biotechnologies continue to advance, APHIS anticipates that developers will petition for deregulation of GE plants with traits such as disease resistance, drought tolerance, and nutrient use efficiencies. The development of stacked-trait GE plant varieties is increasingly more common, which will require additional scrutiny in determination of their potential as a plant pest, or noxious weed.

Gene Flow and Deregulated GE Plants

Minimizing the potential adverse effects of gene flow lays, in part, in the regulation of GE organisms during research and development, and the collective evaluations among APHIS, the EPA, and other federal agencies, as applicable, for commercial use when science provides evidence that the risks for, and outcomes of, gene flow are manageable. Gene flow between GE crop plants and sexually compatible wild relative species happens all the time and is not itself a risk. A risk may occur if the trait confers a fitness advantage to a weedy relative that makes it even weedier. The GE trait may present an economic risk to growers who are raising sexually compatible crops for a non GE market and this fact is discussed in more detail in section (4.6.1.). Once APHIS determines the GE plant (or other organisms) is unlikely to pose a plant pest or weed risk, and that gene flow to wild relative species is also unlikely to result in plant pest or weed risks, it will deregulate a GE organism under part 340.

Under the No Action Alternative, APHIS does not impose any conditions on users of deregulated GE crops to limit gene flow to other crop plants or sexually compatible relatives.

Generally, gene flow mitigation strategies in agriculture are well-established and where implemented minimize the likelihood of gene flow. Producers of GE and non-GE crops have available and can use practices prescribed by the USDA National Organic Program (USDA-AMS 2015b), ASTA (ASTA 2015b, ASTA 2015a), and AOSCA (AOSCA 2015) to protect their crops from undesired pollen and seed in order to meet market standards for IP and certification of their seed and crop products as applicable. The USDA has several efforts to promote coexistence through education, outreach, and voluntary measures at the local level. The USDA's Advisory Committee of Biotechnology and 21st Century Agriculture (AC21) supports coexistence efforts by actively engaging in interagency efforts to address issues related to coexistence among conventional, organic, identity-preserved, and GE crop production.[163]

4.3.6.2 Preferred Alternative: Gene Flow and Weediness

4.3.6.2.1 Regulatory Scope

The Preferred Alternative broadens the scope of organism that could be considered under regulations, and potentially regulated, by incorporating the noxious weed authority provided APHIS under the PPA (7 U.S.C. §7701(7)), and adopting the terms and definitions for "genetic engineering" and "GE organism." In response to USDA OIG recommendations APHIS would remove the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures, and strengthen its compliance and enforcement program by clarifying the full range of authorities and penalties granted under the PPA and augmenting its reporting requirements. Collectively, these revisions would provide oversight of a broader range of organism where gene flow and weediness may be a concern.

4.3.6.2.2 Authorization of Interstate Movement and Importation

Movement and importation of GE organisms would be conducted solely under APHIS permit. Shipping standards would be less prescriptive and more generally applicable, requiring GE organisms be handled in such a way that their identity is maintained and that they are imported or moved in a secure shipment.[164] Movements of regulated organisms would have to meet the containment requirements defined within the new regulations and shipped in such a way that there is no release into the environment. Specifics regarding labeling and the methods of secure shipment would be included as permit conditions. All locations where regulated organisms are received, stored, distributed, or released into the environment would have to be identified within a permit if movement occurs. This includes

[163] USDA - Agricultural Coexistence: http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=coexistence.html

[164] APHIS would define secure shipment as shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

but is not limited to greenhouses; laboratories; growth chambers; field trial locations; production, propagation, sale, distribution, and manufacturing locations.

Under the Preferred Alternative APHIS regulation of interstate movement and importation would encompass APHIS oversight of the movement of a broader range of GE organism-trait combinations as result of adoption of terms and definitions for "genetic engineering" and "GE organism," and codification of noxious weed authority. Movement of regulated organisms would be conducted by authorized permit only, which would allow for issuing of specific confinement requirements where there were particular concern in regard to gene flow or weediness.

4.3.6.2.3 Authorization of Environmental Release

As with movement and importation environmental releases/field tests would be conducted only under APHIS authorized permits and APHIS would prescribe permit conditions designed to prevent the unauthorized release of GE organisms from the test site, and its persistence in the environment on conclusion of the field test.

Because the notification procedure uses only the performance-based standards issued in the regulations, it is more administratively streamlined, but the general nature of the standards has made it difficult for APHIS inspectors to determine if a notification holder is in compliance with the standards. This, in turn, can make enforcement of compliance with regulations more difficult. With permits, but not with notifications, APHIS can accept the proposed measures to be implemented for preventing gene flow, or add to them, as conditions of the permit. The result is a set of binding, customized permit conditions that must be met in order to comply with authorization for the release. Hence, release only via permit under the Preferred Alternative is expected to further reduce the likelihood of gene flow between regulated GE organisms, and sexually compatible non-GE species. Permit applications for release into the environment would have to address the spread, persistence risk, and potential harm of the regulated organism in the environment, including but not limited to a description of how the phenotype of the regulated organism differs from the phenotype of the recipient organism, particularly with respect to potential interactions with, and its likelihood of spread and/or persistence in, the environment; and the location and size of all proposed environmental release sites, including area, geographic coordinates, addresses, land use history of the site and adjacent areas, and name and contact information of a person at each environmental release site.

Consequently, the Preferred Alternative could provide more protections than No Action Alternative as a result of the broader range of GE organisms considered under regulations, potentially regulated, and release of regulated organism only under permit, which would assign confinement requirements specific to the conditions of the release, and requirements for eradication of the GE organism from the release site on termination of the field test. Compliance and enforcement activities under the Preferred Alternative, discussed below, would further strengthen APHIS' ability to limit gene flow during authorized releases of regulated organisms.

Certain GE organisms, such as eukaryotic microorganisms, prokaryotic microorganisms, and viruses, are developed for use as microbial pesticides. These types of GE organisms are

regulated by the EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq., FIFRA). The EPA also issues outdoor experimental use permits under FIFRA to allow persons to release these organisms into the environment on a limited basis in order to obtain information necessary to apply to have products containing the organisms registered as microbial pesticides. Because both permitted and registered GE organisms developed for use as microbial pesticides are already subject to extensive regulation by EPA, APHIS entered into a memorandum of understanding (MOU) with the EPA stating that APHIS will not exercise duplicative regulatory oversight of such organisms. Under the Preferred Alternative, the revised regulations would codify this MOU. However, under the Preferred Alternative APHIS would regulate a GE organism that is intended for use as a biological control (biocontrol) agent if APHIS determines that it is a plant pest or noxious weed, with limited exceptions.

4.3.6.2.4 Compliance, Enforcement, and Remediation

APHIS is proposing to strengthen its compliance and enforcement program in order to manage compliance with the regulations more efficiently, by augmenting the approaches currently used to prevent or remediate potential risks to plant health. APHIS would clarify what locations and regulated organisms may be subject to inspection and expand reporting requirements. Responsible persons would be required to provide APHIS inspectors access to any relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other articles related to the importation, interstate movement, and environmental release of organisms regulated under 7 CFR part 340.

APHIS would revise requirements for the establishment and maintenance of records, and provision of APHIS inspectors with all required records upon request. APHIS proposes to require that certain records would have to be retained for periods of up to 10 years after completion of obligations required under permit or exemption. Record keeping requirements would facilitate compliance, and implementation of remedial measures and penalties in the event of an unauthorized release of a regulated organism.

Failure to comply with the regulations could result in denial of a permit application or revocation of a permit, application of remedial measures in accordance with the PPA, or criminal or civil penalties (§ 7734 - Penalties for violation). Pursuant to sections 7714 and 7731 of the PPA, APHIS may seize, quarantine, treat, destroy, or apply other remedial measures to a regulated organism that is new to or not widely prevalent or distributed in within the United States to prevent dissemination of the organism. APHIS typically issues an Emergency Action Notifications or administrative order to the owner of the regulated organism to specify these remedial measures.

Since 1995, major incidents of noncompliance with APHIS biotechnology regulations have included failure to comply with notification performance standards for field trials; failure to notify APHIS of an accidental/unauthorized release within the required time period; failure to contain or devitalize regulated seed as required; failure to maintain appropriate isolation distances between regulated organism and non-regulated organisms; and failure to monitor for volunteer GE plants in the year following a field test on an insect resistant corn variety. In all instances APHIS required remediation actions, and in many instances, civil penalties issued.

Considering the proposed revisions, the Preferred Alternative is expected to strengthen prevention of the unauthorized release and dissemination of a regulated organisms during field testing, and remediation measures implemented in the event an unauthorized release occurs. With extended oversight of GE organisms that may present a noxious weed risk, and those that would fall under the terms and definitions for "genetic engineering" and "GE organism," compliance and enforcement actions could potentially encompass a broader range of GE organisms, trait genes and their products, and the potential risks such organisms may pose relative to gene flow and weediness. By analyzing first and regulating when appropriate to winnow out those GE organisms that are unlikely to pose plant pest and noxious weed risks, APHIS can devote its resources to provide better oversight of those GE organisms that do pose plant pest and noxious weed risks.

4.3.6.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct an upfront plant pest risk assessment (PPRA) and/or a weed risk assessment (WRA) to inform the determination of whether a GE organism is subject to regulation and required permitting under 7 CFR part 340. As part of the risk analyses APHIS would evaluate the potential for gene flow and weediness of a GE organisms prior to making a determination that the organisms was or was not subject to regulation. APHIS would also conduct NEPA analyses as appropriate, on a case-by-case basis, which would further evaluate the potential impacts of gene flow on the human environment. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk.

The inclusion of noxious weed provisions of the PPA, expanded scope of organisms evaluated under regulations using the revised terms and definitions, conduct of an upfront PPRA and/or WRA that assesses the risks for gene flow and weediness, and review pursuant to NEPA as required, provides a regulatory review framework that would make it unlikely that any GE organisms determined not to be subject to regulation would have a significant adverse impact on the environment through gene flow or weediness.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined was not a plant pest or noxious weed risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

As described previously, because APHIS' process in determining the regulatory status of GE organisms will be more efficient, it is expected that the total number of GE organisms regulated under the Preferred Alternative would likely decline; that the list of regulated organisms would be limited to those organisms that pose a plant pest or noxious weed risk. GE organisms developed for food, fiber, wood, or other purposes, and not regulated by APHIS, would still be subject to review and approval by the EPA prior to commercial use. As described for field testing, the EPA would regulate the commercial production and use of

GE organisms developed as microbial pesticides, and those GE plants possessing pest- or disease resistant properties (or rather, the PIP itself).

The outcomes of APHIS determinations that a GE organism is not subject to regulation are not expected to significantly differ from the No Action Alternative. Management of gene flow in the commercial production of deregulated GE crop plant would be the same as described for the No Action Alternative. GE plants comprised of PIPs and GE microorganisms developed for biological control would be regulated by the EPA. Strategies for management of gene flow in agriculture are considered well-established, and where implemented can minimize the likelihood of gene flow. Producers of GE and non-GE crops have available and can use practices prescribed by the USDA National Organic Program (USDA-AMS 2015b), ASTA (ASTA 2015b, ASTA 2015a), and AOSCA (AOSCA 2015) to minimize unintended presence, meet market standards for IP, and certification of their seed and crop products as applicable. Growers of GE agricultural commodities will share responsibilities, as part of standard industry practices, to ensure their production systems facilitate meeting market standards for IP that organic growers can maintain NOP certification, and that commingling of their crop commodities with other non-GE crops and crop products is precluded. Adoption and use of GE organisms for commercial purposes would also have to comply with all other federal and state laws and regulations for protection of fish and wildlife, and natural resources.

Considering the broader scope of GE organisms that would be evaluated under the Preferred Alternative, and potentially regulated, GE organism-trait combinations that otherwise would not be regulated under the current 7 CFR part 340 would be subject to regulation and permitting requirements. These would be in the way of those that may present as noxious weeds, and those GE organisms derived from "genetic engineering" as defined under the Preferred Alternative. In these instances, certain GE organisms that are beyond the scope of current regulations would be evaluated for plant pest and noxious weed risk under the Preferred Alternative. For example, plants that lack plant pest sequences are not captured under the current part 340. To the extent regulation of such GE organisms reduces the potential risks of gene flow to other non-GE crops, and introgression of potentially weedy traits into sexually compatible wild relatives, there could be seen environmental protections not realized under the No Action Alternative.

If a GE organism were determined by APHIS not to be subject to regulation, and it were later found to present potential plant pest or noxious weed risks, APHIS would have the authority to revise its determination, and regulated that GE organism under 7 CFR part 340.

4.3.6.3 Alternative 3: Gene Flow and Weediness

4.3.6.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it codifies noxious weed authority, utilizes the revised definitions for "genetic engineering" and "GE organism," and risk analyses would be conducted via the PPRA and WRA. However, under this Alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms from the mere presence of GE plant material in non-GE

crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. The only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.3.6.3.2 Authorization of Interstate Movement and Importation

The importation and interstate movement of regulated organisms that presented a plant pest or noxious weed risk would be conducted solely under APHIS permit. The importation and interstate movements of regulated organisms that presented only potential economic harms would not require a permit for importation or interstate movement, although their environmental release would.

The potential impacts associated with gene flow in relation to movement and importation of regulated organisms would be the same as the Preferred Alternative, because the scope of GE organisms evaluated as plant pests and noxious weeds would be the same, as well as permitting requirements and technical review criteria. Consequently, as with the Preferred Alternative, Alternative 3 would potentially provide better protections during the shipment/movement of regulated organism than the No Action Alternative due to the expanded scope of GE organisms considered under regulations, potentially regulated, and revisions to permitting and compliance programs (described following). That said, interstate movement and importation generally present little risk of gene flow from GE organisms to crop or wild/feral relative species with which reproduction is possible, and any benefits of this or the Preferred Alternative over the No Action Alternative would be marginal.

4.3.6.3.3 Authorization of Environmental Release

Under Alternative 3 authorized environmental releases would include GE plants grown for both field testing and commercial purposes. In essence, APHIS would function as a wide-scale permitting authority; permitting not only the field testing of GE organisms, but the production of all GE crops in the United States that were determined to present a potential economic impact on non-GE crop producers. One of the basic principles of this approach would be issuance of permit confinement requirements for commercial cultivation of GE crops that minimized the likelihood of cross-pollination of crops. This framework would support the coexistence of conventional, GE, and organic crop production systems.

Field Testing

Field testing of regulated organisms would be conducted solely under permit with prescribed conditions for confinement as required. Relative to protections against gene flow, permit requirements for field testing would be the same under the Preferred Alternative and Alternative 3. Alternative 3 would not differ from the Preferred Alternative in regard to risk analyses conducted for gene flow, or confinement requirements issued as part of permit authorization. The environmental risks considered in authorizing permit requests, and the protective conditions that may be applied to the permits, would be the same.

Under this and the Preferred Alternative the PPRA and WRA review criteria, to include risk analysis for gene flow and weediness, and criteria for permits, would largely be the same. The only difference would lay in regulation and permitting of MPNW, which would increase the volume of reviews and environmental release permits, but not the scope of environmental risks considered and regulated by APHIS. The potential environmental impacts of trait genes and their products would be assessed on a case-by-case basis as part of the PPRA and WRA, and environmental release permits issued by APHIS with conditions prescribed to isolate field tests to specific sites, prevent gene flow, and preclude propagation beyond authorized areas of field testing. Fundamentally, Alternative 3, as the Preferred Alternative, would provide better protections than the No Action Alternative in limiting the potential impacts of gene flow to non-GE crops and wild or feral relative species as a result of the broader range of GE organisms considered under regulations (revised definitions), potentially regulated, and authorization of environmental releases solely under conditional permits.

Commercial Crop Production

All noxious weeds determined by APHIS to pose potential economic impacts (MPNW) and desired for use in commerce would require a permit for cultivation. Plant biotechnology developers and growers of regulated organisms would be required to track and record the location and acreage of regulated crops being grown and implement a GE plant volunteer management program. They would also be required to cultivate their crops using isolation distances (buffer zones) specified by APHIS. Records demonstrating compliance with permit conditions would be required to be made available to APHIS upon request. In order to identify the location and proximity of non-GE crops to GE crops, all non-GE crop producers desiring to receive protections under regulations would need to certify their operations with APHIS to confirm they are legitimate business entities, and participate in a voluntary nation-wide crop pinning system. These measures are expected to reduce gene flow, facilitate coexistence, and benefit organic and IP cropping systems. These measures are likewise expected to facilitate trade and commerce through reductions in gene flow and limiting of unintended presence of GE crop plant material in non-GE commodities.

While reductions in gene flow would be expected, as described for the Preferred Alternative, where there is an increase in adoption of new GE crop varieties, such as for small grains, there could be seen an increase in the potential for gene flow into non-GE crops in some areas. Any increase in the risk for gene flow would be highly dependent on the species of crop plant, proximity of non-GE crops that are sexually compatible, and compliance of developers and growers with APHIS permit requirements for buffer zones and volunteer plant management. For the GE crops that have seen a high degree of adoption, are at peak saturation (e.g., corn, soybean, cotton), the rate of gene flow to non-GE crops is not expected to appreciably increase with the release of new GE varieties of that crop.

There is the likelihood that some growers will choose to produce conventionally bred, non-regulated crops, as opposed to regulated GE crop varieties. Where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate conventional non-GE crops, or organic crops. Hence, if due to regulatory compliance costs, and burden of compliance requirements, it becomes economically unfeasible or difficult to produce GE crops, some growers will likely

choose to produce a crop under a conventional or organic cropping system. In this instance, there would be an obvious reduction in the potential for gene flow from to GE to non-GE cropping systems.

Bearing these considerations in mind, overall, the revisions proposed under Alternative 3 would be expected to minimize the occurrence of pollen flow among commercial GE and non-GE crops, and commingling among crops via distribution of seed or other plant material during crop production.

4.3.6.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative, however, these activities would be extended to MPNW, and would incur expanded responsibilities for developers, growers of GE crops, growers of non-GE crops, and APHIS. Inspection and enforcement actions would extend to commercially cultivated MPNW, and enforcement of violations of permit requirements for preventing gene flow to non-GE crops. This authority would extend to preventing and remediating economic harms, and as such, discussed under the socioeconomics impacts section. In regard to APHIS authorized movements, importations, and environmental releases of regulated organisms; both this and the Preferred Alternative address USDA OIG recommendations and strengthen APHIS' compliance program, which would be expected to provide better protections in limiting the potential for gene flow, relative to the No Action Alternative.

4.3.6.3.5 Determination of Regulatory Status

As with the Preferred Alternative, the petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and WRA. As part of these risk analyses APHIS would evaluate the potential for gene flow and weediness of a GE organisms prior to making a determination that the organisms was or was not subject to regulation; this would include evaluation of the potential impacts on the weediness of other plants with which the GE plant can interbreed, and potential impacts from transfer of genetic information to organisms with which the GE organism cannot interbreed. APHIS would also conduct NEPA analyses as appropriate, on a case-by-case basis, which would further evaluate the potential impacts of gene flow on the human environment. Regulated organisms would include those that presented a plant pest or noxious weed risk, or those determined by APHIS to present a MPNW risk.

Hence, it is expected that APHIS would be regulating the majority of GE crops in commercial production (MPNW), in addition to those GE organisms determined to present a potential plant pest and noxious weed risk. Specifically, APHIS would be regulating GE and non-GE cropping systems for the purposes of minimizing gene flow among GE and non-GE crops.

For those GE organisms APHIS determined were not subject to regulation, the risk for introgression of weedy characteristics to sexually compatible wild relative species via pollen mediated gene flow would be unlikely. If such risks existed, APHIS would regulate the GE organism.

Apart from regulation of gene flow among GE and non-GE crops: considering the broader scope of GE organisms evaluated under Alternative 3, there could be seen regulation of certain GE organisms that otherwise would not be regulated under the current 7 CFR part 340. These would be in the way of those GE organisms subject to revised definitions for "genetic engineering" and "GE organism." In these instances, certain GE organisms that are beyond the scope of current regulations may be determined to be subject to regulation under Alternative 3 (e.g., unique GE organism-trait combinations conferring stress tolerance, or enhancement of nutrient utilization), and would not be produced anywhere in the United States without APHIS authorization. To the extent regulation of such GE organisms reduces potential risks that could result from gene flow, there could be seen environmental protections not realized under the No Action Alternative.

As with the Preferred Alternative, if a GE organism were determined by APHIS not subject to regulation, and it were later found to present potential plant pest or noxious weed risks, or cause other agricultural harms, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340.

4.3.7 Biodiversity

4.3.7.1 No Action Alternative: Biodiversity

4.3.7.1.1 Regulatory Scope

APHIS would continue to authorize the movement, importation, and environmental release of GE organisms that are considered plant pests under permit or notification (USDA-APHIS 2011, USDA-APHIS 2012). These activities may be authorized in any U.S. state, commonwealth, or territory, as described in section 3.3.4.

In general, species abundance and variety will be less on and around intensively managed agricultural lands than in undisturbed ecosystems. These highly managed landscapes impact biodiversity largely due to the loss of habitat, fragmentation of habitat, and conversion of unmanaged environments to highly managed ones.

4.3.7.1.2 Authorization of Interstate Movement and Importation

APHIS authorized movements and importations of GE organisms are required to adhere to the notification performance standards and permit conditions that ensure confinement of the GE organism during shipping or movement (USDA-APHIS 2011, USDA-APHIS 2012). Conducted pursuant to APHIS requirements movements and importations under current regulations have no effect on biodiversity. These activities typically involve small quantities of GE material transported in secure shipping containers between clearly defined locations. When entities authorized to move or import GE organisms adhere to current notification and permit requirements the potential for inadvertent release of GE organisms is limited to instances of accidents or human error. Accidental releases, such as spillage of seed as a result of container failure or human error are possible, and if they occurred would result in remediation actions at the site of release. Conceptually, seed spilled during transport could germinate along roadsides or similar routes of transport; however, if it occurred, any remediation actions would be transient in nature, localized to the site of release, and adverse effects on biodiversity considered highly unlikely. These types of incidents would generally

have no lasting effect on wildlife, wildlife habitat, or ecosystem dynamics in the area of release and remediation.

4.3.7.1.3 Authorization of Environmental Release

Field testing is part of standard research and development practices and pre-market evaluation of GE organisms. To date, APHIS has authorized more than 18,400 permits and notifications for field testing of GE organisms (the vast majority plants). In 2015 APHIS issued 37 permits and acknowledged 447 notifications for environmental release in 39 states, Puerto Rico, and U.S. Virgin islands.[165] To control and minimize GE plants or other organisms occurring beyond the area where it is intended to be tested, notifications and permit criteria are designed to limit regulated GE organisms to the field site and preclude persistence of the GE organism beyond termination of the field trial.

The median size of an approved field trial is approximately 5 acres, and average size about 20 acres. Collectively, authorized field trials have comprised, in recent years, around 400,000 acres per year or less. Potential impacts on biodiversity that may derive from authorization of field trials are dependent on the species of GE organism (e.g., annual or perennial plant, occurrence of sexually compatible species in the area of field testing, extent of domestication), the trait (e.g, insect or herbicide resistance), the management practices involved in field testing of the GE organism (e.g., tillage, pesticide use), and the environment in which the field trial is conducted (e.g., proximity to wilderness areas, wildlife refuges, critical habitat). These would be considered on a case-by-case basis as authorization requests are received by APHIS. In general, due to the small scale and transient nature of field trials, the potential for adverse effects on biodiversity is rather limited.

Certain GE organisms may present unique issues that warrant special restrictions during field release, and in some instances permit requests may be denied if the request does not meet APHIS regulatory requirements. Examples would be GE trees developed for commercial purposes, and certain GE grasses (which include rice). Due to the capacity for outcrossing of certain GE plants with sexually compatible wild or feral species, APHIS may prescribe permit conditions designed to preclude dissemination of the GE plant beyond the authorized area of release.

Plants genetically engineered to tolerate stressful climate conditions could result in use of marginal lands to field test such plants, or they could be tested in areas in which they are not native. Marginal lands are those unsuitable for growing most row crops due to water availability (too much or too little), soil suitability (e.g., extreme pH, limited nutrients, high salinity, etc.), extreme temperatures (too high or too low), high altitudes, and other factors. Freeze tolerant eucalyptus has been field tested in the Southern United States, a region in which unmodified populations of eucalyptus would not typically persist. The same general concept applies to development of any stress tolerant plant and possible expansion or shifting

[165] Permit and notification request information for import, movement, and field release is publically available on the USDA funded Information Systems for Biotechnology website ISB (2015). *Information Systems for Biotechnology (ISB)*. USDA Cooperative State Research, Education, and Extension Service (CSREES), USDA Agricultural Research Service (ARS), and Agricultural Experiment Station at Virginia Tech. Retrieved December 19, 2016, from http://www.isb.vt.edu/Default.aspx..

of the region in which it may be field tested. Development of GE plants for stress tolerance or for adaptation to marginal lands is likely to continue (with or without the use of plant biotechnology). Hence, these types of GE plants could see field testing in areas where GE plants have not commonly been introduced (are alien), such as desert and mountain regions, or regions with colder or warmer climates.

Field trials of GE organisms are subject to all federal and state regulations governing protections of wildlife, habitat, and biodiversity. Any GE organism field tested would be subject to USFWS and NMFS authorities for protection of threatened and endangered species under the Endangered Species Act (ESA) of 1973,[166] EPA regulations protecting air and water quality (discussed throughout this dPEIS), and various state requirements for protection of wildlife and threatened and endangered species. APHIS authorization for notifications and permits requires applicants to identify whether the proposed release site and/or area to be monitored are within, or in close proximity, to designated critical habitat for a listed threatened or endangered species or within habitat proposed for designation under the ESA (see Chapter 6).

Unauthorized releases can and do occur, hence, the purpose of APHIS' compliance and enforcement program (discussed following). APHIS publishes major noncompliance incidences on its website. Noncompliance incidences have involved failure of permittees to maintain appropriate isolation distances, maintain the regulated articles separate from other organisms, failure to devitalize GE plants on termination of the field trial, and failure to monitor for volunteer GE plants as required by permit. In all instances remediation was required by APHIS, and in most civil penalties issued.

When field testing is conducted pursuant to the present notification and permitting requirements (USDA-APHIS 2011, USDA-APHIS 2012) the likelihood of escape or unauthorized release of a GE organism is considered minimal. Unauthorized releases largely derive from weather events (strong winds or rain), human error, or in rare instances, neglect. The safeguards used to prevent escape and dissemination of the GE organism during field trials include physical isolation distances (segregation from other crops and sexually compatible species), temporal isolation, flower removal, or other appropriate controls. Under the current regulatory framework, APHIS authorized field testing is considered to present negligible risk to biodiversity in the area of testing, or surrounding areas. Field testing generally has limited adverse effects on the diversity and abundance of species extant at the site of release. Species populations and community structures would not be expected to be significantly altered by APHIS authorized field trials. No adverse effects on wilderness areas, forestlands, or critical habitat has been identified in over 20 years of field testing.

Any future requests for APHIS authorization of environmental releases of GE organisms would be assessed on a case by case basis, and permit conditions prescribed as necessary to preclude dissemination or persistence of the GE organism beyond the authorized area of release.

[166] By example, see http://www.fws.gov/endangered/laws-policies/regulations-and-policies.html, and https://www.fws.gov/permits/ltr/ltr.html

4.3.7.1.4 Compliance, Enforcement, and Remediation

APHIS compliance and enforcement activities are to ensure confinement of the GE organism to the areas authorized for import, movement, or field testing. APHIS works with state and other federal agencies, including the USFWS, EPA, and Department of Justice (DOJ) to facilitate compliance with APHIS regulations.

Remediation can be required if a violation of APHIS notification or permit requirements has occurred. Remediation can involve disturbance of wildlife habitat and potential exposure of wildlife to pesticides. For example, if germination of GE seed occurred outside an authorized area, or volunteer plant presented, APHIS could order treatment of the area with a broad spectrum herbicide or mechanical removal to eradicate the GE plants. The effects of remediation actions on vertebrate and invertebrate organisms, and their habitats, where such activities occur would generally be transient in nature and have no lasting effects on the affected area once remediation actions were determined to be completed. However, some areas may require long term monitoring, and, in the event of extenuating circumstance, eradication of GE plants or other organisms could require months to years to complete. This considered, and as discussed above, no significant adverse impacts on wilderness areas, forestlands, or critical habitat has been identified in over 20 years of APHIS oversight of field testing of regulated organisms.

4.3.7.1.5 Determination of Regulatory Status

When APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance with EPA, and other federal and state agency requirements. Agricultural lands will continue to comprise the dominant use of non-regulated GE organism, hence, potential impacts on biodiversity would be limited to these and surrounding areas.

While agricultural practices can contribute to conserving and promoting biodiversity, some practices can also serve a major driver of biodiversity loss. Agronomic practices associated with cultivation of GE plants, such as pesticide application, fertilizer applications, tillage, and crop rotation (all of which be part of IPM and IWM practices) can all affect animal and plant populations, and their habitats. Likewise, utilization of GE microbial pesticides can affect target, and in some instances non-target species, in and around the areas such pesticides are used. The same applies to non-GE cropping systems.

For instance, herbicide use decreases weed prevalence and modifies the weed species complex present in agricultural fields. These changes could in turn modify the populations of species that rely on agricultural weeds as a food source or habitat. Hence, a shift in weed species can affect insects, birds, and mammals that depend on agricultural weeds, directly or indirectly, for sustenance. Similarly, both tillage and insecticide use can influence biodiversity. These potential impacts are not any different for non-GE agricultural systems, save for variances in the types of tillage, and insecticide use that can occur with GE plants. To the extent GE HR plants facilitate conservation tillage practices, these would be expected to benefit biodiversity in and around the area where such crops were cultivated through provision of food and habitat for vertebrates and invertebrates. To the extent insect and disease resistant GE plants facilitate reductions in use of insecticides and fungicides, there

would be expected a reduction in exposure of non-target biota to such chemicals, and consequently, benefits conferred to sustaining the biological diversity in the areas where these GE plants are cultivated. On the other hand, poor management of HR crops (as well as non-GE crops) can result in development of herbicide resistant weeds, and an increase in herbicide use and conventional tillage to manage resistant weed populations, neither of which serve to promote biodiversity. Hence, biodiversity in and around areas where GE plants are cultivated is highly dependent on the particular variety of GE crop plant, and the agronomic practices chosen and implemented by the grower in production of the plant.

Various studies over the last 10 years have investigated the differences in the biological diversity among GE and non-GE crop fields, particularly those GE crop plants that are resistant to insects (e.g., *Bt* crops) or resistant to certain herbicides. Some studies have found negligible to modest decreases in biological diversity or abundance attributed to GE crops that are insect resistant or herbicide resistant, where other studies have found no effects (e.g., see (NRC 2010a, Carpenter 2011, NAS 2016b)). Since 2008, over 360 original research articles have been published examining the non-target effects of Bt crops, in particular, on invertebrate organisms (mostly arthropods)(Naranjo 2009).

Laboratory based studies have generally identified negative effects of Bt crops on life-history characteristics among various taxonomic and functional groups when the organisms were exposed directly to Bt proteins in plant tissues or through artificial diets (Naranjo 2009). Some of these effects would be expected based on the taxonomic affinity of the non-target organisms to the orders of insect pests targeted by Bt crops. For field trials, few harmful non-target effects of Bt crops have been observed; hence, a greater number of adverse effects have been identified in laboratory studies than have been observed in the field. This may be explained partially by the fact that protein exposures in laboratory studies were more controlled and often at levels in excess of field concentrations, and the fact that field populations are governed by many interacting and uncontrollable factors, including prey and host abundance (Naranjo 2009). In general, field studies have found expected reductions in parasitoids of target pests in Bt corn systems, but no studies have shown any change in levels of predation of either target or non-target pests between Bt and non-Bt crops, even when population densities of some predator species are lower in the Bt crop (Sisterson, Biggs, Olson et al. 2004, Naranjo 2009).

A fairly recent meta-analysis of 42 field experiments, which are more apt to provide data relevant to the potential adverse effects of IR crops on non-target populations, indicates that non-target invertebrates are generally more abundant in Bt cotton and Bt corn fields than in non-GE crop fields managed with insecticides (Marvier, McCreedy et al. 2007). However, in comparison with insecticide-free control fields, certain non-target taxa are observed to be less abundant in Bt fields (Marvier, McCreedy et al. 2007). A similar review by Ronald (2011) found the use of Bt based crop plants has been found to enhance the biodiversity of beneficial insects, and use of HR crop plants, where conservation tillage practices are employed, can improve water quality via reductions in tillage, which is beneficial to sustaining biodiversity (Ronald 2011).

Overall, the use of Bt crops has the potential to reduce insecticide use, and enhance the role of biological control in IPM systems. Between 1996 and 2006, the efficacy of Bt corn and

cotton against major pest species has been associated with an estimated 136.6 million kg (301.2 million lbs) global reduction in insecticide active ingredient used; a 29.9% reduction (Naranjo 2009). In 2011, the global insecticide reductions from using GE IR corn and cotton in were estimate to be 6.9 million kg/15.2 million lbs (equivalent to 86% of insecticides typically targeted at corn stalk boring and rootworm pests prior to the use of Bt corn) and 17 million kg/37.5 million lbs (equivalent to 37% of all insecticides used on cotton prior to the use of Bt cotton) of active ingredient use, respectively (Brookes and Barfoot 2013b).

Where the potential impact of GE crops on biodiversity, in particular, has been a topic of general interest, a recent review of over 360 research articles on this topic suggests that commercial GE crops can reduce the impacts of agriculture on biodiversity through facilitating adoption of conservation tillage practices, potential reductions in insecticide use, the use of more environmentally benign pesticides, and in some instances increased yields that can alleviate pressure to convert additional land into agricultural uses (Carpenter 2011). The continued facilitation of biodiversity will depend on the GE plant varietal cultivated and agronomic practices employed, which will determine at the abundance and variety of species extant at the farm level.

Growers of both GE and non-GE crops recognize that they are custodians of their environment and that practices facilitating biodiversity serve to benefit crop production and consistent with the public interest. Various federal and state programs serve to support biodiversity and sustainability in commercial agriculture. Sustainable agriculture was addressed in the 1990 Farm Bill (Food, Agriculture, Conservation, and Trade Act of 1990 [FACTA], Public Law 101-624, Title XVI, Subtitle A, Section 1603).[167] Under FACTA the term sustainable agriculture means "an integrated system of plant and animal production practices having a site-specific application that will, over the long term: satisfy human food and fiber needs; enhance environmental quality and the natural resource base upon which the agricultural economy depends; make the most efficient use of nonrenewable resources and on-farm resources and integrate, where appropriate, natural biological cycles and controls; sustain the economic viability of farm operations; and enhance the quality of life for farmers and society as a whole."

The USDA recognizes that conservation by farmers, ranchers, and forest owners is required for sustaining agriculture for the future and provides various programs that support biodiversity and sustainability, such as landscape-scale conservation initiatives and Conservation Reserve Program (CRP).[168] The USDA funds the Sustainable Agriculture Research & Education (SARE) program (http://www.sare.org/), which provides grants to farmers, ranchers, researchers, educators, and community groups;[169] and a SARE-supported network of sustainable agriculture educators in every state and island protectorate – comprised of expert farmers, ranchers, and agriculture professionals.

In general, relative to any undisturbed ecosystem, species abundance and variety will be less in intensively managed agro-ecosystems. However, practices as summarized above can foster

[167] USDA - NAL, Sustainable Agriculture: https://www.nal.usda.gov/afsic/sustainable-agriculture-information-access-tools
[168] USDA- Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation
[169] SARE- Sustainable Agriculture Grants: http://www.sare.org/Grants

greater diversity and abundance of biota. Where the potential impact of GE crops on biodiversity, in particular, has been a topic of general interest, current science-based evidence suggests that commercial GE crops can reduce the impacts of agriculture on biodiversity through facilitating adoption of conservation tillage practices, potential reductions of insecticide use, use of more environmentally benign pesticides..

4.3.7.2 Preferred Alternative: Biodiversity

4.3.7.2.1 Regulatory Scope

The Preferred Alternative would incorporate the noxious weed authority provided APHIS in the PPA; expand the range of organisms considered and potentially regulated using the revised definitions for "genetic engineering" and "GE organism"; remove the notification procedure and require all authorizations for import, interstate movement, or environmental release be conducted under permitting procedures; and strengthen the compliance and enforcement program by clarifying APHIS authorities under the PPA and augmenting current approaches used to prevent or remediate potential risks to plant health.

4.3.7.2.2 Authorization of Interstate Movement and Importation

Movement and importation of GE organisms would be conducted solely under APHIS permit. APHIS would prescribe permit conditions, as applicable, designed to preclude unauthorized release. APHIS would use a performance-based approach for shipping of GE organisms and require they are handled in such a way to secure the shipment and maintain labeling and identity.[170] Movements of regulated organisms would have to meet containment and handling requirements to prevent release into the environment. Specifics regarding labeling/marking and the methods of secure shipment would be prescribed as part of the permit conditions.

As with the No Action Alternative, conducted pursuant to APHIS requirements under the Preferred Alternative, movements and importations would have no effect on biodiversity. These activities would typically involve small quantities of GE material transported in secure shipping containers between clearly defined locations. When entities authorized to move or import GE organisms adhered to permit requirements the potential for inadvertent release of GE organisms would be limited to instances of accidents, unforeseen and severe weather events, or human error. If an unauthorized or noncompliant release occurred and APHIS required remediation, any remediation actions (e.g., removal of a GE plant from an unauthorized area, application of herbicides pursuant to EPA requirements) would be transient in nature, localized to the site of release, and adverse effects on species abundance and diversity considered highly unlikely. These types of incidents may have transient effects on individuals of animal or plant populations, but would generally have no lasting effect on animal or plant communities, or ecosystem dynamics in the area of release and remediation.

[170] APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation".

4.3.7.2.3 Authorization of Environmental Release

Under the Preferred Alternative APHIS would be considering a broader range of organisms that would include not only potential plant pests, but potentially noxious weeds, and other organisms subject to the definitions for "genetic engineering" and "GE organisms." The notification process (7 CFR § 340.3) and courtesy permits (§340.4(h) would be eliminated, and all environmental releases conducted solely under permit. APHIS would prescribe permit conditions to prevent the unauthorized release of GE organisms from the field site and their persistence in the environment on termination of field trial. APHIS compliance and enforcement actions (discussed following) would also be revised under the Preferred Alternative. Collectively, the proposed revisions constitute a broadening of APHIS' oversight of the field testing of GE organisms, which was suggested by the USDA OIG (USDA-OIG 2015) and 2008 Food, Conservation, and Energy Act of 2008 (Farm Bill).

Under the Preferred Alternative potential impacts on biodiversity as a result of APHIS authorized field releases would be similar to those under the No Action Alternative. As a result of institution of a more efficient risk-based regulatory review process it is expected that the total number of GE organisms regulated under the Preferred Alternative would likely decline, as the list of regulated organisms would be limited to those organisms that pose a plant pest or noxious weed risk. While the total number of APHIS authorized field releases may decline under the Preferred Alternative, developers would continue to field test non-regulated GE organisms, and total annual acreage for field testing of regulated and non-regulated GE organisms would likely continue along current trends, in the range of 350,000 to 450,000 acres. This is a crude estimate, and total acreage for field testing would be relative the rate of innovation and development in the agricultural biotechnology sector.

For those GE organisms that APHIS determines do not present potential plant pests or noxious weed risks, and therefore not subject to regulation, those GE organism may be field tested anywhere in the United States or its territories. Field trials of GE organisms would be subject to all federal and state regulations governing protections of wildlife, habitat, and biodiversity. Any GE organism field tested would be subject to USFWS and NMFS authorities for protection of threatened and endangered species under the Endangered Species Act (ESA) of 1973,[171] EPA regulations protecting air and water quality (discussed throughout this dPEIS), and various state requirements for protection of wildlife and threatened and endangered species.

Potential impacts on biodiversity would be the same as described for the No Action Alternative; derived from the agronomic practices employed in cultivation of the GE plant and temporary loss of habitat on the site of the field trial. Considering the revisions proposed and factors discussed above, regulation of environmental releases under the Preferred Alternative would have negligible impact on species abundance and diversity in and around authorized field release sites due to the rather limited acreage involved in most field trials, and transient nature of field trials. Over the last 15 years the median size of an approved field trial has been around 5 acres and average size about 20 acres, although field trials may comprise an area of around 100,000 in some cases. This trend would be expected to continue.

[171] By example, see http://www.fws.gov/endangered/laws-policies/regulations-and-policies.html, and https://www.fws.gov/permits/ltr/ltr.html

For future field releases APHIS would review and authorize proposed releases for regulated organisms on a case by case basis, to include review for critical habitat in the area of release, prior to authorization of the release.

4.3.7.2.4 Compliance, Enforcement, and Remediation

Under the Preferred Alternative APHIS would strengthen its compliance and enforcement program by augmenting the approaches currently used and clarifying its enforcement authority under the PPA. APHIS would require that the responsible person provide APHIS inspectors access to all relevant premises, facilities, locations, storage areas, waypoints, materials, equipment, means of conveyance, and other aspects related to the importation, interstate movement, and environmental release of organisms regulated under 7 CFR part 340.

APHIS would revise reporting requirements. Permits would require plant biotechnology developers to track and record the plantings, acreage, and location of their biotech products being grown as well as implement a GE plant volunteer management program. Records required to be maintained would include all locations and acreage where the regulated organism was planted during field testing; records for transport; and copies of contracts between the responsible person and all of his/her agents as well as copies of other records (e.g., emails, telephone records). APHIS would require that records for import or movement of a regulated organisms be retained for at least 2 years, and records for environmental releases to be retained for at least 10 years after completion of all obligations required under a relevant permit or exemption. APHIS would increase these time frames because many of APHIS' investigations into instances of noncompliance involve activities that were conducted a number of years before noncompliance was discovered. Maintenance of these records would facilitate the efficient enforcement of the regulations, and remedial measures and penalties issued by APHIS in the event of an unauthorized release of a regulated organism (i.e., where a regulated organism was planted in area not authorized by APHIS).

Failure to comply with the regulations could include denial of future permits; revocation of current permits; destruction, treatment, and removal of regulated organisms; issuance of penalties; and a means to settle civil violations prior to the issuance of an administrative complaint. [172] A responsible person could be held liable for the violation of any APHIS requirement by any agent working for the responsible person (including persons contracted to conduct or carry out the controlled outdoor use on their own or on leased properties).

With oversight of a broader range of GE organisms, compliance, enforcement, and remediation actions would encompass a broader range of potential risks that could be presented by novel GE organism-trait combinations. This is not to imply that novel GE organism-trait combinations will present any risk, only that if any risk of biological harm or insult may be possible, APHIS would have regulatory oversight of that risk, to include remediation of harm if any occurred. To the extent the proposed revisions help improve the management decisions of permit holders during field testing and transport, and reduce

[172] Prior to the issuance of a complaint seeking a civil penalty, the Administrator may enter into a stipulation, in accordance with 7 CFR 380.10

instances of noncompliance, potential impacts on biota could be reduced, largely in the way of reduction of remediation actions.

4.3.7.2.5 Determination of Regulatory Status

The petition procedure for determination of non-regulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct plant pest risk assessments (PPRA) and/or a weed risk assessments (WRA) to inform the determination of whether a GE organism is subject to regulation and required a permit under 7 CFR part 340. GE organisms would be listed on a regulatory status register on APHIS' website as regulated or not regulated. Regulated GE organisms would include those that APHIS determined to pose a plant pest or noxious weed risk via a PPRA or WRA, or APHIS has otherwise determined pose a plant pest or noxious weed risk. If APHIS determined a GE organism was not subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulate that GE organism under 7 CFR part 340 regulation.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined is unlikely to pose a plant pest or noxious weed risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements.

In regard to the potential beneficial and adverse effects of non-regulated GE organisms on biodiversity, APHIS determinations of non-regulated status under the Preferred Alternative would differ little from the No Action Alternative. When APHIS determined that a GE organism is not subject to 7 CFR part 340, that organism would still be subject to compliance with EPA, and other federal and state agency requirements. As with the No Action Alternative, agricultural lands would continue to comprise the dominant use of non-regulated GE organism, hence, potential impacts on biodiversity would be limited to these and surrounding areas.

Biodiversity in and around areas where GE plants were cultivated would be highly dependent on the particular variety of GE crop plant, and the agronomic practices chosen and implemented by the grower in production of the plant. The USDA would continue to provide for various programs that support biodiversity and sustainability, such as landscape-scale conservation initiatives and Conservation Reserve Program (CRP),[173] and the USDA funded Sustainable Agriculture Research & Education (SARE) program (http://www.sare.org/). As described under the No Action Alternative, current science-based evidence suggests that commercial GE crops can reduce the impacts of agriculture on biodiversity through facilitating adoption of conservation tillage practices, potential reductions of insecticide use, use of more environmentally benign pesticides, and increased yields that can alleviate pressure to convert additional land into agricultural uses (Carpenter 2011, Ronald 2011). To the extent these types of agronomic practices are implemented with GE crop plants, these

[173] USDA - Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation

would be expected to foster greater diversity and abundance of biota in and around fields where commercial GE crops are cultivated. Where GE plants were chosen for cultivation, these would not be expected to present any greater risk to loss of biodiversity than traditionally bred plants produced under conventional cropping systems.

GE ornamental plants, which have seen limited development, would be subject to regulation as either plant pests or noxious weeds. These species of plants can have a significant number of sexually compatible wild relatives, and as a commercial commodity, could be introduced into suburban, urban, and rural environments far less managed than commercial cropping systems. Important considerations for GE ornamentals are whether the particular species of GE ornamental may out-compete other plants in the ecosystem into which it is introduced, adversely affect animals that may feed on the plant, or generate allergens. Newly developed GE ornamental plants would require particular analysis in regard to their potential for invasiveness, and potential adverse effects animal and plant communities.

The same applies to GE plants developed for pharmaceutical, industrial, or phytoremediation purposes. The particular risk presented would be relative to any weediness tendencies inherent to the plant species selected for development, its degree of domestication (or lack thereof), presence of sexually compatible species in the area of use, and the particular plant-trait combination. Relative to biodiversity, it is APHIS's intention to incorporate the noxious weed authority provided APHIS under the PPA, in 7 CFR part 340. The purpose of incorporation this authority is to provide APHIS the explicit means to regulate GE organisms that may present noxious weed risks. These types of weeds can be harmful to habitat as they themselves can be invasive and difficult to eradicate or they may also potentially pass fitness traits to sexually compatible wild relative species that in turn can become more invasive or difficult to eradicate. GE plants identified by the APHIS WRA as potential noxious weeds, which could adversely affect local biodiversity if not regulated, would not be removed from regulatory oversight.

4.3.7.3 Alternative 3: Biodiversity

4.3.7.3.1 Regulatory Scope

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in that it incorporates noxious weed authority, utilizes the revised definitions for "genetic engineering" and "GE organism," and risk analyses would be conducted via the PPRA and WRA. However, it expands the scope of regulation to encompass potential economic impacts from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. Under this Alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms that could derive from the impacts of a GE crop on a non-GE crop (e.g., unintended presence as a result of pollen flow). The WRA would include an economic effects analysis, and APHIS would distinguish those GE organism that presented only potential economic impacts from those that presented plant pest and noxious weed risks.

If, after conducting a PPRA and/or WRA, APHIS determines that a GE organism is unlikely to pose a plant pest or noxious weed risk in the traditional sense (biotic effects), then it would not be regulated under 7 CFR part 340. However, if APHIS concludes that a GE organism is unlikely to pose a plant pest or noxious weed risk (biotic) but presented potential economic harms, then APHIS would regulate that GE organism and require APHIS permitting for use. For the purposes of this dPEIS those with potential market impacts are termed mere presence noxious weeds (MPNW). All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. Hence, under Alternative 3 potential harm under regulations would be extended to mean any economic harm and the only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown.

4.3.7.3.2 Authorization of Interstate Movement and Importation

As with the Preferred Alternative the notification process would be eliminated. The importation and interstate movement of regulated plant pests and noxious weeds would be conducted solely under APHIS permit. The importation and interstate movements of GE organisms that presented potential economic harms (MPNW) to non-GE producers would not require a permit for interstate movement or importation, although environmental release would. Consequently, relative to potential impacts of APHIS authorized interstate movements and importations on biodiversity; Alternative 3 is the same as or similar to that described for the Preferred Alternative, as the scope of GE organisms that would be permitted for transport, permit requirements, and compliance, enforcement, and remediation actions, would be the same.

4.3.7.3.3 Authorization of Environmental Release

Under Alternative 3 authorized environmental releases, conducted solely under permit, would include GE plants and other organisms that were field tested, as well produced or otherwise utilized for commercial purposes and presented an MPNW risk. Permits for field testing of GE organisms that present risks as plant pests or noxious weeds would have more stringent requirements than permits for commercial cultivation of MPNW, as MPNW would not present any biotic risk as plant pests or noxious weeds. Under this and the Preferred Alternative the PPRA and WRA review criteria, and criteria for permitting, would be the same, save for inclusion of MPNW. Permits would require identification of critical habitat in the proposed area of environmental release for compliance with the ESA. Agricultural lands would comprise the dominant use of regulated and non-regulated GE organism, hence, potential impacts on biodiversity would be limited to these and surrounding areas.

All non-GE crop producers wishing to receive protections under APHIS regulations would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning system on a regular basis. These requirements would be instituted in order to effect the purposes of Alternative 3, which is to minimize commingling of GE and non-GE crops and associated economic impacts.

Where the extensive permitting, monitoring, and reporting requirements of this Alternative prove to be burdensome, some growers of GE crops may opt to cultivate the traditionally bred crop plant under a conventional or organic cropping system. Were this to occur, this Alternative could potentially lead to agronomic practices that were less conducive to conservation of biodiversity in and around crop fields. The likelihood of some farmers opting to produce a particular non-GE plant utilizing a conventional or organic cropping system, as opposed to the GE plant variety, and the degree to which it may occur, is indeterminate. Potential changes in agronomic practices associated with such a shift in the choice of crop cultivation could adversely affect biodiversity, relative to the particular agronomic practices utilized in production of the non-GE crop plant under a conventional cropping system (e.g., increased insecticide use). Where a grower decided to cultivate a traditionally bred crop plant under a USDA certified organic cropping system, these cropping systems would be expected to have minimal adverse effects on biodiversity in and around these cropping systems.

Bearing these considerations in mind, when APHIS determined that a GE organism is not subject to 7 CFR part 340, that organism would still be subject to compliance with EPA, and other federal and state agency requirements, to include those laws and regulations providing protection of wildlife (e.g., ESA) and conservation of natural resources (e.g, CWA). Use of pesticides on GE and non-GE crops would be regulated by the EPA, as under the No Action and Preferred Alternatives. Likewise, cultivation of GE crop plants comprised of an EPA registered PIP, and use of GE microbial pesticides, would be regulated by the EPA.

Biodiversity in and around areas where GE plants were cultivated would be dependent on the particular variety of GE crop plant, and the agronomic practices chosen and implemented by the grower in production of the plant; this applies to all the Alternatives considered. The USDA would continue to provide for various programs that support biodiversity and sustainability, such as landscape-scale conservation initiatives, the Conservation Reserve Program (CRP),[174] and the USDA funded Sustainable Agriculture Research & Education (SARE) program. Fundamentally, Alternative 3 would differ little from the Preferred Alternative relative to biodiversity considerations, save for a potential reduction in production of insect and disease resistant GE crop plants, and concomitant increase in synthetic chemical use to control plants pests and disease.

4.3.7.3.4 Compliance, Enforcement, and Remediation

Compliance, enforcement, and remediation activities would be similar to that described for the Preferred Alternative; however, these activities would be extended to MPNW, and entail expanded responsibilities for developers, growers of GE crops, growers of non-GE crops, and APHIS. APHIS would include revised requirements in the regulations for the establishment and maintenance of records and provision of APHIS inspectors with all required records upon request. Biotechnology developers would be required to track and record the plantings, acreage, and location of their GE crop products being grown as well as implement a GE plant volunteer management program. Records required to be maintained would include the locations and acreage where the regulated organism was planted during field testing and copies of contracts between the responsible person and all of his/her agents

[174] USDA - Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation

as well as copies of other records (e.g., emails, telephone records). Maintenance of these types of records conjoined with random and targeted inspections would facilitate preventing non-compliance incidents, and remediation of unauthorized releases of a regulated organism in the event they occur. Regulations under this and the Preferred Alternative are designed to strengthen APHIS' compliance program, and consequently expected to provide better environmental protections than the No Action Alternative.

As with all the Alternatives considered, remediation actions in response to an unauthorized or noncompliant release could potentially affect biota in the area of remediation. Remediation actions, such as the eradication of a GE plant with herbicides, aggressive tillage, or hand removal, would be expected to be isolated to the area of the incident and transient in nature. Lasting or significant adverse effects on the diversity of biota as a result of APHIS remediation activities is unlikely, as most plants are controlled via mechanisms that do not preset any significant long-term risks to terrestrial or aquatic biota, or their habitats (e.g., controlled use of herbicides, tillage, use of biological controls).

4.3.7.3.5 Determination of Regulatory Status

Determination of regulatory oversight would essentially be the same as described for the Preferred Alternative. The petition process (7 CFR § 340.6) would be eliminated and APHIS would determine the regulatory status of GE organisms by conducting a PPRA and/or WRA. Because APHIS would also consider economic harms as part of the WRA, the only GE organisms that would not be regulated under Alternative 3 would be those that did not cause economic harms to non-GE crop producers. Consequently, APHIS would regulate many of the GE crops currently in commercial production.

Any person would be able to consult with APHIS on the regulatory status of a GE organism as described under section 2.2 – Program Alternative 2. Any GE organism that APHIS determined was subject to regulation would not be grown or otherwise utilized for commercial purposes unless permitted by APHIS. Any organism that APHIS determined is unlikely to pose a plant pest, noxious weed, or MPNW risk could be grown or utilized anywhere in the United States or its territories, subject to applicable federal and state laws and regulations, as well as county or other local requirements. For those GE crop plants APHIS determined were not subject to regulation under Alternative 3, the potential impacts on biodiversity, both beneficial and adverse, would be the same as that described for the Preferred Alternative.

As with the Preferred Alternative, GE ornamental plants, which have seen limited development, would be subject to regulation as either plant pests or noxious weeds. These species of plants can have a significant number of sexually compatible wild relatives, and as commercial commodity, could be introduced into suburban, urban, and rural environments far less managed than commercial cropping systems. Important considerations for GE ornamentals are whether the particular species of GE ornamental may out-compete other plants in the ecosystem. Newly developed GE ornamental plants would require particular analysis in regard to their potential for invasiveness, and potential adverse effects animal and plant communities. Likewise, GE plants developed for pharmaceutical, industrial, or phytoremediation purposes also need to be considered. The particular risk presented would be relative to any weediness tendencies inherent to the plant species selected for

development, its degree of domestication (or lack thereof), presence of sexually compatible species in the area of use, and the particular plant-trait combination.

Alternative 3 would provide that same protections for noxious weed concerns as described the Preferred Alternative. It is APHIS's intention to incorporate under part 340 the noxious weed authority provided APHIS under the PPA. The purpose of incorporating this authority, and implementation of the WRA, is to provide APHIS the explicit means to regulate GE organisms that may present noxious weed risks. These types of weeds can be harmful to habitat as they can be invasive and difficult to eradicate. They may also potentially pass fitness traits to sexually compatible wild relative species. GE plants identified by the APHIS WRA as potential noxious weed, which could adversely affect local biodiversity (e.g., disturbed habitat, toxicity), would not be removed from regulatory oversight.

4.4 Human Health

4.4.1 No Action Alternative: Human Health

4.4.1.1 Regulatory Scope

APHIS' legal authority to consider and regulate potential human health impacts is limited to that of the noxious weed provisions of the PPA. Harm to "public health" was included in the definition of "noxious weed" in the earlier Federal Noxious Weed Act, enacted in 1974. The term ''noxious weed'' means any plant or plant product that can directly or indirectly injure or cause damage to crops…the natural resources of the United States, the *public health*, or the environment.

As currently written, the scope of 7 CFR part 340 regulations does not explicitly incorporate noxious weed authority. APHIS evaluates potential impacts on human health under NEPA reviews, as in the dPEIS, and in EAs, EISs, and similar NEPA analyses associated with APHIS decisions made under 7 CFR part 340 (USDA-APHIS 2015a). Historically, APHIS' interpretation of the public health provision of the noxious weed authority has been limited. APHIS has listed four noxious weeds in which it cited "public health" as a reason for listing: Giant hogweed in 1981, kodo millet and African boxthorn in 1983, and Cape tulips in 2000. Each of these weeds is toxic to both humans and livestock. Apart from these listings, there is no history of use of the "public health" provision in the USDA's implementation of the plant quarantine statutes.[175]

APHIS actions related to human health under the current regulatory framework is to limit the exposure of the public to GE organisms during research and development and the regulatory review process, which occurs prior to the entry of a GE organisms into the commercial market. This primarily concerns field testing of regulated articles. In parallel to the field testing, GE organisms may be evaluated for food safety through the FDA's voluntary consultation process. The EPA also regulates field testing via experimental use permits (EUPs), and sets a tolerance limits for plant incorporated protectants (PIPs). The EPA also

[175] Pew Initiative on Food and Biotechnology (2004). Issues in the regulation of genetically engineered plants and animals of the plant quarantine statutes. P. 92

regulates pesticide use during field trials, as well as in commercial crop production, to limit worker exposure to pesticides, and pesticide levels in human and animal food.

Under the No Action Alternative GE organisms would continue to be evaluated for safety by the FDA as described in Section 3.8 - Human Health. Based on over 15 years of peer reviewed research and regulatory review rather broad agreement among the scientific and regulatory communities has emerged that food and food products derived from GE crops currently on the market, those that derive from GE plants that have been deregulated by APHIS, are as safe as and nutritionally equivalent to their non-GE counterparts, and pose no more risks to human health than foods derived from non-GE crops (e.g., see (CAST 2005, Batista and Oliveira 2009, Ronald 2011, AAAS 2012, AMA 2012, Bartholomaeus, Parrott et al. 2013, Goldstein 2014, Nicolia, Manzo et al. 2014, WHO 2015) (NAS 2016b), and memorandums by FDA (US-FDA 2015). All foods from GE plants intended for commercial production in the United States have been evaluated by FDA through its consultation, or other more relevant regulatory process, and have not entered commercial production until the FDA's questions about the safety of such products has been resolved.[176]

The most recent National Academy of Sciences (NAS) report concluded that "On the basis of detailed examination of comparisons of currently commercialized GE with non-GE foods in compositional analysis, acute and chronic animal toxicity tests, long-term data on health of livestock fed GE foods, and human epidemiological data, the committee found no differences that implicate a higher risk to human health from GE foods than from their non-GE counterparts" (NAS 2016b). The NAS report found that available time-series epidemiological showed no correlation between disease or chronic conditions in populations that consumed foods derived from GE crop plants. The NAS report did find however that there is some evidence that insect and disease resistant GE crops have had human health benefits by reducing insecticide poisonings and decreasing exposure to fumonisins (fungal toxins that can contaminate foods) (NAS 2016b).

The American Association for the Advancement of Science, in a 2012 statement, concluded that crop improvement by the modern molecular techniques of biotechnology is safe (AMA 2012). The World Health Organization concluded that GE foods on the international market have passed risk assessments, are unlikely to present a risk to human health, and that no effects on human health have been shown as a result of the consumption of GE foods by the general population in the countries where they have been approved.[177] The European Commission, in its 2010 review, found that "The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies(E.C. 2010)."

Current U.S. standards and processes for evaluation of the safety of human and animal food derived from GE plants are considered protective of human and animal health and would be

[176] FDA - Questions & Answers on Food from Genetically Engineered Plants: http://www.fda.gov/food/ingredientspackaginglabeling/geplants/ucm346030.htm

[177] WHO answers questions on genetically modified foods: http://www.who.int/mediacentre/news/notes/np5/en/

unaffected by this Alternative. Food and food products derived from GE crops must be in compliance with the FFDCA, and all other applicable laws and regulations. All developers of GE plants used for food have, to date, undergone a voluntary consultation or other more relevant regulatory process with the FDA prior to release into commerce. Such consultations are expected to continue. Any pesticide used in association with a GE organisms requires review and approval by the EPA pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) and Food Quality Protection Act of 1996 (FQPA).

In addition to U.S. standards and processes, food and food products derived from GE crops plants undergo review and approval by international authorities such as the European Food Safety Authority (EFSA) (EFSA 2015a) and the Australia and New Zealand Food Standards Agency (ANZFS)(ANZFS 2015), in accordance with the Food and Agriculture Organization's Codex Alimentarius (FAO 2009).

Worker safety standards and processes, as described in subsection 3.8.2 - Worker Safety, would remain unchanged. Agricultural workers would remain protected by several Occupational Safety and Health Act standards including Agriculture (29 CFR 1928), General Industry (29 CFR 1910), and the General Duty Clause. Further protections for workers would be are provided through the National Institute of Occupational Safety and Health (NIOSH), and the EPA's Worker Protection Standard (WPS) (40 CFR Part 170).

Under PPA authority, APHIS currently regulates outdoor plantings of GE P/I-producing plants. Although the number of permits issued by APHIS for GE P/I-producing plants varies somewhat from year to year, in recent years, the number of permits for this type of outdoor planting has been 5 or so per year. These outdoor plantings are subject to significant oversight, typically with seven inspections of each planting per year, from planting through post-harvest. Under the No Action Alternative, GE P/I-producing plants engineered using plant pests would continue to be regulated under the plant pest authority. GE P/I-producing plants that were created without the use of plant pests would not be regulated by APHIS, unless voluntarily submitted to APHIS for regulatory oversight.

4.4.1.2 Authorization of Imports and Interstate Movements

Under current regulations APHIS authorizes movements under notification or issues import and interstate movement permits for regulated GE organisms, including those that could be used for human or animal food. Permit applications and notifications, which are reviewed by APHIS, provide details about the nature of the GE organism, where the organism will be moved from and to, and a description of the facility that will be used to contain the organism.

The risk to human health as a result of importation or movement is considered negligible when APHIS containment requirements for shipment are adhered to (see 7 CFR part 340.8). In general, GE organisms would cause no harm to humans from direct exposure. The main risk associated with shipping of GE organisms is commingling of GE organisms with non-GE crops. This could conceptually occur as a result of human error, and the primary impact in this instance would be primarily economic. A small number of organisms are modified to produce pharmaceutical or industrial compounds and conceivably these organisms could present a risk to humans from unauthorized exposure. However the risk of exposure during

shipment is considered negligible, as shipments are in secured containers designed to preclude accidental release, and handled in a closed loop system that minimizes human error.

4.4.1.3 Authorization of Environmental Releases

APHIS currently uses notifications and permits to authorize environmental releases of regulated GE organism. Permits and notifications requirements limit the regulated GE organism to the field test site and designed to preclude persistence of the GE organism beyond the termination of the field test. Permits may prescribe further conditions to confine the GE organism to the release site. The safeguards to prevent escape and dissemination of the GE material include physical isolation distances (segregation from other crops), temporal isolation, flower removal, or other appropriate controls. APHIS may also require equipment cleaning, segregated storage, and labeling to preclude inadvertent mixing of regulated and non-regulated materials.

When a field release involves a GE plant engineered to produce pharmaceutical or industrial products APHIS requires additional safeguards that may indirectly protect human health before, during, and after the field trial (USDA-APHIS 2011, USDA-APHIS 2012). These include numerous inspections of each field trial, review of design and handling protocols, and requirements for training of personnel. In particular, APHIS only authorizes releases in low production geographies to eliminate the chances of cross-pollination/commingling with nearby food crops. The additional conditions used by APHIS for pharmaceutical and industrial related field trials reduces the likelihood of human exposures to these regulated plant varieties during field testing.

As with authorization for imports and movements, it is considered highly unlikely that any risk to human health would presented in the event of an unauthorized or inadvertent release during the field testing of GE organisms. The primary adverse outcome, or potential adverse outcome, of an unauthorized release is the commingling of GE organisms with non-GE crops or crop products, which is primarily a socioeconomic concern. When unauthorized or inadvertent releases have occurred remedial actions have been taken to remove seed or grain from the commercial food supply, and limit the dispersal and persistence of the GE organism in the environment. When notification performance standards and permit conditions are followed, the unintended release of GE organism during field testing would be of low probability. APHIS is not aware of any adverse impacts on human health that have derived from field trials authorized under notification or permitting procedures.

Bearing these considerations in mind, in 2005 and 2015 the USDA's Office of Inspector General (OIG) conducted audits of APHIS' current regulatory program for GE organisms (USDA-OIG 2005, USDA-OIG 2015). The OIG suggested that APHIS revise the regulations to minimize the risk of inadvertent dissemination of regulated articles from an authorized field site, and encouraged APHIS to revise the regulations to make explicit APHIS' evaluation of GE organisms for noxious weed risk (USDA-OIG 2015). Both the OIG audit and the Farm Bill expressed concern with the use of performance standards issued under notifications to regulate field tests of regulated organisms, and recommended that APHIS amend the regulations to exercise greater oversight and enforcement of such field tests and to require more extensive reporting and record retention regarding such tests.

4.4.1.4 Compliance, Enforcement, and Remediation

Any importation, interstate movement, or environmental release of GE organisms inconsistent with APHIS regulations and permitting/notification requirements is subject to APHIS compliance, enforcement, and remediation actions. The current regulations require APHIS to be notified if an unauthorized release occurs, or if the GE organism is found to have characteristics substantially different from those anticipated by the permit during release. Compliance involves monitoring, reporting, and inspection. Compliance actions indirectly protect human health by ensuring that APHIS permitting and notification requirements are followed. When current APHIS requirements are adhered to the general public would not be exposed to regulated GE organisms during transport of field testing.

Should APHIS inspections, or self-reporting by notifiers or permittees, reveal noncompliance APHIS assesses the risk and determines what action is necessary to control the regulated organisms. These actions are in part intended to protect people from exposure to a regulated GE organism. When a compliance infraction has proven to be a violation of APHIS requirements, APHIS may take enforcement actions. Where APHIS enforcement actions are legal remedies that would have no direct effect on human health, the specter of enforcement actions before the public may serve to encourage compliance with regulations. This could indirectly benefit human health if compliance with APHIS regulations is improved, and the incidence of unauthorized releases reduced. Remediation actions may be ordered if necessary, and involve quarantine or destruction of GE material. The decision of when and how remediation will be accomplished is based on the risk presented by the infraction and directed by APHIS.

Low levels of regulated GE crop products or seeds could inadvertently mix with commercial seeds or the food supply when released into the environment, with or without APHIS authorization of the environmental release. If such an event does occur there may be human or animal health concerns, particularly when the GE crop contains a pharmaceutical or industrial protein not intended for food use (e.g., a GE crop plant producing a pharmaceutical intended for animal use). In 2007, APHIS issued its "Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials (USDA-APHIS 2007). This policy described how APHIS responds when low levels of regulated GE plant materials occur in commercial seeds or grain that may be used for human or animal food. Although the material might be safe and non-actionable, the developer remains responsible for complying with APHIS regulations. Investigations may result in findings of noncompliance with subsequent enforcement actions and penalties. If low levels of unregulated material in food was unsafe or illegal, the FDA has authority to take regulatory action, including possible seizure or recall, against food that is unsafe or otherwise unlawful under the Federal Food, Drug and Cosmetic Act.

APHIS also instituted the Biotechnology Quality Management System (BQMS) Program in 2010, which helps organizations involved in biotechnology research and development, including small businesses and academic researchers, analyze the critical control points within their management systems to better maintain compliance with the APHIS regulations (7 CFR part 340) for the import, interstate movement, and field release of regulated GE

organisms. The BQMS Program provides clarity and expectations of regulatory responsibilities to the regulated community.

Compliance, enforcement, and remediation actions taken by APHIS under current regulations have been and are expected to continue to be protective of human health by ensuring that APHIS permitting and notification requirements are followed. These actions help prevent GE plant material that has not completed scientific and regulatory food and environmental safety analyses from entering the environment and food supply.

4.4.1.5 Determination of Regulatory Status

APHIS makes a determination of non-regulated status for GE organisms under current 7 CFR part 340 regulations based on the likelihood of the GE organism causing injury, damage, or harm to plant health. APHIS evaluates potential human health impacts under NEPA, as in this dPEIS and considers FDA and EPA evaluations in the NEPA document. However the decision whether to deregulate is based solely on plant pest risk.

For those GE plants that are intended for food purposes, and for which APHIS has determined are not subject to 7 CFR part 340, developers routinely consult with the FDA, as part of their voluntary consultation process, on the safety and composition of the food product. For GE plants issued determinations of non-regulated status by APHIS and traded or grown internationally, data and other relevant information demonstrating the safety and nutritional value of the plant are also routinely submitted to pertinent authorities such as European Food Safety Authority (EFSA 2015a) and Australia and New Zealand Food Standards Agency (ANZFS 2015), under guidelines specified by the Food and Agriculture Organization of the United Nations (FAO 2009).

The commercial use of deregulated GE crop plant varieties is considered to largely have had, to some degree, beneficial impacts on the health of agricultural workers and general public through the reduction of insecticide use, and the replacement of some of the more toxic herbicides with less toxic active ingredients (as discussed in Sections 3.3 – Genetically Engineered Organisms in Agriculture and Forestry, 3.4 – GE Crops and the Environment, and 3.8 – Human Health). In general, after over 20 years of cultivation and a cumulative total of 2 billion acres planted, no adverse human health effects have been identified as a result of commercialization of current GE crop varieties (Goodman and Tetteh 2011, Ronald 2011). The majority of scientific review of this topic has concluded that foods derived from current GE plants pose no more risks to human health than foods derived from non-GE crops (e.g., see (CAST 2005, Batista and Oliveira 2009, Ronald 2011, AAAS 2012, AMA 2012, Bartholomaeus, Parrott et al. 2013, Goldstein 2014, Nicolia, Manzo et al. 2014, WHO 2015).

To the extent GE crops can meet or increase agricultural productivity in supplying market demand, support the provision of healthful foods and food products at affordable prices, and reduce the use of insecticides, deregulated GE crop varieties would be expected to have beneficial impacts on human health. Some GE crop plants could potentially serve important purposes in addressing challenges facing producers of agricultural commodities worldwide. These include providing a consistent and ample supply of human and animal food for expanding populations in areas with scarce arable land, addressing the impacts of climate change on crop production, helping ameliorate the potential agricultural and economic

impacts that can derive from agricultural pests and diseases, and maintaining affordable supplies of foods in regions where poverty is high (Qaim and Kouser 2013, Telem, Wani, Singh et al. 2013, Ammann 2014). Hence, current and emerging plant biotechnologies may help address such challenges, particularly where GE crops are produced using sustainable agricultural practices.

On the topic of potential benefits of GE crop plants: An emerging area of interest is the nutritional modification of crop plants through the use of biotechnology to provide potential human health benefits. Golden Rice, a GE variety with high β-carotene content, has been developed to help provide vitamin A in diets deficient in this essential nutrient, particularly among rice-consuming populations. Rice has also been engineered to address other forms of malnutrition, such as iron and folate deficiency (Hefferon 2015). Wheat has been genetically engineered for a number of health benefits, to include reduction in the levels of celiac-disease causing gliadins, and increased levels of lysine and zinc. Zinc deficiency is the fifth leading cause of disease in low-income countries, affecting billions of people whose diet is based on cereal grains low in zinc content (Hefferon 2015). Cassava is an important food source in tropical countries, but roots and leaves of cassava plants contain the cyanogenic glucoside linamarin, which when hydrolyzed, yields cyanide. There are current efforts to develop a cyanogen-free cassava plant, with the hope of eventually providing a safer alternative to cultivars currently grown by subsistence farmers. To be clear, none of these crops have been commercialized as yet or have completed regulatory evaluations in the United States.

Pesticides used on food crops can present risks to human health, relative to the specific hazards posed by the pesticide (i.e., toxicity of the active ingredient), and the potential for exposure to such pesticides. The EPA evaluates potential human health risks, which range from short-term toxicity to long-term effects such as cancer and reproductive system disorders. Under the Food Quality Protection Act, of 1996, which amended both FIFRA and FFDCA, the EPA must find that a pesticide poses a "reasonable certainty of no harm" before it can be registered for use on food crops. Consequently, adverse impacts to human health from the collective cultivation and use of GE and non-GE crops would not be expected.

A commonly cited risk with GE crops plants is that genetic engineering techniques could have pleiotropic effects - unwanted side effects on a plant's natural production of proteins or metabolic pathways that could result in the unexpected production and occurrence of toxins or allergens in food (Fagan, Antoniou and Robinson 2014). Similarly, some stakeholders express concern that pleiotropic effects, and the presence of toxins/toxicants or allergens in GE foods, are more likely based on the assumption that a plant's catabolism/metabolism is more likely to be disrupted through the introduction of new genetic elements via genetic engineering, as opposed to conventional breeding. A recent National Academy of Sciences (NAS) review did not confirm these assumptions (NAS 2016b). Rather, the NAS concluded that the compositional analyses of GE foods has revealed no differences that would implicate a higher risk to human health from eating GE foods than from eating their non-GE counterparts (NAS 2016b); that available epidemiological data do not show any disease or chronic conditions in populations that correlate with consumption of GE foods (NAS 2016b); and that the review committee could not find persuasive evidence of adverse health effects directly attributable to consumption of GE foods (NAS 2016b). The NAS review committee also examined epidemiological data on incidence of cancers and other human-health

problems and found no substantiated evidence that foods from GE crops were less safe than foods from non-GE crops (NAS 2016b). Further, the NAS report recommended that "in determining whether a new GE plant variety should be subject to a premarket government approval for health and environmental safety, regulators should focus on the extent to which the characteristics of the plant variety (both intended and unintended) are likely to pose a risk to health or the environment on the basis of the novelty of traits, the extent of uncertainty regarding the severity of potential harm, and the potential for exposure regardless of the process by which the novel plant variety was bred (NAS 2016b)."

As part of pre-market evaluation, GE crop plant developers are responsible for ensuring that no new toxins or allergens have been introduced into the modified plant. This is most often done by considering the new gene and its source organism. Developers also perform compositional analyses of the GE plant and/or plant food products. These types of analyses are presented to the FDA during premarket consultation.[178] As part of the consultation process, FDA considers whether any newly introduced protein is likely to be allergenic or otherwise unsafe, and whether levels of important nutrients or anti-nutrients have been changed in a way that is relevant to food safety or nutrition. The FDA also considers whether any newly introduced substance requires premarket approval as a food additive.[179]

Under the No Action Alternative future determinations of non-regulated status for a GE organism would be based on current regulations and processes on a case-by-case basis. The potential adverse health effects that would be considered would be related to the species of GE organism, the trait incorporated, and its intended use. As described above, any GE plant determined not subject to part 340 and intended for use as human or animal food would likely be submitted to the FDA for consultation, and international authorities where imported as human or animal food by other countries (e.g., (ANZFS 2015, EFSA 2015a)). Any pesticide used on a GE crop would be regulated under the authority of the EPA.

4.4.2 Preferred Alternative: Human Health

4.4.2.1 Regulatory Scope

APHIS would include the noxious weed provisions of the PPA (7 U.S.C. §7701(7)), expand the range of organisms considered and potentially regulated using the terms and definitions for "genetic engineering" and "GE organism," remove the notification procedure and require all authorizations for import, interstate movement, or controlled outdoor use be conducted under permitting procedures; and strengthen its compliance and enforcement program by clarifying the full range of enforcement authorities and penalties granted under the PPA and augmenting its reporting requirements.

As discussed previously, all human and animal foods derived from GE crop plants, which have been evaluated by APHIIS, the EPA, and FDA, as appropriate, and that are currently on the market, are as safe as and nutritionally equivalent to their non-GE counterparts; they pose no more risks to human and animal health than foods derived from conventional crop

[178] FDA Issues Guidance to Help Prevent Inadvertent Introduction of Allergens or Toxins into the Food and Feed Supply: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108674.htm

[179] FDA's Regulatory Program for Foods Derived from Genetically Engineered Sources: http://www.fda.gov/NewsEvents/Testimony/ucm468833.htm

varieties (e.g., see (CAST 2005, Batista and Oliveira 2009, Ronald 2011, AAAS 2012, AMA 2012, Bartholomaeus, Parrott et al. 2013, Goldstein 2014, Nicolia, Manzo et al. 2014, WHO 2015).

There is however one class of GE plants that are of particular concern in regard to food safety; these are plants that have been genetically engineered for non-food uses such as the production of pharmaceutical and industrial compounds. Historically, APHIS has provided the principal oversight of regulated field trial of GE P/I-producing plants. APHIS' approach under the No Action Alternative has been to "regulate first, analyze later." When a permit is submitted to APHIS for review, APHIS typically does not consider whether the organism triggers 7 CFR part 340 or whether it poses a risk to plant health. Rather, APHIS focuses on what conditions are necessary to confine the field trial.

Under the Preferred Alternative, prior to permitting of GE organisms, APHIS will conduct an upfront risk assessment to evaluate whether a GE organism poses a plant pest or noxious weed risk. Plants genetically engineered for pharmaceutical and industrial purposes would require a permit under the Preferred Alternative only when APHIS determined such GE plants presented a plant pest or noxious weed risk. Because most plants do not inherently present plant pest or noxious weed risks, particularly domesticated plants, and traits introduced for the production of pharmaceutical or industrial compounds are unlikely to confer plant pest or noxious weed risk to a domesticated plant, it expected that most of the GE P/I-producing plants that APHIS evaluates will be found unlikely to pose a plant pest or noxious weed risk. Hence, there is a possibility that APHIS could reach a determination that a GE plant that produces pharmaceutical or industrial compounds is not a regulated organism. Such a plant would not be subject to field trial oversight by USDA, and could be planted before without evaluation by FDA or EPA.

While there are significant economic and public health benefits that can potentially be provided by plant made pharmaceutical and industrial compounds, these may also present risks if such plants are consumed by wildlife, or are inadvertently introduced into the human or animal food supply. Consequently, this potential gap in federal oversight of the field testing of GE P/I-producing plants presents a concern. As discussed later in Section 4.8 – Federal, Tribal, and State Governance, APHIS has identified several options that would provide for sufficient federal oversight of outdoor plantings of GE P/I-producing plants.

4.4.2.2 Authorization of Interstate Movement and Importation

APHIS would oversee the movement and importation of a broader range of GE organisms that included potentially noxious weeds and those subject to the new regulatory definitions for "genetic engineering" and "GE organism." Movement and importation would be conducted solely under permit and APHIS would assign permit conditions to make it unlikely these activities would result in an unauthorized release.

APHIS would provide a more performance-based approach for shipping of GE organisms by stating that products of biotechnology be handled in such a way that their identity is maintained (e.g., marked, labeled) and that they be imported or moved interstate only in a secure shipment. APHIS would define secure shipment as "shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents,

shocks, pressure changes, and other conditions incident to ordinary handling in transportation." Specifics regarding labeling/marking and the methods of secure shipment would be included as permit conditions.

4.4.2.3 Authorization of Environmental Release

Under the Preferred Alternative APHIS would require permitting for the environmental release of GE organisms APHIS determines pose a risk as a plant pest or noxious weed. As described for the No Action Alternative, the environmental release of GE organisms is not expected to pose a risk to public health, and in this regard the No Action Alternative and the Preferred Alternative can be considered comparable.

Under the Preferred Alternative APHIS would require permitting for the environmental release of GE P/I-producing plants when APHIS determined such GE plants posed a risk as a plant pest or noxious weed, or under an authority other than the PPA possibly in coordination with other federal agencies (see Section 4.8 – Federal, Tribal, and State Governance).

4.4.2.4 Compliance, Enforcement, and Remediation

Under the Preferred Alternative APHIS is proposing to strengthen its compliance and enforcement program by augmenting the approaches currently used and clarifying enforcement strategies. These revisions are in part responsive to recommendations of the 2015 USDA OIG audit report on controls over the release of genetically engineered organisms into the environment (USDA-OIG 2015).

APHIS would require the responsible person provide APHIS inspectors access to inspect any relevant premises, facility, location, storage area, waypoint, materials, equipment, means of conveyance, and other articles related to the importation, interstate movement, and controlled outdoor uses of organisms regulated under 7 CFR part 340. While this requirement is functionally the same as current inspection requirements, it clarifies what locations and regulated organisms may be subject to inspection.

APHIS would also include revised requirements for the establishment and maintenance of records related to permits, and require that the responsible person provide APHIS inspectors with all required records upon request. Maintenance of these records would facilitate remediation measures and penalties in the event of an unauthorized release of a regulated organism.

The possible consequences of failure to comply with the regulations would include denial of future permits; revocation of current permits; destruction, treatment, and removal of regulated organisms; issuance of penalties; and a means to settle alleged civil violations prior to the issuance of an administrative complaint. A responsible person could be held liable for the violation of any APHIS requirement by any agent working for the responsible person (including persons contracted to conduct or carry out the controlled outdoor use on their own or on leased properties).

Considering those provisions described above (and in detail in the proposed rule – provide link/cite), the compliance and enforcement framework that would be implemented under this

Alternative would likely provide broader protections for public health relative to the No Action Alternative.

4.4.2.5 Determination of Regulatory Status

APHIS would expand the scope of organisms reviewed and considered for regulation using the terms and definitions for "genetic engineering" and "GE organism," and include consideration of GE plants as noxious weeds. While the scope would be expanded, APHIS would regulate, overall, fewer numbers of GE crop plants, focusing on regulating those GE plant-trait combinations that may present plant pest and noxious weed risks.

As part of its WRA, APHIS could consider potential public health impacts under noxious weed authority. If a GE organisms were determined by APHIS not subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulated that GE organism under 7 CFR part 340. Any organism developed using genetic engineering as defined in the regulations that were determined not subject to 7 CFR part 340 regulation, and intended for use as human or animal food, would still require review and approval by the EPA. For GE plants developed for human or animal food, the FDA recommends that sponsors and developers of GE plant varieties intended for food use consult with the FDA about the safety of any new proteins produced in such plants prior to their introduction into the food supply. Developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006). If such a plant were a food commodity intended for international trade it would require review and approval by international authorities, as described for the No Action Alternative.

Considering the revisions proposed, the Preferred Alternative would likely provide for a more thorough and efficient process in determination of which GE organisms should be regulated as risks to plant health, and which should not. While evaluating a broader range of organisms, the Preferred Alternative should provide comparable if not greater protection for public health, as compared to the No Action Alternative, by virtue of the expanded range of GE organisms evaluated under the Preferred Alternative, and incorporation of the public health provisions under noxious weed authority.

Of consideration, are the specific means by which GE P/I-producing plants will be regulated under the Preferred Alternative. Under the Preferred Alternative there is a possibility that APHIS could reach a determination that a GE P/I-producing plants is not a regulated organism. Such a plant would not be subject to field trial oversight by USDA, and could be planted without evaluation by FDA or EPA. While there are significant economic and public health benefits that can potentially be provided by plant made pharmaceutical and industrial compounds, these may also present risks if such plants were to inadvertently be introduced into the human or animal food supply. Consequently, oversight of the field testing of GE P/I-producing plants is an outstanding concern. As discussed later in Section 4.8 – Federal, Tribal, and State Governance, APHIS is proposing several options to address this potential gap in oversight, and requesting specific public comment regarding these options, as well as any other options commenters may identify for regulating GE P/I-producing plants.

4.4.3 Alternative 3: Human Health

4.4.3.1 Regulatory Scope

Alternative 3 is similar to the Preferred Alternative in many respects, although expands the scope of regulation to include potential economic impacts. Under this alternative APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. The WRA would include an economic effects analysis, and APHIS would distinguish those GE organisms that cause market impacts from those that did not. As a result of inclusion of potential economic harms under the noxious weed authority of the PPA, the majority of GE P/I-producing plants would be regulated and require permitting under Alternative 3.

4.4.3.2 Authorization of Interstate Movement and Importation

Relative to potential impacts on human health – Alternative 3 and the Preferred Alternative are equivalent.

4.4.3.3 Authorization of Environmental Release

Unlike the Preferred Alternative, GE plants that present potential economic impacts would require permitting for commercial production (permitted planting). The purpose of regulation of potential economic impacts under noxious weed authority is to prevent commingling and the unintended presence of GE crop material in non-GE crops and crop products. To the extent the ideals of coexistence of GE, conventional, and organic cropping systems are facilitated by this Alternative, and instances of commingling and unintended presence reduced, this would likely appeal to certain consumers, namely those opposed to the production and consumption of food or food products derived from GE crop plants.

Hence, to the extent that this Alternative achieved its goals in facilitating coexistence, and minimizes cross-pollination and commingling of GE and non-GE crops, there could be seen, among some consumers, an improvement in their perception of a more secure food supply. Where unintended presence and commingling are prevented, this would be seen as beneficial for consumers opposed to foods derived from GE plants.

These factors considered, the physiological health benefits that may be conferred by prevention of commingling and unintended presence would not be expected to be or more less than that provided under the Preferred Alternative or No Action Alternative. FDA oversight of food safety, and EPA oversight of pesticides, PIPs, and human and animal food tolerances would remain unchanged. As described for the No Action and Preferred Alternatives, GE plants intended for human and animal food are expected to be submitted to the FDA as part of their recommended voluntary consultation (US-FDA 1992, US-FDA 2006) prior to commercial production.

Current human and animal foods derived from GE crop plants, which been through the appropriate regulatory reviews and consultations, have been found to have no more, or less,

nutritional value than foods and food products derived from crop plants produced through conventional breeding. It is expected that future human and animal food products derived from GE plants will be as safe as, and perhaps in some instances more nutritional, than their conventionally bred counterpart.

If instances of commingling were reduced as a result of the regulatory framework under Alternative 3, while this would likely appeal to certain consumers, this would have little beneficial or adverse effect on the healthfulness of food commerce. The primary impact of Alternative 3 is socioeconomic in nature, and discussed further in Section 4.6.

4.4.3.4 Compliance, Enforcement, and Remediation

Relative to potential impacts on human health, Alternative 3 and the Preferred Alternative differ in that, for Alternative 3, compliance and enforcement activities would be extended to those GE organisms that may cause economic harms, and it is expected that most GE P/I-producing plants would require APHIS permitting under Alternative 3, but not the Preferred Alternative.

4.4.3.5 Determination of Regulatory Status

Unlike the Preferred Alternative, the only GE organisms that would not be regulated by APHIS would be those that had no adverse economic impacts on non-GE crop producers. In addition, GE P/I-producing plants are not expected to be removed from regulatory oversight under Alternative 3. These factors would substantially increase the number of GE crop plants under APHIS regulation. While this would impact plant biotechnology developers and growers of GE crops, as well as growers of non-GE crops, it is unlikely to have a substantive direct effects on human health, as the purpose of this Alternative would be to focus regulatory oversight on coexistence among GE, conventional, and organic cropping systems. This would not, in the short term, significantly change the types of GE crop plant traits, or species of GE crop plants that may be cultivated. There may be seen, to some degree, a modest increase in the production of some crops under conventional and organic cropping systems. This could occur where the regulatory burden on growers of GE crops under Alternative 3 is deemed excessive or provides no significant economic benefit. In these instances, some growers may opt to produce an agricultural commodity using a non-GE plant variety under a conventional or organic system. Where such a shift in production may occur, this would not change the inherent healthfulness of foods derived from GE, conventional, or organic cropping systems: The nutritional value of current crop plants will not change. Organic cropping systems, however, because they utilize less synthetic chemical inputs, can present less risk to human health. In this regard, to the extent organic production increases and is able to supply the market demand for human and animal food, and there are commensurate reductions in synthetic chemicals inputs (at the scale of commercial cropping systems), this would be considered a beneficial shift in production, relative to human health considerations.

The above considered, the sustainable production of sufficient human food, animal food, and fiber to meet the market demands of an ever expanding global population will require the utilization of conventional, organic, and GE cropping systems. To meet consumer demand, by 2050 global food production will have to increase by 60% from its 2005 – 2007 levels

(FAO 2014b). However, agricultural production can place well recognizes stresses on natural resources, as described in this dPEIS, and present some risks to public health through use of pesticides and fertilizers. In addition, climate change is likely to present challenges to crop producers (IPCC 2014). Increasing agricultural productivity in a sustainable manner is indispensable to provision of human and animal foods, fibers, and biofuels on an increasingly constrained natural resource base (FAO 2014b). Crop producers will need to increase production on the available land to meet the growing demand for agricultural commodities.

Technological innovations in agriculture can facilitate meeting human health and environmental needs. It may allow farmers to produce more with extant resources and inputs and reduce their costs of production (FAO 2014b). It can also allow them to expand, change, or diversify their commodity output, increasing the profitability of their farms (FAO 2014b). GE crops that have already been adopted and have generated large productivity gains. The technology has made important contributions to increasing global production levels of the 4 main crops; corn, soybeans, cotton, and canola. For example, GE crops added around 150 million tons and 300 million tons to the global production of soybeans and corn, respectively, since the introduction of the technology in the mid-1990s (Klümper and Qaim 2014, Brookes and Barfoot 2015).

To the extent the Preferred Alternative facilities innovation in the agricultural biotechnology sector as well application of the technology to crop production, it would likely better serve the public health, in provision of ample and diverse healthful human and animal foods, as well as fibers and biofuels. Reduced synthetic chemicals inputs (e.g., insecticides, fungicides) that are associated with insect and disease resistant GE crop plants also benefit public health. To the extent Alternative 3 has a chilling effect on research, development, and innovation in the agricultural biotechnology sector, the benefits such technology can provide to sustainable agricultural production, and the contribution of such technology to public health, may not be realized; relative to the Preferred Alternative.

4.5 Animal Food and Welfare

Consideration of the potential impacts of the Alternatives on animal food are largely the same as those discussed for human health, as food derived from GE crops must be in compliance with the FFDCA, FSMA, and all other applicable laws and regulations governing the safety of human and animal food. As such, this section is abbreviated to avoid redundancy.

4.5.1 No Action Alternative: Animal Food

4.5.1.1 Regulatory Scope

Animal food is evaluated for safety by the FDA, as described in subsection 3.9 – Animal Food. Pesticides used on human or animal food crops must comply with EPA tolerance limits described under Section 408 of the FFDCA and Section 405 of FQPA (US-EPA 2015f). Similar to tolerance values for human food, EPA tolerance limits for animal food are established to ensure the safety of animal food. Tolerance limits may include conventional pesticides, and proteins from GE crop plants such as PIPs (e.g., Cry proteins), or proteins conferring herbicide resistance (e.g., PAT protein). As part of its NEPA analysis APHIS

considers FDA and EPA decisions, and evaluates potential impacts on animal food under NEPA, as in this dPEIS.

As described for Human Health, under the No Action Alternative GE P/I-producing plants engineered using plant pests would continue to be regulated under plant pest authority.

To date, all of the GE plants determined by APHIS to have non-regulated status that are actively used for animal food have been evaluated for safety by the FDA, and the effects of pesticides on animal health, to include PIPs, reviewed by the EPA. Those GE crops approved for commercial production under the Coordinated Framework and traded or grown internationally may also undergo human and animal food safety reviews under pertinent authorities such as the European Food Safety Authority (EFSA 2015a), and Australia and New Zealand Food Standards Agency (ANZFS 2015). There are no reasonably foreseeable adverse impacts to animal food and welfare that would derive from APHIS continued oversight of GE organisms under current 7 CFR part 340. In general, current regulations are beneficial to food markets and animal welfare in providing oversight of the importation, interstate movement, and environmental release of GE organisms.

4.5.2 Preferred Alternative: Animal Food

4.5.2.1 Regulatory Scope

The scope of the Preferred Alternative would be the same as that described under the Human Health section of this chapter.

4.5.2.2 Authorization of Interstate Movement, Importation, and Environmental Release

APHIS would oversee the movement, importation, and environmental release of a broader range of GE organisms that included potentially noxious weeds and those subject to the new regulatory definitions for “genetic engineering” and “GE organism.” These activities would be conducted solely under permit and APHIS would assign permit conditions to make it unlikely these activities would result in an unauthorized release.

4.5.2.3 Compliance, Enforcement, and Remediation

Under the Preferred Alternative compliance and enforcement activities would consider a broader range of GE plants, some of which may be plant commonly used for animal food (e.g., corn, soybean). Due to the expanded range of GE organism-trait combinations considered, permitting revisions, and clarification of compliance and enforcement authorities and actions, this Alternative could be more protective of animal food than the No Action Alternative. APHIS would be able to evaluate a broader range of GE plant-trait combinations, and inform the FDA if the Agency had questions as to the food safety of the GE plant, or other organism. APHIS would be able to regulate the field testing, interstate movement, and importation of GE plant-trait combinations, and other organisms, it currently cannot regulate. If such GE plants or other organisms may pose potential risks to animal health and welfare, then the Preferred Alternative provides protections not realized under current regulations.

4.5.2.4 Determination of Regulatory Status

APHIS would expand the scope of organisms reviewed and considered for regulation using the terms and definitions for "genetic engineering" and "GE organism," and include consideration of GE organisms as noxious weeds. If a GE organisms were determined by APHIS not to be subject to regulation, and it were later found to present potential plant pest risk or noxious weed risks, APHIS would have the authority to revise its determination and regulated that GE organism under 7 CFR part 340. Any organisms developed using genetic engineering as defined in the regulations that were determined not to be subject to 7 CFR part 340 regulation, and intended for use as human or animal food, would still require review and authorization by the EPA, as applicable (e.g., regulation of PIPs). It is expected that any new animal food derived from GE plants would be submitted to the FDA as part of their voluntarily consultation program (US-FDA 1992, US-FDA 2006). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived using genetic engineering, in the Federal Register on May 29, 1992.[180] Under this policy, the FDA implements a voluntary consultation process to ensure that animal food safety issues or other regulatory issues are resolved before commercial distribution of food derived from GE plants. This voluntary consultation process provides a way for developers to receive assistance from the FDA in complying with their obligations under federal food safety laws prior to marketing.

Considering the proposed revisions, this Alternative could potentially be more protective of animal welfare than the No Action Alternative due to evaluation of the GE organism as both a potential plant pest and noxious weed risk (e.g., some noxious weeds are toxic to livestock, such as kochia, Johnson grass, nightshades), and clarification of APHIS compliance, enforcement, and remediation actions. There are no foreseeable adverse impacts to animal food and animal welfare that could derive from the Preferred Alternative, with the noted exception.

As discussed for human health considerations, under the Preferred Alternative there is a possibility that APHIS could reach a determination that a GE P/I-producing plant is not a regulated organism, and could be planted before it has been evaluated by the FDA or EPA. Consequently, such plants may present risks if they were to inadvertently be introduced into the human or animal food supply. As discussed later in Section 4.8 – Federal, Tribal, and State Governance, APHIS is proposing several options to address this potential gap in oversight, and requesting specific public comment regarding these options, as well as any other options commenters may identify for regulating GE P/I-producing plants.

4.5.3 Alternative 3: Animal Food

4.5.3.1 Regulatory Scope

Under Alternative 3, APHIS would substantially increase oversight of GE organisms. Alternative 3 is similar to the Preferred Alternative in many respects, although, under this alternative, APHIS would interpret the noxious weed authority provided APHIS under the

[180] FDA: Statement of Policy - Foods Derived from New Plant Varieties; http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm

PPA to include potential economic harms that could derive from the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurs as a result of cross-pollination, or commingling of GE plant material with non-GE crops or their products during harvest, post-harvest shipping and processing, or other means. All GE organisms that were determined to present a plant pest or noxious weed risks, or an economic risk (including all previously deregulated organisms), would be regulated. The only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown. GE P/I-producing plants would be captured by the expansion of the noxious weed authority under Alternative 3. Thus, this Alternative would ensure that all GE P/I-producing plants are regulated by APHIS.

4.5.3.2 Authorization of Interstate Movement and Importation, and Environmental Release

Permitting of these activities would be the same as the Preferred Alternative, save for regulation and permitting of MPNW and GE P/I-producing plants. Hence, unlike the Preferred Alternative, GE plants that present potential economic impacts (MPNW) and GE P/I-producing plants would require permitting for environmental release and commercial production (permitted planting). Alternative 3 would provide the same potential benefits for animal food and welfare as provided under the Preferred Alternative, however, APHIS would have extended oversight of MPNW and GE P/I-producing plants.

4.5.3.3 Compliance, Enforcement, and Remediation

Compliance and enforcement activities, relative to animal food, would be the same as that described for the Preferred Alternative.

4.5.3.4 Determination of Regulatory Status

APHIS would substantially increase oversight of GE organisms. Hence, this Alternative could theoretically, to the extent this Alternative reduced commingling of GE crops with non-GE crops, reduce instances of unintended presence. This would, however, have negligible impact on the nutritional quality of animal food or welfare. Review of GE organisms as to food safety would be the same as under the Preferred Alternative. Food derived from GE plants would continue to have to comply with all applicable FDA requirements, and laws and regulations implemented by the FDA. The FDA recommends that developers of GE plant varieties intended for food use consult with the FDA about the safety and composition of the GE plant variety prior to its introduction into the food supply. Sponsors and developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006). Determinations of non-regulated status under this Alternative differs little from the Preferred Alternative relative to potential effects on animal food and welfare.

4.6 Socioeconomic Impacts

In addition to this draft PEIS, APHIS has conducted a Regulatory Impact Analysis (RIA) & Initial Regulatory Flexibility Analysis of the proposed rule and Alternatives, and the reader is referred to this document for a more thorough analysis on potential economic impacts

(USDA-APHIS 2016c). This section summarizes the RIA analyses, entities potentially affected by revisions to 7 CFR part 340, and potential socioeconomic impacts of the Alternatives considered.

4.6.1 Overview of Sources of Potential Impact

For clarification of the discussion in this section, there are two primary ways by which GE plant material may move into harvested crops: 1) cross-pollination and 2) commingling. Cross-pollination means the fertilization of one plant by pollen from another. Commingling is the result of mechanical or non-biological mixing that can occur during harvest, and post-harvest transport, storage, and processing.

Unauthorized release refers to a GE organism that is not in compliance with the requirements for an APHIS authorized release. Unintended presence refers to the occurrence of GE plant material in harvested crops where it is not expected, which can occur via pollination or commingling. APHIS currently has oversight of regulated GE organisms during interstate movement, field trials, and importation. However, after deregulation, if the GE plant material is found unwanted in harvested crops in any amount, APHIS does not have authority to take action. Unintended presence may result in market impacts domestically when identity preservation is breached (e.g. organic or "non-GMO" crops), or in foreign markets where it would be considered a low level presence (LLP) situation if the GE plant had not received approval in that country. [181] It would be considered an LLP situation in that country because it had obtained appropriate regulatory reviews among APHIS and the EPA, and submitted to FDA for consultation, as appropriate, for commercial uses in the United States, but had not been authorized in the importing country. It would not be considered LLP in the United States (the exporter). Something would qualify as LLP in the United States if it had not been through appropriate APHIS and EPA regulatory reviews and FDA consultation, but had been approved in another country and was being imported into the United States. However, the United States would treat such unintended presence the same as if it had been developed in the United States but had not been evaluated by the USDA, EPA, and FDA, as applicable.

4.6.2 Domestic Socioeconomic Environment

4.6.2.1 No Action Alternative: Domestic

4.6.2.1.1 APHIS Costs

Costs to APHIS are incurred through conducting plant pest and noxious weed risk assessments; review of submitted notifications, permit requests, and petitions; NEPA analyses – such as developing environmental impact statements and environmental assessments; and in conducting inspections and compliance enforcement actions. Annual personnel costs of conducting biotech activities under current regulations that would be affected by the proposed rule are estimated to total about $5.6 million, out of an annual APHIS-BRS budget of about $19 million. This estimate is based on activities in 2015, when

[181] Low level presence (LLP): Once a GE crop is authorized for commercial use in a given country, trace amounts of that GE crop may become mixed with other crop varieties in that country during processing or transit. As a result, a GE crop that is authorized in an exporting country may be present at low levels in grain, or human or animal food that is imported into another country, where that particular variety of GE crop has not been authorized.

APHIS processed 164 importation and interstate movement permits and 190 environmental release permits; conducted 800 inspections; issued 39 import permits and 104 interstate movement permits; and acknowledged 97 import notifications, 325 interstate notifications, 232 combined interstate and release notifications, and 102 release notifications.

4.6.2.1.2 Biotechnology Industry

Estimates of the costs of regulatory compliance in development and commercialization of GE organisms are limited due to the proprietary nature of some information related to the research and development of GE organisms. This is not unique to development of GE organisms, proprietary data and information is common to many industries.

Regulatory compliance involves a variety of activities such as management of field trials; biochemical, molecular, and bioinformatic analyses; animal studies for food safety; and development of data and information for other comparative safety assessments. These apply to most GE organisms, particularly plants. The data that is available, is for GE crop plants. One study by Phillips McDougall found that the average time required for discovery, development, regulatory review, and authorization for a new biotechnology trait is 13.1 years at an average cost of $142.8 million (2015 dollars) (Phillips-McDougall 2011). Collectively, the costs of meeting all regulatory requirements, including those incurred as a result all federal regulation of GE organisms, amounts to around $36.9 million (2015 dollars), or 25.8 percent of total costs. Kalaitzandonakes, et al (2007) estimated regulatory costs associated with research and development expenses, providing greater insight to the potential cost savings associated with this rule (Kalaitzandonakes, Alston and Bradford 2007). The estimated costs for development of a biotechnology product, including regulatory costs, were highly variable ranging from about $8 million to $17.6 million in 2015 dollars for insect resistant corn, and from about $7 million to $16.5 million in 2015 dollars for herbicide resistant corn (Table 4-1). These estimates are roughly one-half of the total regulatory costs estimated by Phillips McDougall (2011).[182]

It is important to note that studies by McDougall and Kalaitzandonakes are based on surveys of private sector corporations, and involve the development of high value trait products such as herbicide resistant corn, and simultaneous deregulation and release in developed countries (Schiek, Hareau, Baguma et al. 2016). The costs to not-for-profit institutions in development of GE crop plants with traits of low economic value, and for deregulation in one or two developing countries can be substantially lower (Schiek, Hareau et al. 2016). For example, recent analyses find that the cost to not-for-profit institutions developing a GE potato variety resistant to late blight disease, and for release in one developing country, is well under $2 million U.S. dollars over eight to nine years (Schiek, Hareau et al. 2016). The upper end costs reported by McDougall and Kalaitzandonakes are used to estimate the maximal range of costs that could potentially be incurred in development of a GE crop plant.

[182] APHIS does not have access to enough detailed information to account for this discrepancy.

Table 4-1. Developer Costs for Insect Resistant Corn and Herbicide Resistant Corn	
Cost Categories	**Range of Costs Incurred ($1,000) [1]**
General costs	
Preparation for hand-off of events to regulatory	23 - 57
Molecular Characterization	342 - 1,368
Compositional Assessment	855 - 1,710
Animal Performance and safety studies	342 - 963
Protein production and characterization	185 - 1,967
Protein safety assessment	222 - 975
Agronomic and phenotypic assessment	148 - 524
Production of tissues	775 - 2,508
ELISA development, validation and expression analysis	473 - 695
EU specific import (detection method, fees)	262 - 462
Canada specific costs	46 - 222
Stewardship	188 - 1,140
Toxicology (90-day rat)—when done	285 - 342
Facility and Management overhead costs	638 - 5,130
Costs specific to Insect Resistant Corn	
Non-target organism studies	114 - 684
EPA expenses for PIP (e.g., permitting)	171 - 815
Environmental fate studies	36 - 912
Total Insect Resistant Corn	**8,048 - 17,602 [2]**
Costs specific to Herbicide Resistant Corn	
Herbicide residue study	120 - 627
Total Herbicide Resistant Corn	**7,045 - 16,541 [2]**

Source: (USDA-APHIS 2016c)
The costs of withdrawn events are not included in the figures. To preserve the confidentiality of firm-level data used, the means of the total compliance costs or of the individual cost categories were not presented.
(1) Inflation adjusted to 2015 dollars.
(2) Because an individual firm could have costs anywhere in the range of each individual category, the totals do not sum from the figures shown. Where the estimated cost in a general cost category differed between insect resistant and herbicide resistant crop, we included the entire range.
Source: (USDA-APHIS 2016c)

Under the Coordinated Framework GE organisms are regulated by USDA, EPA, and FDA. However, not every GE organism will require review and regulation by all agencies. For a human or animal food crop that does not include a PIP, only USDA and FDA would have regulatory oversight. For a crop that was not used for food use but contained a PIP, the crop would be regulated by both USDA and EPA. In some cases, USDA is the only regulatory agency involved. Examples of articles regulated exclusively by USDA include horticultural plants such as petunias or carnations modified to produce different flower color. Hence, APHIS considered two regulatory oversight scenarios: USDA either has sole regulatory authority or shares oversight with EPA and/or FDA.

Estimates of the current regulatory compliance costs under the two regulatory oversight scenarios considered are shown in Table 4-2. Under sole oversight by USDA, compliance

costs are estimated to range from around $2.3 million to $12.7 million for a given GE trait. When USDA in addition to EPA and/or FDA have regulatory oversight, compliance costs are estimated to range from $4.6 million to $18 million for an herbicide resistant trait, and $4.8 million to $19.8 million for an insect resistant trait.

Table 4-2. Estimated Current Developer Costs under Two Oversight Scenarios for Herbicide Resistant and Insect Resistant Corn, per trait, 2015 dollars

Activity	USDA	USDA & EPA and/or FDA
	($1,000)	
Preparation for hand-off of events into regulatory	23-57	23-57
Molecular characterization	342-1,368	342-1,368
Compositional assessment	N/A	855-1,710
Animal performance and safety studies	N/A	342-963
Protein production and characterization	185-1,967	185-1,967
Protein safety assessment	N/A	222-975
Agronomic and phenotypic assessments	148-524	148-524
Production of tissues	775-2,508	775-2,508
ELISA development, validation and expression analysis	N/A	473-695
Toxicology (90-day rat)	N/A	285-342
Facility & management overhead costs	638-5,130	638-5,130
Stewardship	188-1,140	188-1,140
Subtotal [1]	**2,299-12,693**	**4,476-17,379**
Herbicide residue study	N/A	120-627
Total for Herbicide resistance	N/A	**4,596-18,006**
Non-target organism study	N/A	114-684
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	171-815
Environmental fate studies	N/A	36-912
Total for Insect resistance	N/A	**4,798-19,790**

Source: (USDA-APHIS 2016c)

(1) This subtotal represents the sum of costs for all activities that were in common between insect and herbicide resistant corn.

N/A: Not Applicable

The above costs are largely applicable to GE food and fiber plants. The regulatory costs for GE ornamental plant approval in the United States would be expected to be similar to that itemized for USDA regulatory compliance costs, in column one of Table 4-2; in most cases no food safety tests would be required. However, some estimates have the costs to developers of GE ornamentals potentially running much lower, in the hundreds of thousands of dollars per event (Chandler and Sanchez 2012). In APHIS' experience the majority of regulatory cost is associated with requirements for molecular analysis (Kalaitzandonakes, Alston et al. 2007, Chandler and Sanchez 2012), which would also be the case for GE ornamentals (Chandler and Sanchez 2012).

For the United States, it has been estimated that acquiring non-regulated status for GE forestry trees is likely to make up at least 30 percent of the costs of development, and could be higher (Sedjo 2004). The uncertainty in the cost of development of GE trees is largely attributed to the variance in the time and data required in achieving deregulation. At the

outset of development, how many tests will need to be undertaken to demonstrate that deregulation is justified is simply unknown (Sedjo 2004).

4.6.2.1.3 Producers and Consumers

Producers of GE Crops

GE crops can improve profitability at the farm level (Brookes and Barfoot 2013a, Klümper and Qaim 2014, Brookes and Barfoot 2015). U.S. farmers have realized increased net gains due to their use of GE crops, totaling approximately $58.4 billion in extra income between 1996 and 2013 (Brookes and Barfoot 2015). Potential economic benefits to producers of GE crops are expected to continue if not improve.

GE corn, soybean, cotton, canola, and sugar beet acreage comprise over 90% of the acreage farmed for these crops in the United States. A much smaller percentage of alfalfa, sweet corn, squash, and papaya crops were cultivated using GE varieties. The current primary use of GE crop products is animal foods (e.g., soybean meal, canola meal, corn), and for processed foods and food ingredients such as corn chips, breakfast cereals, soybean protein bars, corn syrup, cornstarch, corn oil, soybean oil, and canola oil (Greene, Wechsler et al. 2016). As for potentially emerging GE crops: Recently, APHIS deregulated GE varieties of apples and potatoes, two of the most widely grown fruits and vegetables in the United States. Potatoes are the top U.S. vegetable crop in terms of acreage, with over a million acres in 2014, and account for 15 percent of total vegetable farm sales. Apple trees occupied 322,000 U.S. acres in 2014, and the second most popular fresh fruit (after bananas) in America (Greene, Wechsler et al. 2016). Hence, considering the market demand for these commodities, there may be seen adoption of GE potato and apple, where these reduce the cost of production and provide the same or superior product quality.

Consumers

Under the Preferred Alternative, potential beneficial impacts to consumers of commodities derived from GE crops and commercial markets is expected to continue as described in section 3.10. Agricultural commodities derived from GE crops are recognized as economically beneficial to domestic markets and are expected to remain so (Fernandez-Cornejo, Wechsler et al. 2014a, Brookes and Barfoot 2015, Lucht 2015).

Producers of non-GE Crops

The longstanding market for organically grown products continues to expand and a market for conventionally grown foods produced without GE plant products has also emerged ("non-GMO" labeled foods). In 2014, there were 14,093 USDA certified and exempt organic farms in the United States (USDA-NASS 2014a).[183] Organic food sales in the United States approached an estimated $35 billion, and sales of organic personal care products, linens, and other non-food products were an estimated $3.2 billion in 2014 (Greene, Wechsler et al.

[183] The National Organic Standard states VIII Introduction 2012 Census of Agriculture USDA, National Agricultural Statistics Service that all farms and handling operations that display the "USDA Organic" seal must be certified organic by the state or by a private agency, accredited by the USDA, to ensure the National Organics standards are followed. Farms that follow the National Organic standards and have less than $5,000 in annual sales can be exempt from certification. These exempt farms may use the term "organic" but may not use the "USDA Organic" seal.

2016). The Organic Trade Association estimates that organic food purchases now account for nearly 5% of total U.S. food sales.

Despite the strong interest in organic food in the United States, organic cropping systems comprise less than 1% of the total U.S. crop acreage (around 3.6 million acres in 2014)), compared to the approximately 47% of GE and 52% of conventional crop acreage (Greene, Wechsler et al. 2016). The somewhat modest rate of growth of organic cropping systems could be due in part to the price premium on organic products relative to the cost of foods (and other products) produced through conventional cropping systems. In general, price premiums for organic products average around 30%, but can be much higher (Crowder and Reganold 2015). For example, the USDA's Agricultural Marketing Service reports organic corn and soybean prices that are generally two to three times higher than conventional prices (Greene, Wechsler et al. 2016). Grower prices for fresh organic apples and organic apples for juice were more than twice as high as for conventionally grown apples in 2007, and premiums for organic milk averaged 69% in 2010 (Greene and McBride 2015).

The United States also has a growing export and import market for organic products. In 2013, the United States exported organic products, largely fresh fruits and vegetables, to over 80 countries and imported organic products, including coffee, bananas, and olive oil, from nearly 100 countries (Greene 2014). Total organic export value increased from $412 million in 2011 to $553 million in 2014 (Greene 2014). Apples were the top organic export in 2014, at an estimated $115 million (Greene, Wechsler et al. 2016).

One of the challenges in organic and conventional non-GE crop production is preventing the accidental comingling with GE crop material in order to protect price premiums. Potential adverse impacts to non-GE crop producers are those related to cross-pollination and commingling of GE crop material with non-GE crops or crop products, leading to instances of unintended presence. This is particularly important for identity preserved and organic crop commodities. For example, from 2011 to 2014, eighty-seven of the over 12,000 USDA certified organic farms collectively lost approximately $6.1 million due to the presence of GE material in the organic cropping system (USDA-NASS 2015a).[184] This equates to an average loss of $70,099 per organic farm for removal of the GE material, remediation, lost sales, or lost price premiums over eighty-seven farms. In 2014, the total value of sales of certified and exempt organic field crops was $3.3 billion. From 2006-2010, nine of over 9,000 certified organic farms had a collective loss of $68.9 thousand, at an average loss of $7,664 per farm (USDA-NASS 2015a). Hence, as the number of organic farms and adoption of GE crops increased over this period, the incidence of affected organic farms increased from 0.1% to 0.7%. While these instances of unintended presence comprised a small percentage of total USDA certified organic farms and total market sales for organic products, such impacts are important to the individual farmer. Unintended presence and its potentially adverse economic impacts may also be applicable to non-GE conventional crop producers.

Farmers catering to the non-GE market will be negatively impacted where instances of cross-pollination or commingling of GE and non-GE crops occurs. In areas where the GE and the

[184] The bulk of reported losses, approximately 3.8 million, were isolated to 3 farms in Texas, which somewhat skews the statistics.

corresponding organic or identity-preserved non-GE conventional crops are grown, such as IL, NE, OK, and TX, incidences of cross-pollination or commingling will be higher than in areas such as CA, where there are relatively few GE crops grown relative to non-GE crops grown (e.g., 0.2% of farms reporting losses).

In considering GE, conventional, and organic cropping systems; grain crops such as wheat, rice, barley, sorghum, oats, corn, and soybean are commingled upon harvest. Because the harvested commodity is comprised of seed, and seed production can acquire GE traits through cross pollination, it is possible for the unintended presence of GE plant material to occur in the harvested crop. In addition, commingling can also occur from the use of shared equipment or during post-harvest processing. GE grain crops such as wheat, barley, sorghum, and oats have not been commercialized to date. Cross-pollination among GE and non-GE vegetable crops is unlikely to present economic concerns as these crops are harvested prior to flowering, the harvested crop commodities are large (heads of lettuce, carrots, cabbage), and unlikely to be commingled accidentally through shared equipment or post-harvest processing. Similarly, vegetable seed production usually takes place in limited areas where large isolation distances are employed to preserve seed crop identity (Identity preservation (IP)). For example, pollination of non-GE sugar beets, table beets, and Swiss chard by GE sugarbeet has to APHIS' knowledge, not been a recurring problem because of the stewardship and best practices employed by the industry. Other field crops such as beans, lentils, and peas are self-pollinating and therefore unlikely to be adversely affected by cross-pollination if GE varieties are developed. These crops could however be affected by commingling through shared equipment or post-harvest processing. The non-GE crops that will be most susceptible to unintended presence are grain crops such as wheat, rice, barley, sorghum, corn, soybean, and oats. Other crops such as hops, rye, and peanuts, could also be affected, in the event such GE varieties are appropriately evaluated by U.S. regulatory agencies and commercially produced.

As acreage devoted to GE, non-GE conventional, and organic crops increases, these agricultural production systems may be located in closer proximity to each other, potentially increasing the challenges for farmers to limit cross-pollination and other kinds of commingling among GE and non-GE crops. Likewise, as the number of products derived from GE, conventional, and organic cropping systems enter the market, it may become more likely for GE and non-GE conventional crop materials to become commingled during transport, storage, and processing. As previously described producers and handlers of non-GE and GE agricultural commodities have available production and handling methods to limit the unintended presence of GE material so that their product meets standards specified either by the USDA National Organic Program (NOP), Association of Official Seed Certifying Agencies (AOSCA 2015, USDA-AMS 2015b, USDA 2015b), ASTA (ASTA 2015b), or through contracts, as relevant. These are fundamentally based on temporal and spatial isolation, use of dedicated equipment, storage, and/or clean out procedures.

Bearing these factors in mind it is expected that GE, non-GE conventional, and organic crop production systems will further evolve in supplying the domestic and global demands for human and animal food, and fiber, while seeking to meet the need for sustainability, farm profitability, and improving environmental performance. In order to receive the price premiums that can be obtained for organic and non-GE agricultural commodities, producers

will need to, and likely will, minimize the presence of GE materials in their crop products. Precluding incidents of unintended presence is a responsibility shared among producers of GE, non-GE conventional, and organic cropping systems. Coexistence is and will remain a basic concept and practice in the production and marketing of agricultural commodities derived from non-GE, GE, and organic systems, because there will likely be an increase in crop types that require segregation in the marketplace. Developing and refining systems engendering coexistence is stimulated by preserving the choices of consumer and farmer among different methods of production of crop commodities (Beckmann, Soregaroli and Wesseler 2014), and managing requisite segregation of non-GE conventional, GE, and organic systems pursuant to consumer, market, and producer preferences.

4.6.2.1.4 Unauthorized Releases

Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial human and animal food supply have occurred, and, over the long-term, it is possible that such incidents will occur again. While it is possible that such incidents will, over the long-term, continue, it is also expected that such incidents would be rare in occurrence. Financial losses resulting from unauthorized releases are difficult to quantify due to a variety of factors determining the market price of agricultural commodities. However, a couple of examples are provided. One would be that of the well-publicized StarLink corn incident. While not explicitly an unauthorized release for APHIS, it serves as an example of potential costs. StarLink corn was deregulated by APHIS, yet did not have an established tolerance for human food consumption set by the EPA.[185] In 1998, the EPA registered StarLink corn for commercial use, provided that all grain derived from StarLink corn was directed to domestic animal food or to industrial uses (e.g., biofuels). It was not authorized for human food uses, specifically the bacillus thuringiensis (Bt) protein Cry9C, and there were no established tolerance limits for human food. In September 2000, residues from StarLink corn were detected in taco shells, indicating that it had entered the human food supply. While there were and are several varieties of Bt corn on the market, StarLink (Cry9C) was illegal in human food; it was only approved for animal food.

Of the few estimates available, this incident resulted in $298 to $964 million in lost revenue for producers in market year 2000/2001 (Lin, Price et al. 2003). A separate study estimated that the presence of StarLink in the food supply caused a 6.8% drop in the price of corn, lasting for 1 year. In total, nearly 300 human food products were taken off the market (Lin, Price et al. 2003), not necessarily because StarLink corn had been detected in all of the products, but as a precaution taken by the manufacturers of the products. The U.S. share of corn imports into Japan for starch use declined from 93% to 62% during November 2000 through March 2002. South Korea's imports of U.S. corn for food manufacturing during the same year-and-a-half period were down 53% from the comparable period before the incident, a decline of about 1.2 million tons (Lin, Price et al. 2003).

[185] Section 408 of the FFDCA authorizes the Environmental Protection Agency (EPA) to establish a tolerance for the maximum amount of a pesticide residue that may be legally present in or on a raw agricultural commodity. The Food and Drug Administration (FDA) is responsible for the enforcement of pesticide tolerances. This enforcement authority is derived from section 402(a)(2)(B) and of the FFDCA.

Similarly, GE Liberty Link rice 601 (LLRICE 601), which was regulated by APHIS, was detected in samples taken from commercial long grain rice. While Both USDA and FDA reviewed the available scientific data and concluded that there was no human health, food safety, or environmental concerns, the economic consequences of the unauthorized release were substantial. The market costs of commingling of APHIS regulated LLRICE 601 with non-GE rice, worldwide, including the costs associated with the loss of export markets, seed testing, elevator cleaning, and food recalls in countries where the variety of rice had not been approved, ranged from $741 million to $1.3 billion (US-GAO 2008).

Federal agencies took a number of actions to divert StarLink corn from the human food supply. For example, APHIS began purchasing bushels of StarLink corn at a 25-cent premium, with Aventis agreeing to reimburse the Agency for the costs. In addition, the human food industry initiated recalls of over 300 products that could have contained the regulated trait protein. The FDA also issued guidance for sampling and testing corn for the presence of trait protein (US-GAO 2008). While the USDA, EPA, and FDA subsequently determined that these incidents of unauthorized release had no adverse impacts on human or animal health, they led to financial losses, particularly from lost sales to countries that would not accept crops containing the regulated GE varieties.

APHIS currently does not have legislative authority to hold applicants financially responsible for costs incurred by USDA due to an unauthorized release of regulated GE organisms (US-GAO 2008). Because APHIS cannot require applicants to provide proof of financial responsibility before it authorizes field tests, USDA may have to bear the expense of removing GE organisms from the environment in the event of an unauthorized release (US-GAO 2008).

While there is no evidence that prior unauthorized releases affected human or animal health, or the environment, some instances have resulted in significant adverse impacts on domestic markets, inclusive of lost trade opportunities.

4.6.2.2 Preferred Alternative: Domestic

4.6.2.2.1 APHIS Costs

APHIS costs of regulating GE organisms that pose plant pest and/or noxious weed risks are expected to change under the Preferred Alternative. Current annual costs of $5.6 million may decline to $2.5 million per year, or increase to $7.8 million, depending on the volume of permits, weed risk assessments, inspections, and NEPA/ESA activities (Table 4-3). For both lower- and upper-bound scenarios, there would be no notification, petition, courtesy permit, or “Am I Regulated” (AIR) processes. NEPA/ESA activities are estimated to range from 50 percent to double the current level. Permits for importation/interstate movement and environmental releases are each expected to number from 100 to 200. The courtesy permit and accompanying Letter of No Jurisdiction, valid for three years and country-specific, would be replaced by a Letter of No Permit Required, valid in perpetuity for imports from any country. APHIS resources needed to issue a Letter of No Permit Required would be about the same as currently required to issue a courtesy permit; however, there would be savings realized over time, as fewer are issued. Inspections are expected to range in number from the current 800 per year to 1,500, and inspection time may increase by 50 percent.

APHIS assumes that BRS staffing would remain at the current level, and that resources freed-up by the reduction in notifications and permits will be reallocated to risk assessments and inspections.

Table 4-3. Expected APHIS Cost Changes

	Current Regulations		Proposed – Lower Bound		Proposed – Upper Bound	
	Annual Number	Cost ($1,000)	Annual Number	Cost ($1,000)	Annual Number	Cost ($1,000)
Notifications	756	203	0	0	0	0
Petitions for non-regulated status	5	2,130	0	0	0	0
Permits, import and interstate movement	190		100		200	
		239		139		261
Permits, movement and environmental release	164		100		200	
Courtesy permits	650	19	0	0	0	0
Letters of No Permit Required	0	0	91	3	91	3
"Am I Regulated" Process	10	7	0	0	0	0
Weed Risk Assessment	0	0		700		1,265
Compliance and Inspections	800	361	800	361	1,500	1,014
NEPA/ESA	1,110	2,648	One-half of current	1,324	Twice as many as current	5,297
TOTAL		**5,607**		**2,527**		**7,840**

Source: (USDA-APHIS 2016c)

APHIS would also likely incur modest additional costs in conducting outreach activities for the proposed rule, developing guidance documents to ensure that the regulated community is familiar with the requirements of the rule, updating the inspection manual, and providing certain staff training in regard to the regulatory revisions. APHIS estimates that the public outreach, guidance and training would cost about $88,000.

Under the provisions of the proposed rule, there is a possibility that APHIS could reach a determination that a GE plant that produces PMPIs is not a regulated organism. Such a plant would not be subject to field trial oversight by USDA, and could be planted without evaluation by FDA or EPA. Several options have been identified for addressing this potential gap in oversight (discussed following in Section 4.8 – Federal, Tribal, and State Governance), including APHIS entering into a MOU and services agreement with FDA and/or EPA to provide personnel and other resources to assist those Agencies in their oversight of PMPIs, FDA and EPA supplying their own personnel and resources to exercise

oversight of PMPIs, and/or amended statutes or the promulgation of new legislation to provide one or more federal agencies with explicit authority to regulate plants that produce PMPIs.

Over the last three years, APHIS has conducted an average of 44 PMPI site inspections. Accounting for pre-inspection preparation, actual inspection time, travel time and travel costs, the administration of the inspections including report writing and correspondence, as well as miscellaneous expenses including permit insurance, APHIS estimates that current PMPI inspections have cost roughly $35,000 in total annually, or about $800 each on average. A similar government expenditure could be expected under any of the above PMPI oversight scenarios.

If FDA and/or EPA were to supply their own personnel and resources to exercise oversight over PMPIs, there will likely be costs incurred in setting up oversight programs, particularly if the federal agency does not currently conduct field inspections if a PMPI is subject to APHIS regulations. Any of the PMPI oversight options may necessitate a federal agency changing policies, regulations, and/or procedures, with the corresponding costs based on how such changes are implemented.

The EPA has regulatory oversight of PIPs. If the field trials are on greater than 10, the EPA requires an experimental use permit (EUP). If the field trials are on 10 acres or less, APHIS assumes regulatory oversight. Under the proposed rule, APHIS would only require permits for PIPs planted on 10 acres or less if they present a plant pest or noxious weed risk or have not yet been evaluated by APHIS for such risk. Hence, under the Preferred Alternative (proposed rule), federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs would shift to the EPA. The EPA may decide to require EUPs for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of such PIPs. The EPA would need to develop a program to oversee small-scale testing of PIPs and issue regulations if warranted. As described above, current inspection costs incurred by APHIS average roughly $800 per inspection.

4.6.2.2.2 Biotechnology Industry

Direct regulatory costs to biotechnology developers would be reduced under the Preferred Alternative. Petitions for non-regulated status, and the petition costs incurred, would be eliminated. Under the Preferred Alternative, permitting would only be required for those GE organisms that APHIS determines pose a plant pest or noxious weed risk. No APHIS regulatory oversight would be needed once APHIS has concluded, via a PPRA and/or WRA, that a GE organisms is unlikely to present a plant pest or noxious weed risk. Under the Preferred Alternative, when APHIS is the only agency with regulatory oversight, there are four developer activities that would not be required:

1. Preparation for hand-off of events into regulatory process
2. Protein production and characterization
3. Agronomic and phenotypic assessments

4. Production of tissues

In cases where the EPA and/or FDA are involved, agronomic and phenotypic assessments would still be eliminated under the Preferred Alternative. The costs of preparing USDA dossiers and permits (included within facility and management overhead costs) would be reduced in all scenarios. APHIS estimates that the reduction in management and administrative costs would be around $337,000 per trait (USDA-APHIS 2016c).

APHIS assumes that even in cases where USDA is the sole regulatory agency and the agency concludes that regulation is not necessary, biotechnology developers would still incur costs for development of GE organisms. These costs would include molecular characterization, regulatory costs for international markets, stewardship, and facility and management overhead.[186] Table 4-4 describes the estimated regulatory compliance costs under the proposed rule for the four oversight scenarios.

Table 4-4. Estimated Developer Costs When USDA Regulation is Not Necessary, 2015 Dollars

Activity	USDA	USDA & EPA and/or FDA
	($1,000)	
Preparation for hand-off of events into regulatory	0	23-57
Molecular characterization	342-1,368	342-1,368
Compositional assessment	N/A	855-1,710
Animal performance and safety studies	N/A	342-963
Protein production and characterization	0	185-1,967
Protein safety assessment	N/A	222-975
Agronomic and phenotypic assessments	0	0
Production of tissues	0	775-2,508
ELISA development, validation and expression analysis	N/A	473-695
Toxicology (90-day rat)	N/A	285-342
Facility & management overhead costs	301-4,593	301-4,593
Stewardship	188-1,140	188-1,140
Subtotal [1]	**832-7,101**	**3,992-16,318**
Herbicide residue study	N/A	120-627
Total for Herbicide resistance	N/A	**4,111-16,944**
Non-target organism study	N/A	114-684
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	171-815
Environmental fate studies	N/A	36-912
Total for Insect resistance	N/A	**4,313-18,729**

Source: (USDA-APHIS 2016c)

[186] For APHIS' proposed risk assessment process for determining regulatory status, the biotech developer would be responsible for validating that the GE organism corresponds to that which was intended. Therefore, molecular characterization would need to be performed even though the results would not need to be sent to APHIS. Similarly, companies would still need to bear stewardship costs to maintain best practices for field trials to maintain varietal purity and protect intellectual property interests.

(1) Subtotal represents the sum of costs for all activities common between insect resistant and herbicide resistant corn.
N/A: Not Applicable

There would be some new costs borne by regulated entities under the proposed rule including rule familiarization and recordkeeping. Recordkeeping cost tabulations are based on the information collection categories from the paperwork burden section of the rule, and are estimated to have a total cost of about $275,000. There have been about 1,100 unique entities who have applied for permits or notifications under 7 CFR part 340, and APHIS estimates that those entities would spend about 8 hours becoming familiar with the provisions of this rule at a total cost of about $576,000.

In terms of net reductions in costs to developers, APHIS estimates that biotechnology developers could save from $485,000 to $861,000 per GE trait when EPA and/or FDA also have regulatory oversight, and from ~ $1.5 million to $5.4 million per GE trait when USDA is the only regulatory agency (Table 4-5). Because the Preferred Alternative is expected to facilitate research, development, and innovation in the agricultural biotechnology sector, APHIS expects that the number of new GE organisms developed annually will increase over time. For the purposes of economic analysis, APHIS assumes, on an annual basis, a range of newly developed GE organisms of 6 (the approximate annual average), 10 (an intermediate number), and 12 (twice the average). For GE organisms that would solely require USDA oversight, the annual savings could be from $8.8 to $32.4 million if 6 new organisms are developed, from $14.7 million to $53.9 million if 10 are developed, and from $17.6 to $64.7 million if 12 are developed. For GE organisms that are submitted for multi-agency evaluation, the annual savings could be from $2.9 million to $5.2 million if 6 new organisms are developed, from $4.9 million to $8.6 million if 10 are developed and from $5.8 million to $10.3 million if 12 are developed.

Because the regulatory cost savings for GE crops that require only USDA approval are expected to be much larger, the proposed rule may provide added impetus to the development of new horticultural varieties. Very few such crops have been deregulated, presumably because the regulatory costs have been too high in relation to a relatively small market.

Table 4-5. Possible Developer Costs Savings under the Preferred Alternative

Activity	USDA	USDA & EPA and/or FDA
	($1,000)	
Preparation for regulatory	23-57	0
Trait characterization	185-1,967	0
Agronomic and phenotypic assessments	148-524	148-524
Production of tissues	775-2,508	0
Facility & management overhead costs	337	327
Total Savings	**1,468-5,393**	**485-861**

Source: (USDA-APHIS 2016c)

As APHIS completes risk assessments under the Preferred Alternative, similar organisms would not need to be subsequently reviewed by APHIS, saving the agency and industry from spending financial and human resources on repetitive and unnecessary regulatory processes. APHIS is also proposing several exemptions under the Preferred Alternative that may lead to additional modest cost savings to the regulated community, but substantial resource savings for APHIS. These exemptions are intended to reduce the need for APHIS to conduct a risk assessment in cases where the modified organisms are equivalent to what otherwise would be achieved through conventional breeding.

When USDA is the only agency with oversight, the approval time is expected to decrease to a month or less for GE organisms that are unlikely to pose plant pest or noxious weed risk, due to a more efficient regulatory review process (described in section 2.2). This would be a significant time savings. APHIS has completed 8 petitions requesting non-regulated status since 2013. The time required to complete these 8 petitions averaged about 16 months, and ranged from 7 to 24 months. While the proposed rule would shorten the regulatory process for USDA, it is not expected to affect the time needed by FDA or EPA.

APHIS' experience over the past 20 years is that most of the GE organisms that have been evaluated by the Agency are unlikely to pose a plant health risk and have not merited regulatory oversight. Hence, APHIS has determined many of these organisms are not subject to the PPA or APHIS regulation.

There would be both direct and indirect economic benefits of not subjecting GE organisms to current regulatory requirements, and rather, reviewing and regulating such organisms under the regulatory framework proposed under the Preferred Alternative (USDA-APHIS 2016c). First, direct regulatory costs to biotechnology developers would be reduced for those organisms that are not considered to pose a risk to plant health. Savings to the regulated community would result from a reduced need to collect certain field data, refined reporting requirements, and lower management costs when compared to current costs for permits and petitions. Second, a number of indirect benefits are expected to result from a more efficient USDA approval process. These include earlier international regulatory approvals, reduced regulatory uncertainty that may facilitate small companies' ability to raise venture capital, and reduced regulatory requirements that may increase greater participation by the public sector in biotech research. The latter effects can be expected to spur innovation in the agricultural biotechnology sector.

4.6.2.2.3 Producers and Consumers

Producers of GE Crops

Under the Preferred Alternative, potential beneficial and adverse impacts to producers of GE organisms are similar to those under the No Action Alternative. As noted under the No Action Alternative, producers of GE crops can derive economic benefits from GE crop plants. For example, U.S. farmers realized higher incomes due to their use of GE crops, totaling approximately $58.4 billion in extra income between 1996 and 2013 (Brookes and Barfoot 2015). If the regulatory relief expected under the Preferred Alternative spurs innovation in the agricultural biotechnology sector, farmers may benefit by having access to a wider variety of GE crop plants, and plant-trait combinations to meet their specific needs in

managing agricultural plant pests, weeds, and disease. Among the types of innovations expected are crops with resistance to disease and insect pests; tolerance of stress conditions such as drought, high temperature, low temperature, and salt; and more efficient use of fertilizer. These types of traits can potentially lower farmer input costs (water, fertilizer, pesticide) and help sustain yields during times of adverse growing conditions. Hence, in comparison to the No Action Alternative, the proposed revisions to APHIS' regulation of GE organisms may more readily help sustain or even improve farm-level profitability.

Consumers

Potential beneficial impacts to consumers of commodities derived from GE crops would be expected to continue, as under the No Action Alternative. Agricultural commodities derived from GE crops are recognized as economically beneficial to domestic markets and improve profitability at the farm level, and are expected to remain so (Brookes and Barfoot 2013a; Fernandez-Cornejo, Wechsler et al. 2014a; Klümper and Qaim 2014; Brookes and Barfoot 2015).

The proposed rule may also indirectly benefit public sector agriculture biotechnology research. University researchers have often commented that the cost of regulation can deter their ability to use modern laboratory methods to innovate and improve crop varieties. The Preferred Alternative is expected to lower the cost of conducting field trials and completing regulatory approvals at USDA. To that extent, it may spur innovation by public sector researchers. Such innovation may ultimately benefit biotech companies, farmers, and consumers.

Producers of non-GE Crops

As described for the No Action Alternative, the risk to organic and non-GE growers from cross-pollination would depend on the extent to which the new GE varieties of crops that could result in cross-pollination or commingling are commercialized, the degree to which those new varieties are adopted, and the proximity of fields where the new GE crops are grown to organic or other identity-preserved crops. The same applies to the identity preserved market, particular for seed crops. Certain buyers in the agricultural commodities markets are looking for products with specific identity-preserved traits. When these products are found to have been commingled with GE crop material, their value to the buyer, and market pricing, can be diminished.

During the years 2011 – 2014, the incidence of affected organic farms was around 0.7%. In 2014, 31 farms, out of a total of 14,093 certified organic farms (~0.2%) lost a total $506,552. In 2014, the total value of sales of certified and exempt organic field crops was $5.5 billion (USDA-NASS 2015a). The total value of sales from certified and exempt organic crops in 2014 was $3.3 billion.[187] In 2015, 32 farms, out of 21,818 total certified organic farms (~0.1%), reported a total of $520,671 on losses due to the unintended presence of GE crop material, with an average loss of $16,271 (USDA-NASS 2016). In 2015, certified organic farms sold $6.2 billion in organic commodities. The total value of sales from certified organic crops in 2015 was $3.5 billion. Based on data from 2011 to 2015, the incidence of losses to organic production from the unintended presence of GE material in organic crops or

[187] This includes nursery and greenhouse crops, which skews the total sales data when evaluating food crops.

crop products would be expected to follow this trend, with affected organic farms comprising less than 1% of total organic farms.

However, if the Preferred Alternative leads to the development and adoption by growers of new varieties of GE crop plants, there may be an increase in the potential for incidents of unintended presence of GE crop material in non-GE crops or crop products. This would primarily concern the fact that there could be more crop types in production; crops that are targeted for specific markets that need segregation. Hence, an increase in development and adoption of new varieties of GE crops would entail maintaining segregation of GE crop products from those produced via conventional, organic, "non-GMO" and identity preserved cropping systems along supply chains. While neither the pace of commercialization nor volume of GE products commercialized is expected to significantly change from current levels; nor is the developer's control over the development process, innovation in the agricultural biotechnology sector is expected to increase under the Preferred Alternative, and there could be seen a wider variety of GE crop plants in commercial production.

The economic impact to growers of organic and non-GMO commodities from such unintended presence would depend on the price premium affected. For instance, as discussed under the No Action Alternative, organic commodities receive a significant price premium in the food and personal care products markets (e.g., from 30% to 500%) relative to the price of commodities derived from conventionally grown crops. Because "organic" and "non-GMO" commodities can always be sold as "conventional" commodities, it is the price premium above the conventional price that represents a measure of the value affected by the unintended presence of GE plant material.

Currently, the organic field crops of barley, buckwheat, flaxseed, hops, oats, peanuts, proso millet, rice, rye, sorghum, sunflower seeds, and wheat, have no GE comparators in the market These are crops where the seed is the valued part of the plant, and therefore the crops most likely to be impacted by commingling or cross pollination with GE crops, in the event such GE crops are commercialized.

4.6.2.2.4 Unauthorized Releases

There could be seen a reduction in the potential economic impacts of unauthorized releases under the Preferred Alternative. In contrast to commingling of non-regulated GE plant material in non-GE crops or crop products, which can affect the price premium of certain commodities, as described above, commingling of regulated GE plant material in agricultural commodities can render a product unmarketable, and consequently can have significant economic impacts (as discussed under the No Action Alternative). The Preferred Alternative is expected to reduce the number of unauthorized releases of regulated GE plants by limiting unnecessary regulation of GE organisms, and focusing regulation on GE organisms that pose a plant pest or noxious weed risk. Hence, as fewer GE organisms will likely be regulated, the probability of unauthorized releases declines. To the extent the Preferred Alternative reduces the incidence of unauthorized releases and facilitates mitigation, there would be a reduction in the adverse economic effects of such unauthorized releases.

4.6.2.3 Alternative 3: Domestic

Under Alternative 3 APHIS would substantially increase oversight of GE organisms. APHIS would interpret the noxious weed authority provided APHIS under the PPA to include potential economic harms that could derive from a GE crop. Under the definition of noxious weed, the term "injury or damage" would be interpreted to include adverse effects due to the mere presence of a GE plant where it is not wanted (designated mere presence noxious weeds – MPNW). This would include economic harms derived from the cross-pollination or commingling of GE crops with non-GE crops, exclusive of evidence of biological harms.

All GE organisms that were determined to present plant pest or noxious weed risks, or an economic risk (including all previously deregulated GE crop plant and other organisms), would be regulated. The only GE organisms not regulated by APHIS would be those that had no economic impacts on non-GE crop producers. In effect, APHIS would serve as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and that will be grown. Hence, APHIS would regulate many of the GE crops currently in commercial production, and those that would be introduced for commercial use in the future.

All GE plants designated MPNW by APHIS and desired for use in commerce would require a permit for cultivation. The permit conditions for these organisms would be specifically designed to limit cross-pollination and commingling between GE crops and non-GE crops by specifying separation distances between crops; require a management program for volunteer plants to prevent GE crop plants from flowering in abandoned, fallow and rotated fields; and ensure that only GE crops that have been granted approval in the countries that are major export markets are grown in the United States.

Alternative 3 would affect developers and growers of GE crops, growers of non-GE crops, and APHIS. Plant biotechnology developers and growers of regulated crop plants would be required to track and record the location and acreage of the MPNW being grown and implement a volunteer plant management program. In order to identify the location and proximity of non-GE crops to GE crops, all non-GE crop producers would need to certify their operations with APHIS to confirm they are legitimate business entities. Non-GE crop producers would need to report the locations of their operations on a voluntary national pinning map on a regular basis.

4.6.2.3.1 APHIS Costs

APHIS would need to develop a national pinning system to identify the location of non-GE crops, and a system to certify non-GE crop producers. Local pinning map systems have been developed for seed production areas (California Crop Improvement Association).[188] Internet based mapping has also been used to identify producers of organic and pesticide sensitive crops to help mitigate inadvertent pesticide over-spraying by pesticide applicators. While the cost of such a system to APHIS is unknown, the fact that similar systems presently exist suggests it could be implemented at a reasonable cost. USDA would need to develop a registration program to ensure complaints about non-compliance with regulations were from

[188] UC Davis - Crop Isolation Mapping: http://ccia.ucdavis.edu/Crop_Isolation_Mapping/

a legitimate source. The cost of establishing such a system is presently unknown. However, USDA has established registration/certification programs for other applications, such organic cropping systems, so it is expected that this measure could be implemented at a reasonable cost. APHIS would also need to provide a large number of additional inspectors and devote increased resources to the administration of compliance and response to complaints of noncompliance, such as with required crop isolation distances. These costs are expected to be significant considering APHIS inspections currently administer around 400,000 acres, and Alternative 3 would increase the scope of potentially permitted area to about 170 million acres, the area of cropland currently cultivated with GE crops.

4.6.2.3.2 Biotechnology Industry

Developers of GE crop plants would have the responsibility for submitting permit requests and ensuring growers of their products adhered to the separation distances and volunteer plant management requirements specified in the APHIS permit. Developers of crop plants derived from biotechnologies defined under regulations would have increased tracking, monitoring, and reporting responsibilities for regulated crops produced in the United States. Developers of GE plants that were cultivated for commercial purposes and designated by APHIS as MPNWs, would share responsibility for management of a portion of required buffer areas/zones. These requirements could impose substantial costs to the developer. In cases where the permit conditions were not followed and a non-GE crop producer suffered a demonstrated loss, the biotechnology developer and grower would be responsible for paying for the loss. For instance, if APHIS determined that the separation distance requirement was not met by the GE crop producer, biotechnology developers and growers would be responsible for losses to the non-GE crop producer due to the unintended presence of GE plant material. Under Alternative 3 the commercial introduction of GE crop plant may be delayed if approvals for GE crop plant have not been granted in major export markets. Such delays in commercialization of a GE crop plant could substantially impact the net returns on investment for the developer.

The increased tracking, monitoring, and reporting responsibilities, and responsibility for management of buffer areas/zones, would increase potential liabilities for developers of GE crop plants. An increase in potential exposure to liability, whether real or perceived, could dampen or impede innovation and development of new GE crop varieties, reduce grower adoption of GE crop plants, and in some instances may lead to grower abandonment of GE crops for production of a traditionally bred crop plant under a conventional or organic cropping system. Hence, where the cost of regulation proves burdensome, developers may opt to allocate certain resources to more profitable ventures, and there could be seen a decline in investment and innovation in the agricultural biocenology sector. To the extent such a regulatory framework impedes innovation and development in the agricultural biotechnology sector, there may be seen reductions in the economic benefits to GE crop producers, and consumers by way of agricultural commodity market pricing. Under Alternative 3, the costs to biotechnology developers would likely substantially increase.

4.6.2.3.3 Producers and Consumers

Non-GE crop producers (organic, conventional, conventional marketing as “non-GMO”, identity preserved) would also be impacted by this Alternative. The permit conditions for

cultivation of regulated crops would be specifically designed to limit cross-pollination between GE and non-GE crops by specifying separation distances; volunteer plant management requirements to prevent GE crops from flowering in abandoned, fallow, and rotated fields; and to ensure that only crops that have been granted approval in the countries of major export markets are grown in the United States.

Hence, Alternative 3 would provide some protection to non-GE crop producers against losses incurred by unintended presence by requiring establishment of separation distances (or buffer zones) between commercially grown GE and non-GE crops, and management of GE volunteer plants. In order to receive these benefits non-GE crop producers would need to register with APHIS to establish authenticity, and regularly record and report their crop locations on a voluntary national pinning map. Registration of non-GE crop producers would be necessary to prevent non-legitimate claims of non-GE status in order to impose requirements on neighboring GE crop producers. Registration would impose some modest costs on those who wished to benefit from the program.

Some costs for non-GE crop producers may be reduced because growers of GE crops would absorb some of the cost of reducing the risk of unintended presence (e.g., maintenance of separation distances, volunteer plant management). Non-GE crop producers who think neighboring GE crop producers have not maintained required separation distances or managed volunteer plants pursuant to regulations could request an inspection by APHIS. Non-GE growers would be responsible for any commingling that occurs during harvest and transport of the crop commodity as commingling at this stage is within their control.

Growers of GE crops would be responsible for maintaining required separation distances/buffer areas by removing farmland from production or growing non-GE crops on a portion of that land that was required as buffer area. To the extent that this Alternative would increase buffer area requirements, and management of those areas, the cost of providing those areas would be a net loss to the agricultural market in production of food and fiber. To the extent that this Alternative results in reductions in the instances of unintended presence of GE plant material in non-GE crops or crop products, there would be potential economic benefits to growers to both GE and non-GE crops, as well as consumers. To the extent it prevents the production of GE crops that have not been approved overseas, there would be economic benefits to grain exporters, as it would decrease the likelihood of trade disruption due to the presence of GE trait material that has not been authorized in international markets. Organic farmers who grow conventional crops in the required isolation areas (or buffer zones) would be able to sell the harvested crop to the conventional market, as they are currently able to do, but they would lose the price premium on organic commodities that could have been derived from those acres. Farmers of GE crops who grow conventional crops as buffers are also able to sell the harvested buffer zone crop to the conventional market, but they similarly may lose benefits certain GE crops provide on those acres, and incur the costs of inefficiency of planting a separate crop. All of these factors may lead, to some extent, to reduced innovation in the agricultural biotechnology sector, and the associated benefits to biotech developers, GE crop growers, and consumers.

The additional regulatory burden on developers and GE crop producers could discourage certain farmers from cultivating regulated GE crops, choosing rather to produce traditionally

bred crop plants under conventional or organic cropping systems. Such a shift in choice would largely be determined by potential net returns to the farmer for the crop commodity produced.

4.6.2.3.4 Unauthorized Releases

The potential for adverse impacts from unauthorized releases would be similar to that described for the Preferred Alternative. The fundamental purpose of the regulatory framework under Alternative 3 is prevention of cross-pollination and commingling of GE and non-GE crops. While most crops would be regulated, they would be permitted for planting and permitting requirements would be designed to facilitate coexistence of cropping systems. Under Alternative 3, unauthorized releases are primarily a concern limited to APHIS authorized field testing of regulated organisms that are not permitted for commercial crop production, although to a much lesser degree, such releases could potentially occur during commercial cultivation of regulated crop plants, and importation or shipment. Unauthorized releases during field testing could incur expenses to the offender, and market, as described under the No Action and Preferred Alternative. Under the Preferred Alternative there would be expected reductions in the potential for unauthorized releases as a result of revised permitting, reporting, and inspection requirements. However, under Alternative 3, due to the sheer number of commercial GE crops that APHIS would be regulating and permitting for environmental release, it is possible that the incidence of unauthorized releases may increase. For example, any instance of unintended presence by cross-pollination or commingling could comprise an unauthorized release.

4.6.3 International Trade

4.6.3.1 No Action Alternative: International

4.6.3.1.1 APHIS Costs

The costs to APHIS would be the same as described for domestic socioeconomic considerations above, under the No Action Alternative.

4.6.3.1.2 Biotechnology Industry

One of the major obstacles to the commercialization of GE organisms is obtaining synchronization of approvals among various countries that are trading partners. Many countries have legislation for regulation of GE organisms and most countries require prior domestic authorization involving an environmental risk/safety assessment before either confined or unconfined environmental release (i.e., field testing, commercial cultivation) of such organisms is allowed (OECD 2013) as well as a food safety assessment. Authorizations for commercial cultivation for one country generally occur independently of other countries. At any given time, there may be GE plants authorized for commercial cultivation in one country, which have not been authorized in other countries with which the authorizing country trades GE and non-GE commodities. This is often referred to as “asynchronous” approval (AA). Such asynchrony can occur because the time for completing the authorization process is different for various countries, the authorization process cannot be started until completed by the exporting country, or an authorization is never sought from or granted by one or more of the countries involved in the trade of GE seed and/or grain (OECD 2013). For human and animal food commodities, it is particularly important to obtain approvals from

importing countries to minimize trade disruptions that can result from AA that can lead to low level presence (LLP) situations of GE plant material that has been approved in an exporting country, but not approved in a particular importing country.

Today, the number and variety of GE crop commodities being developed, cultivated, and traded worldwide is increasing annually. Consequently, this requires consideration among trading countries of the increased possibility of asynchronous approvals, and the potential for trade disruptions that could result from LLP. LLP and potentially GE plant material that has not received approval in any country found in internationally traded crops are leading concerns among both the private and public sectors (FAO 2014b), and an important consideration for developers field testing regulated GE crop plants. Reducing AA is the most effective way of reducing trade disruptions due to LLP (FAO 2014b), and management of the risk to trade arising from LLP, a risk that impacts importing and exporting countries alike, and global food security in general, is and will continue to be of vital importance to the free flow of trade.

As an example, China refused entry of corn with trace amounts of a GE corn variety (Syngenta MR-162) that had undergone EPA review, had been deregulated by APHIS, and underwent voluntary consultation with FDA, but had not received approval for food use by China. Syngenta MR-162 was produced in the United States, and commingling of this GE variety with other harvested corn occurred during the processing and transport of MIR162 corn and seed. The Chinese government began refusing barges of U.S. corn in which a sample of MIR162 corn was found. The embargo, which lasted from November 2013 until China approved the use of MR-162 on Dec. 16, 2014, affected corn sales valued at approximately $5 billion and prompted law suits in 22 States between U.S. producers and Syngenta.

Both regulatory and development costs can be significant for plant biotechnology developers, as described under the domestic environment above. Further, studies show that the cost of foregone benefits (opportunity costs) stemming from a delay in product release can overshadow both research and regulatory costs. The opportunity costs of the regulatory process include direct expenses and the associated expense of delays in commercialization, regulatory review and authorization by the USDA and EPA, or FDA consultation, as appropriate. In addition to the compliance costs associated with regulatory review and authorization, biotechnology firms also incur debt servicing charges while potential revenues from a commercialized GE commodity are delayed (Phillips 2014). Reducing AA and mitigating the potential for LLP will remain a fundamental and regular practice in the international trade of agricultural commodities derived from GE crops.

4.6.3.1.3 Producers, Handlers, and Consumers

Agricultural commodity markets are comprised of products derived from conventional, organic, identity preserved, and GE based cropping systems. More recently, a “non-GMO” market has emerged, which includes commodities produced using conventional cropping systems and, generally, verified to be comprised of less than 1% of GE plant material. The inability to prevent undesired commingling of commodities derived from GE and non-GE cropping systems can jeopardize export markets for U.S. producers, creating an unfavorable economic climate and uncertainties among importers and exporters of these commodities, as

well as consumers (Van Acker and Bagavathiannan 2011). The repeated inability to meet evolving market requirements for GE and non-GE commodities could affect U.S. farmers' access to entire market segments (Lipson 2011). Hence, as described in subsection 3.10.3, preventing unacceptable levels of GE commodity material in non-GE commodities is a fundamental aspect in the trade of agricultural commodities. The need for maintaining product identity is not unique to GE crop commodities, identity preservation, the process of maintaining agricultural commodity segregation and documenting the identity of products has been practiced for decades, particular for seed markets.

For all crop production systems, 100% purity (or 0% impurities) 100% of the time of any crop commodity or constituent is not possible and costs increase exponentially to achieve this goal (Van Deynze 2011, Kalaitzandonakes and Magnier 2013). As a result, farmers, agricultural groups, and seed certification agencies in many countries have adopted process-based strategies such as those prescribed by the USDA NOP and AOSCA [189] that allow a low and acceptable level of impurities, including pesticides, weed seed, or varietal seed, in the final crop product. Similarly, the 800-plus member American Seed Trade Association (ASTA) works with the global seed industry to ensure that practical standards are developed to support international markets.

Seed testing methods must meet standards developed by the Association of Official Seed Analysts (AOSA) or the International Seed Testing Association (ISTA), which accredit national seed laboratories. International bodies also serve to provide guidance intended to facilitate trade and minimize LLP, per Codex Alimentarius guidelines (FAO 2009), and those of the OECD (OECD 2013, OECD 2015), FAO (FAO 2014c), and WTO (WTO 2015b, WTO 2015c). As part of the current U.S. agricultural production system, the concept and practice of coexistence has evolved to facilitate achieving agreed upon market standards. For instance, ASTA has recently released guides for co-existence (ASTA 2015b) and seed production practices (ASTA 2015a).

The inability to prevent undesired commingling can jeopardize export markets for U.S. producers, creating an unfavorable economic climate and uncertainties among importers and exporters of these commodities (Van Acker and Bagavathiannan 2011). The repeated inability to meet evolving market requirements could affect access to entire market segments (Lipson 2011).

A 2013 survey related to GE crops conducted by the FAO,[190] including questions regarding LLP incidents, and the importance of factors contributing to the trade risks posed by LLP, was sent to a total of 193 countries, with a response rate of 39 percent.[191] In total, 35 percent reported that they had faced LLP incidents in the last 10 years, and 50 percent said they had

[189] The Association of Official Seed Certifying Agencies (AOSCA) develops, monitors, and coordinates standards for seed purity. AOSCA's membership includes Seed Certifying Agencies across the U.S., and Global membership including Canada, Argentina, Brazil, Chile, Australia, New Zealand, and South Africa

[190] The survey was sent to national government organizations through FAO Representations (FAORs), Codex contact points, and individual contacts in early 2013.

[191] Adventitious Presence (AP) means GE plant material that has not received regulatory authorization in any country.

not (FAO 2014b). Most incidences were reported from U.S., Canadian, and Chinese respondents.

Coexistence and commercial segregation of GE, conventional, conventional "non-GMO", and organic commodities will remain and continue to evolve as fundamental requirements for the free flow of trade of agricultural commodities. Large agricultural supply chains involve many actors and processes (e.g., drying, storage, transport), through which routes for commingling of GE and non-GE commodities exist (Van Acker 2012). Total segregation of GE and non-GE production systems under normal commercial production and processing conditions is not practical. Consequently, the effective implementation of stewardship and coexistence programs among GE and non-GE production systems by growers and producers will facilitate trade by meeting agreed upon standards for LLP of importing countries (Van Acker 2012).

For APHIS, matters of unintended presence are related to the authorized field testing of regulated GE organisms in the United States. Current regulations do not explicitly address matters of LLP or importation of GE organisms authorized in another country but not in the United States. However, APHIS clarified its policy for handling situations in which regulated GE plant material becomes mixed at low levels with commercial seeds and grain in 2007 (USDA-APHIS 2007). This policy is not new, but rather a description of how APHIS currently evaluates and responds to these incidents, described below.

4.6.3.1.4 Unauthorized Releases

In authorizing field testing under regulation, a major focus is ensuring appropriate confinement of the regulated GE organism, and the potential for dispersion of GE plant material during field testing. Biotechnology developers must comply with APHIS regulations, and notification and permit requirements to prevent the release of regulated GE plant material. However, when confinement is breached, it is APHIS policy to respond with actions appropriate to the level of risk, determined by a scientific assessment and warranted by the facts in each case. APHIS will initiate an inquiry whenever regulated material is mixed with commercial seeds or grain to evaluate any risk, to determine the circumstances surrounding the release and to determine whether remedial and/or enforcement actions may be appropriate.

If APHIS determines that an incident involving regulated GE plant material could pose a risk to plant health or the environment, APHIS will take appropriate remedial steps using its authority under the Plant Protection Act. In cases in which APHIS determines that remedial action is not necessary to mitigate unintended presence of regulated GE plant material to protect plant health and the environment, APHIS is not precluded from taking enforcement action against a company or individual for violations of APHIS regulations.

4.6.3.2 Preferred Alternative: International

4.6.3.2.1 APHIS Costs

Same as described for the Preferred Alternative for domestic socioeconomic considerations above.

4.6.3.2.2 Biotechnology Industry

Under the Preferred Alternative the time required for APHIS regulatory review and decision processes (i.e., PPRA and WRA) will be shortened for GE organisms solely under the jurisdiction of APHIS. For GE organisms used for human and animal food (and representing the bulk of what is traded), the timing of review decisions are unlikely to be affected by this Alternative and are expected to be similar to the No Action.

4.6.3.2.3 Producers, Handlers, and Consumers

Producers who utilize GE plants for human and animal food, fiber, and ornamental crops could potentially benefit from the Preferred Alternative. A reduction in regulatory burden could spur innovation in agricultural biotechnology leading to the development of new traits that benefit farmers and consumers. To the extent that new GE crop plants are in demand abroad, this could benefit trade. Though innovation may increase, the rate of LLP incidents is not expected to change under this Alternative based on our assumption that the rate of LLP is related to the rate of approvals in this country versus the rate of approval in international markets. It is our expectation that the rate of commercial adoption in the United States will not significantly change under the Preferred Alternative relative to the No Action because the review and approval process for the EPA is not anticipate to substantially differ, nor the FDA's recommended consultation process. One unknown at this point is whether the approval process in other countries will change if USDA codifies the Preferred Alternative. USDA will know more after the proposed rule and dPEIS are published and discussions with regulatory entities in other countries commence.

For APHIS, matters of unintended presence of regulated plant material are directly related to the authorized/permitted field testing of GE organisms as described for the No Action Alternative. Current regulations do not explicitly address matters of LLP due to importation of unauthorized plant material. However, APHIS clarified its policy for handling situations in which regulated GE plant material becomes mixed at low levels with commercial seeds and grain in 2007 (USDA-APHIS 2007). This policy is not new, but rather a description of how APHIS currently evaluates and responds to these incidents.

4.6.3.2.4 Unauthorized Releases

The potential effects on trade are expected to be the same as or similar to those described for the No Action Alternative. However, to the extent the proposed revisions for compliance and enforcement activities, as well as the permitting process, translate to reductions in unauthorized releases, these could potentially help prevent, or rather reduce the risk of unintended presence of regulated plant material in internationally traded agricultural commodities. In effect, it is anticipated that APHIS will be regulating fewer numbers of GE organisms. APHIS will be reviewing more GE organisms for plant pest and noxious weed risk assessment, outside of a petition or request to do so, and making determinations as to their regulatory status. APHIS anticipates this will result in a larger number of certain types of GE organisms having non-regulated status. Most of these GE plant-trait combinations that are already on the market (e.g., Bt corn varieties). APHIS anticipates that those GE organisms determined to be subject to regulation will be those that pose plausible plant pest or noxious weed risks. Hence, instances of unauthorized releases would be expected to decline.

If APHIS determines a GE crop plant intended for human or animal food is not subject to regulation, and that GE plant obtains regulatory review by the EPA and the developers consult with the FDA, as appropriate, this could result in an increase in the numbers of GE crop plants in commerce. As such, there would need to be authorizations of such GE crop plants in foreign countries prior to export, to preclude instances of LLP. If there is seen an increase in regulatory authorization and commercial production of new GE crop plants in the United States that have not been reviewed and authorized by foreign countries, then there is potential increase in the risk of LLP for certain commodities, such as corn and soybean.

4.6.3.3 Alternative 3: International

4.6.3.3.1 APHIS Costs

APHIS costs for international considerations are the same as described under Alternative 3 for domestic socioeconomic environment above.

4.6.3.3.2 Biotechnology Industry

Under Alternative 3, new GE organisms could not be released for commercial use in the United States until major trading partners had also granted regulatory approval.[192] Alternative 3 could put domestic plant biotechnology developers at a competitive disadvantage relative to their international competitors because the release of a newly developed GE crop plant in the United States would be subject to approval of the GE crop plant among foreign trading partners. Hence, in some respects it would allow foreign entities to control which GE crop plants were commercially produced in the United States. A country that wished to "catch up" to the U.S. innovation and technical advantage in commercial cropping systems could systematically avoid approvals in their country and prevent an innovative GE crop plant beneficial to crop production from being used among trading partners.

Hence, plant biotechnology developers in the United States could see significantly diminished net returns as a consequence of such delays. As mentioned earlier, the cost of foregone benefits (opportunity costs) stemming from a delay in product release can overshadow both research and regulatory costs. The opportunity costs of the regulatory process include both the out-of pocket expenses and the associated expense of delays in commercialization, both for biotech companies and consumers. In addition to the compliance costs associated with international regulatory approval, biotech companies also incur debt servicing charges while revenues are delayed. Growers forgo income that could be earned when approval is timelier, and consumers similarly forgo benefits of lower priced or higher quality products.

4.6.3.3.3 Producers, Handlers, and Consumers

This Alternative could provide producers of GE and non-GE crops with protection against losses and export market disruptions that may occur as a result of LLP in bulk commodities

[192] As part of regulation under Alternative 3: The only regulated GE crop plants that would be permitted for commercial-scale cultivation in the United States would be those crop plants that have been granted international approval in the major export markets. This requirement would be instituted to reduce the potential for low level presence (LLP) occurring in countries importing U.S. agricultural commodities.

arriving in those countries. Under this Alternative, only crops that have been granted approval in major export markets could be grown in the United States. This requirement, in conjunction with requisite buffer zones and implementation of volunteer plant management programs, would serve to reduce instances of AA, LLP, and associated losses to producers of agricultural commodities.

The delays incurred from mitigating asynchronous approvals would lead to a delay in the release of GE crops that could benefit producers and consumers. It would put domestic producers at a competitive disadvantage relative to producers in foreign countries. U.S. producers often rely on higher yielding varieties to offset greater labor costs compared to foreign competitors. Delaying the release of new varieties could erode the edge among crop producers who rely on the latest plant biotechnologies to remain competitive in international markets.

4.6.3.3.4 Unauthorized Releases

The potential effects of unauthorized releases on trade would be the same as described for the Preferred Alternative.

4.7 Public Participation

Several mechanisms exist by which the public can participate in the 7 CFR part 340 regulatory decision making process. These mechanisms are summarized below.

4.7.1 No Action Alternative

4.7.1.1 Petitions to Change § 340.2 Listed Taxa that are or Contain Plant Pests

The PPA allows for a person to petition the Secretary to add or remove a plant pest from the regulations. Currently, 7 CFR § 340.5 contains provisions for petitioning the Administrator to amend the list of organisms in § 340.2 by either adding or deleting any genus, species, or subspecies. While most of the procedures are still accurate, some of them have changed, and APHIS would provide an updated postal address for submission of petitions. There is currently no option for electronic submission.

After the filing of a petition to amend the list of organisms APHIS will publish a proposal in the Federal Register to amend § 340.2 and solicit public comments on the proposed listing/delisting. Anyone may submit written comments to APHIS on a filed petition, which would be available on the internet via the federal website; www.regulations.gov.

APHIS is required by regulations to furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: (i) Approve the petition in whole or in part in which case the Administrator will concurrently take appropriate action (publication of a document in the Federal Register amending 340.2 of this part; or (ii) deny the petition in whole or in part. The petitioner will be notified in writing of the Administrator's decision. APHIS' decision would be made available in the form of a notice published in the Federal Register.

4.7.1.2 Determinations of Regulatory Status

APHIS currently evaluates the regulatory status of GE organisms when it receives a petition for a determination of non-regulated status for a GE organism (see Section 2.2.5.1). APHIS publishes notices of petitions submitted to the Agency in the Federal Register. Through these notices APHIS makes petitions available for public review and comment to help identify potential issues and impacts that APHIS should be considering in evaluation of the petition. Petitions are made available to the public through the Federal eRulemaking Portal: http://www.regulations.gov/. Through this website the public can access the petition and related documents, and submit comments to APHIS.

As part of the petition procedure, APHIS also provides public participation via the NEPA review process, when NEPA review is required. An overview of the NEPA review process is described below.

4.7.2 Preferred Alternative and Alternative 3

4.7.2.1 Changes to § 340.2 Listed Taxa that are or Contain Plant Pests

To improve regulatory flexibility and help ensure the list of taxa subject to regulation remains current, APHIS is proposing to remove the list of taxa from § 340.2 and make it available on the internet. APHIS would advise the public of changes to the list of taxa through notices published in the Federal Register.

4.7.2.1.1 APHIS-Initiated Changes to Listed Taxa

APHIS may propose to add or remove a genus, species, or subspecies from the list of regulated taxa through a notice published in the Federal Register. The notice will state why APHIS has determined it necessary to add or remove taxa, and will request public comment, providing for a 30 day public comment period, or longer if required.

If no comments are received on the notice, or the comments received do not affect APHIS' determination, APHIS would publish a subsequent notice in the Federal Register stating that the taxa has been added or removed from the list. APHIS' determination could be affected if a commenter provides evidence that contravenes APHIS' basis for listing the taxon, such as information that calls into question the plant pest characteristics of the taxon.

4.7.2.1.2 Petitions by the Public to Amend the List of Taxa

As described for the No Action Alternative above, the PPA allows for a person to petition the Secretary to add or remove a plant pest from the regulations. The list of requirements for petitioning the Administrator include formatting and submission procedures that are currently contained in § 340.5(b). However, these procedures have not been updated since 1994. While most of the procedures are still accurate, some of them have changed. For example, the requirements do not consider the potential for electronic submission of a petition via email. They also provide an obsolete address for postal submissions. Therefore, APHIS is proposing to change the petition processes in several ways.

APHIS will remove the specific requirements related to formatting and submission procedures for petitions from the regulations, and instead, these procedures would be

provided on the internet. APHIS would also revise the submission procedure to allow petitions to be submitted via email, and to update the address for postal submissions. These changes would update the petition submission procedure, and allow for greater flexibility in revising procedures, if, for example, the address for submissions changes in the future.

Following the receipt of a petition to amend the list of organisms in § 340.2, APHIS would publish a notice in the Federal Register announcing the availability of the petition and solicit public comment on the petition for 60 days. The petitions would be made available to the public through the Federal eRulemaking Portal: http://www.regulations.gov/. Following the close of the public comment period, the Administrator would announce his or her decision to either approve the petition in whole or in part or deny the petition in a subsequent Federal Register notice.

Finally, APHIS is proposing to add an appeals process in the event that the Administrator denies a request to amend the list of taxa that are described in § 340.2. Any person whose petition has been denied would be able to appeal the decision in writing to the Administrator within 10 days after receiving the written notification of the denial. The appeal would have to state all of the facts and reasons upon which the person relies to assert that the petition was wrongfully denied. The Administrator would then grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow.

4.7.2.2 Determinations of Regulatory Status

Proposed paragraph (c) of § 340.4 would discuss APHIS' proposed notice-based process for making evaluation of regulatory status available to the public. APHIS would make both the plant pest and weed risk analyses available for public review through a notice published in the Federal Register. This first notice would request public comment, and would propose a regulatory status for the GE organism. The opportunity for public comment would be made available to the public through the Federal eRulemaking Portal: http://www.regulations.gov/.

If no comments are received on the Federal Register notice, or if the comments do not affect the conclusions of the risk analysis or the proposed regulatory status of the GE organism, APHIS would publish a subsequent notice in the Federal Register affirming its proposed regulatory status for the GE organism.

If, based on the comments received, APHIS determined that the proposed regulatory status for the GE organism was in error, APHIS would publish a subsequent notice in the Federal Register announcing the revised regulatory status of the GE organism.

4.7.3 NEPA Review

APHIS prepares environmental documentation as part of its obligations under the National Environmental Policy Act of 1969 (NEPA) and the APHIS NEPA implementing regulations at 7 CFR part 372. NEPA requires federal agencies to assess the environmental effects of their proposed actions prior to making decisions. Section 102 in Title I of the Act requires federal agencies to incorporate environmental considerations in their planning and decision-making through a systematic interdisciplinary approach. Specifically, all federal agencies are to analyze and document the potential environmental impacts of and alternatives to major

federal actions that may significantly affect the environment. These statements are commonly referred to as Environmental Impact Statements (EIS) and Environmental Assessments (EA). Agencies may also categorically exclude actions which have been found to have no effect on the human environment (40 CFR 1508.4). Categorical exclusion means a category of actions which do not individually or cumulatively have a significant effect on the human environment, and for which, therefore, neither an EA nor an EIS is required.

APHIS would complete the appropriate NEPA analysis (e.g., categorical exclusion, EA, or EIS) prior to making decisions about issuing permits and making decisions on regulatory status. APHIS would publish notices in the Federal Register informing the public that draft EAs and EISs were available for public review and comment on www.regulations.gov. APHIS would provide for a 30 day public comment period, and may extend the public comment period if requested to do so or needed. These procedures for EAs and EISs give the public the opportunity to submit written comments on draft EAs and EISs, so that the Agency can consider these views in developing a final EA or EIS. These environmental reviews help to inform the Agency's decision-making process when considering the environmental release or regulatory status of a GE organism.

Some Agency decisions may not require an EA or EIS, and may be categorically excluded from the need to conduct in depth analyses. APHIS recently published notice that the Agency is proposing to amend its NEPA implementing regulations at 7 CFR part 372. The amendments include clarifying and amending the categories of actions for which APHIS would normally complete an EIS or an EA for an action, expanding the list of actions subject to categorical exclusion from further environmental documentation, and setting out an environmental documentation process that could be used in emergencies [Docket No. APHIS–2013–0049].[193] APHIS is proposing to categorically exclude certain permits for the importation, interstate movement, or environmental releases of regulated GE organisms, provided that permit conditions, such as isolation distances from compatible relatives, control of flowering, or physical barriers minimize the interaction of the regulated article with the environment. APHIS is also proposing to categorically exclude extensions of non-regulated status under 7 CFR part 340 to organisms similar to those already deregulated. If the regulated GE organism subject of the extension request is similar to non-regulated organisms, EAs or EISs have been previously conducted for the non-regulated GE organism, and APHIS finds no difference with respect to the impacts on biological or physical environment between the two organisms, APHIS may issue an extension of determination of non-regulated status, and categorically exclude the extension request from the need to prepare and EA or EIS. If there were any extraordinary circumstances, APHIS would not allow for a categorical exclusion, and require an EA or EIS be conducted.

For Agency decisions and actions conducted under 7 CFR part 340, public participation in the NEPA process would be the same for all the Alternatives considered. This process is described in APHIS NEPA implementing regulations at 7 CFR part 372.

[193] See 81 Federal Register, No. 139, Wednesday, July 20, 2016, p.47051.

4.8 Federal, Tribal, and State Governance

4.8.1 Federal Oversight

The Coordinated Framework, discussed in Section 1.7, provides as a guiding principle that, "[i]n order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable." APHIS considers the proposed revisions to 7 CFR part 340 under the Preferred Alternative to be entirely consistent with this principle: APHIS will no longer consider GE organisms to be regulated articles solely because a plant pest was used as a donor, vector, or vector agent in its development, it will consider whether the GE organisms itself may present a plant pest and/or noxious weed risk.

The proposed revisions to 7 CFR part 340 under the Preferred Alternative would update the regulations by revising terms and definitions, and, in conjunction with incorporation of noxious weed authority, broaden the scope of GE organisms that could be evaluated and potentially regulated under 7 CFR part 340. While the scope of GE organisms that APHIS would evaluate for plant pest and noxious weed risk would be broadened, the revisions would focus and limit ultimate regulatory oversight to GE organisms that posed a plant pest or noxious weed risk, as identified in a science-based risk assessment. The proposed revisions are expected to promote process efficiency by allowing APHIS to focus its resources on oversight of GE organisms that have potential plant pest or noxious weed risks, and eliminating oversight of GE organism that are unlikely to pose such risks. The regulatory framework being considered under the Preferred Alternative is consistent with the principles of the Coordinated Framework, with the noted effects on the Coordinated Framework, discussed below.

Under the Preferred Alternative (proposed rule), APHIS would no longer require permitting for field testing of GE organisms prior to determination of their plant pest or weed risks. Rather, APHIS would conduct plant pest and noxious weed risks first, and only require permits for field testing of GE organism that were determined to pose a plant pest or noxious weed risk. For those GE plants that are determined unlikely to pose a plant pest or noxious weed risk, biotech developers will be able to field test without APHIS authorization. In effect, it is expected that APHIS would be regulating a fewer number of GE plants and other organisms, eliminating unnecessary regulation, but regulating a broader range of GE organisms that presented risks as plant pests or noxious weeds. As a consequence, The regulatory framework under the Preferred Alternative is expected to facilitate research, development, and innovation in the agricultural biotechnology sector.

One concern that has arisen is whether the reduction of APHIS oversight of field trials of certain GE plants that are not subject to 7 CFR part 340 will lead to increased levels of GE plant material in the human or animal food, prior to premarket food consultation with the FDA. While this is considered a possibility, APHIS does not expect the process of GE plant development, field testing, and commercialization to be substantially altered as a result of implementation of the Preferred Alternative, for a couple of reasons.

First, it is in the biotechnology developer's best interest to sustain the same level of supervision over the development process, and comply with legal and industry procedure required for successful commercialization of their product, as at present. In general, developers have various legal, quality control, and marketing motivations to implement rigorous voluntary stewardship measures for field trials. APHIS therefore believes that developers would continue to utilize such measures for field testing even in cases where USDA would not require a permit. As an example, the undesired cross-pollination or commingling of GE plants under development with other plants:

- introduces unwanted characteristics and variability in the GE plant that confounds molecular characterization and other studies for which field tests are conducted;
- increases legal exposure from unauthorized use of intellectual property (if another developer's traits are inadvertently incorporated into their lines);
- increases legal exposure if unauthorized GE plant material is detected in crops; and
- introduces the possibility of the loss of intellectual property and/or confidential business information, such as, if a trait (proprietary information) were to escape a developer's control.

Even after deregulation, seed companies are motivated to adhere to strict stewardship requirements to maintain the integrity of their crops and reduce legal exposure. Best management practices include maintaining appropriate isolation distances from sexually compatible crops; monitoring and removing volunteers in production fields and the local environments; using color tagging and traceability systems for visual identification of GE plants; and using production best practices regarding equipment monitoring, treatment and cleaning procedures for crop production equipment, seed cleaning, storage, shipping container and screenings disposal requirements, grower guidelines, record keeping, inspections, training, and maintaining a continual review and improvement process.[194]

While the aforementioned measures represent the best practices followed by the sugar beet seed industry, similar stewardship measures are followed in other instances such as the production of GE alfalfa seed and Enogen® corn where as little as 1 seed in 10,000 can affect the characteristics of processed corn.[195] In the case of alfalfa seed production, the National Alfalfa Forage Alliance has implemented a non-regulatory coexistence strategy, based on grower opportunity zones. A locality can focus on either GE alfalfa seed production or alfalfa seed production targeted for GE sensitive markets, depending on whether the growers on 80 percent or more of the alfalfa seed acres choose production of GE

[194] Loberg, G to: United States District Court for the Northern District of California, San Francisco Division. 2010. Declaration of Greg Loberg in Support of Intervenors' Opposition to PL. Permanent Injunction Case no. 08-0000484, Regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. United States District Court for the Northern District of California, San Francisco Division. Case No. 3:08-cv-00484 JSW.

[195] NAFA Coexistence Document - Best Management Practices for Roundup Ready® Alfalfa Seed Production: https://www.alfalfa.org/pdf/CSBMPForRRA.pdf | Enogen Corn Growers: http://www.syngenta-us.com/corn/enogen/grower

or non-GE seed.[196] In the United States, there are currently 6 grower opportunity zones catering to GE sensitive markets and 21 opportunity zones where GE alfalfa is produced.[197]

Second, while under the Preferred Alternative research, development, and innovation in the agricultural biotechnology sector is expected to increase, neither the pace of commercialization nor volume of GE crop plants commercialized is expected to significantly change, as the FDA and EPA will still have oversight of GE crop plants developed for commercial purposes. Developers of GE crops plants would remain subject to the FFDCA, FIFRA, and all other laws and regulations providing protection of human health and the environment, and required to comply with these laws and implementing regulations, as under the No Action Alternative.

Lastly, reputational considerations among domestic and international markets, let alone among domestic and international regulatory authorities, and potential loss of standing in the market, would likely serve to preclude field testing activities where there was risk of entry of unauthorized GE plant material entering the human or animal food supply. Just as there are strong incentives for voluntary human and animal food safety consultations with the FDA, developers face various legal, quality control, and marketing pressures where stringent oversight of field trials is in the developers best interest. For these reasons, APHIS believes that developers would continue to use rigorous voluntary stewardship measures in field testing of their products even when APHIS has determined that a GE organism does not pose a plant pest or noxious weed risk.

Bearing these considerations in mind: As the Coordinated Framework notes, a "mosaic" of statutes have, to date, provided Agencies with authority to exercise oversight of GE organisms, and Agencies functioning within the Coordinated Framework oversee different aspects of the risk that a GE organism may pose. Accordingly, for those GE organisms APHIS no longer views as plant pest or noxious weed risks under the Preferred Alternative, other Agencies may continue to exercise oversight, relative their authorities to do so. However, APHIS acknowledges that the proposed revisions to 7 CFR part 340 could have direct or indirect impacts on the manner in which FDA and EPA exercise their roles within the Coordinated Framework; these potential impacts are discussed below.

Plant Made Pharmaceutical and Industrial Compounds

In general, GE plants intended for human or animal food are not required to be evaluated for safety by the FDA before going to market. However, the developer is responsible for ensuring the safety of their food products for human and animal consumption, and complying with all laws and regulations governing food safety. Developers of GE crop plants are encouraged to consult with the FDA prior to marketing human and animal foods, and developers consider these voluntary food safety consultations with FDA to be necessary, if not critical, for successful commercialization of their product in the U.S. market, as well international trade of human and animal food commodities derived from GE plants. To date, there has been an excellent record of compliance with FDA's guidance. For this reason,

[196] NAFA Coexistence Document - Grower Opportunity Zones for Seed Production: https://www.alfalfa.org/pdf/GOZseed.pdf

[197] NAFA - Grower Opportunity Zones & Non-GE Seed Production Areas: https://www.alfalfa.org/bio_growerzones.php

APHIS believes that developers will continue to consult with the FDA and use rigorous stewardship measures in the field testing of human and animal food crops even when APHIS has determined that a GE organism does not pose a plant pest or noxious weed risk.

While APHIS believes this will be the case for GE food plants, a concern under the proposed revisions to 7 CFR part 340 is oversight of GE plants that are not intended for human or animal food; these are varieties of plants, to include crop plants, genetically engineered to produce pharmaceutical or industrial compounds (plant-made pharmaceuticals and industrials). For the purposes of this dPEIS, these are referenced as PMPIs, and GE P/I-producing plants. A recent, well-publicized example of such a plant is *Nicotiana benthamiana*, which was genetically engineered to produce antibodies to the Ebola virus, and used in the development of an Ebola vaccine. When plants are genetically engineered in such a manner, the plants and the pharmaceutical or industrial products they produce may fall within the purview of multiple regulatory agencies: APHIS, the EPA, and/or FDA.

APHIS has authority to evaluate GE P/I-producing plants for plant pest and/or noxious weed risk under the PPA. The FDA has authority to regulate plant made pharmaceuticals under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 9). The EPA has authority to regulate plant made compounds with pesticidal properties (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 et seq.), and PMPIs that are determined to be chemical compounds under the Toxic Substances Control Act (TSCA, 15 U.S.C. 2601 et seq.). Hence, while APHIS may regulate the plant itself, products obtained from GE P/I-producing plants may be regulated by FDA (authority over pharmaceuticals) or EPA (authority over certain industrial compounds), depending on their intended use.

Under current 7 CFR part 340, APHIS regulates GE P/I-producing plants because they were developed using genetic material from plant pest, or a plant pest was part of the development process. Accordingly, APHIS currently exercises oversight of all field trials of regulated GE P/I-producing plants; this oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring.

Under the proposed revisions to 7 CFR part 340, a GE plant would not be regulated solely because a plant pest was used as a vector, vector agent, or donor of genetic materials in its development. Rather, a GE plant would be a regulated organism if it had a plant-trait combination that APHIS has not yet evaluated for plant pest and/or noxious weed risk, if it had received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, or if it was evaluated by APHIS and found to present a plant pest or noxious weed risk. In brief, the GE P/I-producing plant itself would have to pose a plant pest or noxious weed risk to be regulated under the proposed revisions to 7 CFR part 340.

As a result, because most plants do not inherently present plant pest or noxious weed risks, particularly domesticated plants, and traits introduced for the production of pharmaceutical or industrial compounds are unlikely to confer plant pest or noxious weed risk to a domesticated plant, it is expected that most of the GE P/I-producing plants that APHIS evaluates will be found unlikely to pose a plant pest or noxious weed risk. Hence, such plants could be grown

outdoors without the need for permits and without APHIS oversight. Such a plant could also be planted before or without an evaluation by the FDA or EPA.

APHIS recognizes that federal oversight of outdoor plantings of GE P/I-producing plants could be necessary to prevent the unlawful entry into the food supply of material from such plants. Establishing growing and handling conditions to confine such plants, and inspecting to ensure such conditions are followed, may enable corrective actions before material from the plants is inadvertently released and causes public health or economic impacts. One of the reasons APHIS' oversight of such crops has been an important part of the Coordinated Framework for oversight of GE plants is that companies are not necessarily required to notify FDA or EPA when the company plants a GE P/I-producing plant. For example, for GE P/I-producing plants whose products fall under FDA authority, FDA has no regulations governing the planting of such crops. For crops genetically engineered to produce pharmaceuticals, companies only have to come to FDA when they have reached the point that they are ready to begin clinical trials with the pharmaceutical derived from the plant. This could be years after they first started growing the pharmaceutical-producing plant in the field.

Hence, a gap in the federal oversight of GE P/I-producing plants could result in the unintentional or inadvertent introduction into the human or animal food supply of unevaluated PMPI products, even when the intended purpose of the plants is not for human or animal food use. For example, a company could self-determine that the compound produced by the plant is generally recognized as safe (GRAS) for use, and therefore conclude it had no legal obligation to keep surplus GE P/I-producing plants out of the human or animal food supply, to keep such GE P/I-producing plants from spreading pollen to plants grown for human and animal food purposes, or even to notify any federal agency that they were planting such crops. In addition to potential food safety risks posed by such plants should they enter the food supply, a gap in federal oversight could generate concerns from the general public regarding the safety and wholesomeness of the human or animal food supply, which could adversely impact agricultural interests.

APHIS has identified several options that have the potential for adequate federal oversight of outdoor plantings of GE P/I-producing plants.

- Under one option, a statute would be enacted, or existing statutory authority amended, to grant one of more federal agencies explicit authority to provide oversight of outdoor plantings of all GE PMPI-producing plants and to evaluate GE PMPI-producing plants for all possible risks, beyond plant pest and noxious weed risks.
- For industrial-producing plants subject to EPA's jurisdiction, a second option is for EPA to develop a program to regulate industrial-producing plants and issue regulations if warranted.
- Under a third option, APHIS would enter into a memorandum of understanding (MOU) and services agreement with the appropriate federal agencies to provide personnel and other resources to assist those agencies in their oversight of outdoor plantings of PMPI-producing GE plants, recognizing that federal agencies may not

have authority to require notification and/or oversight of the outdoor planting of some of these plants.

- Under a fourth option, those federal agencies would supply their own personnel and resources to exercise oversight of outdoor plantings of PMPI-producing GE plants, recognizing that federal agencies may not have authority to require notification and/or oversight of some of these plants.

APHIS recognizes that there are challenges associated with each of these options. For example, the first option would require legislation to be enacted, which is not within the purview of the Executive Branch of the Federal government. Additionally, all options could require Federal Agencies to incur the costs associated with setting up new regulatory programs. The second option would require time for EPA to stand up a genetically engineered industrial-producing plant oversight program for plants subject to EPA jurisdiction. The third option, in turn, would require policies, procedures, and guidance regarding APHIS' interaction with other Federal Agencies to be developed prior to implementation. To that end, it is important to note that APHIS does not prefer any of these options over the other, nor does the Agency consider the options listed above necessarily to be exhaustive. Rather, we put them forward to indicate that the Agency is aware of the implications of this rule with regard to PMPIs, and to request specific public comment regarding the best manner to address this issue.

Plant Incorporated Protectants – Small Scale Field Testing

Plant-incorporated protectants (PIPs) fall under the regulatory oversight of the EPA. Currently, the EPA requires experimental use permits (EUPs) for small scale field testing of PIP containing GE plants when field tests are over 10 acres in size, and APHIS exercises regulatory oversight of field testing of GE PIP producing plants on or under 10 acres. In brief, to date, the EPA has largely relied on USDA oversight and inspections of small scale filed trials since jurisdictions currently overlap. Under the current regulations in 7 CFR part 340, APHIS requires permits or notifications for the environmental release of all GE plants that meet the definition of a regulated article and produce PIPs, and exercises oversight of all outdoor plantings of these regulated PIP-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring.

To date, APHIS has regulated PIP-producing plants when they were genetically engineered using a plant pest as the donor, vector, or vector agent, and fall under the scope of regulated article as defined in the current regulations at 7 CFR part 340. However, under the Preferred Alternative (proposed rule), a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily meet the definition of a regulated organism. Rather, the GE plant would be a regulated organism if it had a plant/trait combination that the Agency determines presents a plant pest or noxious weed risk, or has not yet evaluated for plant pest and/or noxious weed risk. As discussed above for GE P/I-producing plants, because most plants do not inherently present plant pest or noxious weed risks, particularly domesticated crop plants, and traits introduced for the production of PIPs are unlikely to confer plant pest or noxious weed risk to a domesticated plant, it is expected that most of the GE PIP producing plants that APHIS evaluates will be found unlikely to pose a plant pest or noxious weed risk. Hence, such plants could be grown outdoors without

the need for permits and without APHIS oversight. Under the Preferred Alternative (proposed rule), APHIS would only require permits for field testing of GE PIP producing plants on 10 acres or less if they were determined to present a plant pest or noxious weed risk, or have not yet been evaluated by APHIS for such risk.

APHIS understands that the Preferred Alternative would shift federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs to the EPA. The EPA may decide to require experimental use permits for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. The EPA would need to develop a program to oversee small-scale testing of PIPs and issue regulations if warranted. APHIS is fully committed to coordinating with EPA in this matter in order to give the EPA sufficient time to stand up a program for federal oversight of small scale field testing of GE PIP producing plants, if the Preferred Alternative is implemented (the proposed rule is finalized). APHIS understands that an MOU and services agreement may be necessary to provide personnel and other resources to assist the EPA during the interim period while the EPA implements its own program of oversight for the oversight of outdoor planting of PIPs 10 acres or less.

APHIS recognizes that there are challenges associated with such a transition that would also require EPA to incur the costs associated with setting up a revised regulatory program. Further, such a transition would require policies, procedures, and guidance regarding APHIS' interaction with EPA. APHIS does not consider the approach listed above necessarily to be exhaustive. Rather, APHIS puts it forward to indicate that the Agency is aware of the implications of the Preferred Alternative with regard to small-scale testing of PIPs and to request specific public comment regarding the best manner to address this issue.

Herbicide Resistant GE Plants and Herbicides - Synchronous Decisions with the EPA

The EPA registers and has oversight of the herbicides used on herbicide resistant crop plants, but does not regulate herbicide resistant (HR) plants themselves. Rather, GE HR plants are regulated by APHIS under 7 CFR part 340 To date, the GE HR plants have been regulated by APHIS because they were developed using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. However, as discussed previously in this section, under the Preferred Alternative, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Under the Preferred Alternative, APHIS expects that many of the GE HR plant-trait combinations it evaluates will not be found to present plant pest or noxious weed risks. Due to the more efficient regulatory review process for GE organisms that APHIS is proposing to implement, it is important that regulatory status determinations made by APHIS are in synchrony with the EPA's herbicide registration and review procedures – that the timing of APHIS and EPA regulatory of decisions are effectively coordinated.

Commenters to the proposed update to the Coordinated Framework on the Regulation of Biotechnology published on September 22, 2016 (81 FR 65414-65415), expressed the need for coordination between USDA and EPA regarding the timing of deregulation/determination of non-regulated status of GE HR crops and the registration of herbicides used on these crops. APHIS recognizes that the asynchronous timing of the deregulation of GE HR plants and the associated EPA herbicide registration has led to situations where a developer could

sell the herbicide resistant plant/seed without waiting for the associated herbicide registration. In such a situation, farmers may be tempted to use an herbicide that is not registered for use on the GE HR crop, which would comprise an illegal use of an herbicide.

In light of the challenges associated with the asynchronous regulatory actions on the part of APHIS and EPA, APHIS will work with EPA to explore possible solutions to better coordinate the commercial availability of seed for herbicide resistant crops concomitant with the registration of herbicides intended to be used on those crops. Furthermore, APHIS intends to limit the scope of its decisions to be on an individual/specific herbicide resistant crop basis (e.g., glyphosate resistant cotton) so that the EPA and APHIS are making decisions on the same specific herbicide resistant crop/herbicide combinations.

This coordination presents challenges because once APHIS determines a GE organism does not represent a risk as a plant pest or noxious weed, APHIS cannot continue to regulate the GE organism or delay announcing the regulatory status determination. When APHIS receives a request for regulatory status determination of an herbicide resistant crop, it is likely to be three or more years before a developer is ready to undergo registration review at EPA. If APHIS determines that the herbicide resistant plant is not a risk as a plant pest or noxious weed, APHIS does not have the authority in the PPA to require permits with regulatory controls for the movement and outdoor planting of that herbicide resistant plant during those subsequent years. Nor is it within APHIS authority for APHIS to withhold making a regulatory status evaluation decision for several years and requiring permits for field testing during that time. The issue has not been the illegal use of pesticide during the field testing of herbicide resistant crops by developers but instead is the illegal use of pesticide by farmers on seed that has been deregulated by APHIS and is commercially available before the commercial availability of the herbicide designed for those crops.

One option to address this coordination would be to enact a new statute or amend an existing statute to make it illegal to sell seeds for herbicide resistant crops before the registrations were completed for use on those crops. Another option might involve a voluntary agreement by seed developers to withhold selling seed of herbicide resistant crops until EPA registrations are completed for the herbicide products designed for those crops. In cases where APHIS makes a decision deregulating an herbicide-resistant crop or determines under § 340.4 that an herbicide-resistant crop is unlikely to pose a risk as a plant pest and/or noxious weed and will no longer be a regulated organism and no herbicide product has been registered by EPA for use on that herbicide resistant crop, APHIS would indicate on the APHIS Regulatory Status List website and websites associated with deregulation decisions that no herbicide product is registered by EPA for use on this herbicide resistant crop and it is illegal to use any herbicide product on these crops unless registered by EPA for such use. Additionally, APHIS would include language in deregulation decision letters sent to the developer and Federal Register notices associated with § 340.4 final determinations indicating it is illegal to use herbicides on these crops until the herbicide product is registered by EPA for use on the herbicide resistant crop. This decision letter and all other information regarding APHIS's decisions would also be made available to the public on the APHIS website.

APHIS does not consider the approaches listed above necessarily to be exhaustive and recognizes that one of the options listed would require legislation to be enacted, which is not within the purview of the Executive Branch of the Federal government. However, APHIS puts them forward to indicate that the Agency is aware that asynchronous timing of the deregulation of GE HR plants and the associated herbicide registrations can lead to significant problems, and to request specific public comment regarding the best manner to address this issue.

4.8.2 Interactions with Federally-Recognized Tribes

APHIS consultations with federally-recognized tribal entities[198] are based on their special status as independent governments. APHIS contacted representatives of federally-recognized tribes to facilitate discussions of potential impacts of the proposed revisions to 7 CFR part 340 on tribal resources. APHIS sent a letter to tribal leaders in February, 2016 notifying them of APHIS' intent to prepare this dPEIS. APHIS-BRS held two tribal nations conference calls on February 26 and March 22, 2016 to provide information and answer questions regarding the development of the proposed rules and this dPEIS. It is APHIS' intention to communicate publication of the proposed rule and dPEIS to tribes during the rulemaking process. Individually and collectively, tribal comments and input shapes APHIS decision making for permitting.

Under the current regulations, APHIS identifies where proposed field releases will occur and determines if there are tribal reservation lands located in or near those areas. For example, since 2006 APHIS identified 78 tribes with reservation land that is located in the same county as an approved field release, and APHIS has consulted with appropriate tribal entities prior to issuing permits. Under all of the Alternatives, the opportunity for APHIS consultation with tribe representatives would continue. APHIS would continue to share notifications (for the No Action Alternative) and applications for permits (for all Alternatives) with tribal representatives when there are regulated GE organisms proposed for release on in or in proximity to tribal lands. As described in the proposed rule (Preferred Alternative), and applicable to Alternative 3, APHIS will submit for notice and review a copy of the permit application and any permit conditions to the appropriate Tribal regulatory official. Comments received from the Tribal regulatory official may be considered by APHIS prior to permit issuance.

4.8.3 Interactions with States

The PPA, which 7 CFR part 340 implements, contains a preemption clause (7 U.S.C. § 7756) that prohibits state regulation of any, "plant, biological control organism, plant pest, noxious weed, or plant product" to protect against plant pests or noxious weeds if the Secretary (APHIS) has issued regulations to prevent the dissemination of biological control organisms, plant pests, or noxious weeds within the United States. This creates an opportunity for APHIS to interact with state regulators because states may impose prohibitions or restrictions that are consistent with and do not exceed APHIS regulations. The PPA preemption clause

[198] In May 2016 the Department of the Interior issued a notice in the Federal Register of a list 567 tribal entities recognized and eligible for funding and services from the Bureau of Indian Affairs (BIA) by virtue of their status as Indian Tribes: DOI - Indian Entities Recognized and Eligible To Receive Services From the United States Bureau of Indian Affairs - 81 Federal Register, No. 86, Wednesday, May 4, 2016, p. 26896.

also allows states to impose additional prohibitions or restrictions based on special needs supported by sound scientific data or a thorough risk assessment. Consequently, while the PPA limits states' issuance of laws and regulations governing GE organisms and bars conflicting state regulation, it does allow state oversight when there is a special need for additional prohibitions or restrictions. States commonly institute departments of agriculture, environment and/or natural resources, and health to administer state laws and agency rules in these areas.

Successful implementation of APHIS biotechnology regulations involves collaboration between APHIS and appropriate state agencies and state representatives. Currently, APHIS shares applications for permits and notifications with state regulators identified by the applicant and State Plant Regulatory Officials (SPROs) in the states to which regulated articles will be moved, or in which a field release is planned. APHIS removes confidential business information from these materials. APHIS works with state representatives and departments of agriculture to ensure states are aware of proposed environmental releases in their jurisdictions, share information on how releases will be performed and confined, and allow states to request any additional conditions to mitigate plant pest risk. Before APHIS authorizes field testing, APHIS officials provide detailed information about the proposed field test to state regulatory officials for review and concurrence. If a particular state has concerns about the confinement measures to be implemented as part of the field test, APHIS works with that state to address concerns, and require further measure the state deems necessary to ensure that the field test can be conducted safely. This process notifies states of the requested action; enables state representatives an opportunity to review and comment on the proposed importations, movement, or field release; and creates an opportunity to discuss state concerns. Individual states vary in their responses: some states may agree to the proposed introduction under the conditions imposed by APHIS, other states may request additional permit conditions, and other states choose not to respond.

APHIS verifies compliance with permit and notification requirements by inspecting field sites, records, and associated facilities. The APHIS-BRS Regulatory Operations Programs includes five branches; the Compliance Assistance Branch, the Eastern Region Compliance Assurance Branch, the Western Region Compliance Assurance Branch, the Compliance Evaluation and Enforcement Branch, and the Permits and Program Services Branch. Collectively, these branches manage the administrative aspects of notification acknowledgement and permit issuance for introductions of GE organisms; regulatory compliance inspections; responses to noncompliance incidents; and maintenance of records, which can include field reports and compliance inspections. The APHIS-BRS Regulatory Operations Programs branches initiate and manage compliance inspections. Trained officers within APHIS' Plant Protection and Quarantine (PPQ) program or with a participating state inspection program, conduct inspections on behalf of APHIS-BRS. Verification methods used during inspections include: records review, interview, observation, measuring, and mapping.

APHIS partners with state representatives during inspections, compliance incidents, and while conducting investigations and determining violations. APHIS invites SPROs to participate in inspections of field release sites within the destination states. APHIS also relies on state departments of agriculture to notify APHIS-BRS when an incident occurs, and to

help implement remedial measures. The BRS compliance assurance branches initiate and manage inspections, and trained officers within APHIS' Plant Protection and Quarantine (PPQ) program, or with a participating state inspection program, conduct inspections on behalf of APHIS-BRS.

4.8.4 Status of State Biotechnology Regulation

Nationwide, biotechnology is widely regarded in the agricultural community as a tool to improve on-farm efficiencies in the management of pests and diseases; a way to sustain global competitiveness in provision of food, fiber, and biofuels; and a source of new value-added crop products (Taylor and Tick 2003, Taylor, Tick and Sherman 2004). Consequently, farmer access to products of agricultural biotechnology is of strong economic interest for many states (Taylor, Tick et al. 2004). In some states, agricultural biotechnology is regarded not only as an important tool in support of state farmers, but the agricultural biotechnology industry itself as an engine for broader economic development (Taylor, Tick et al. 2004). For this reason, Puerto Rico (5 L.P.R.A. § 4702 (2013)) and various states create and maintain biotechnology business incentives [such as Arkansas (AR Code § 19-12-115 (2015)), Illinois (20 ILCS §§ 230/1 to 230/10 (2015)), and Iowa (Iowa Code §15E.203 and 15E.209 (2015))], tax credit or deferrals [such as Wash. Admin. Code § 458-20-24003 (2015)], and educational incentive programs [such as West Virginia (W.V.C. §18B-18A-1(2015)].

Permitting

States use a variety of requirements to regulate the movement or release of GE organisms within their jurisdiction. For example, South Dakota simply authorizes holders of a federal permit issued under 7 CFR part 340 to use it within the state (SD Stat § 38-12A-31 (2015)). In contrast, Florida issues a "special permit," charges a fee, and requires a bond to protect public health and safety (FL Stat § 581.083 (2015)). Oklahoma issues permits to maintain as well as release GE organisms (OK Stat § 2-11-40 (2015)). Minnesota issues state permits for release of genetically engineered agriculturally related organisms only after federal applications or permits are on file (MN Stat § 18F.07 (2015)). Idaho uses cooperative agreements with APHIS to provide oversight and regulation of GE organisms that may be plant pests, in addition to reviewing notifications and permits, and inspecting facilities and field release sites (ID Code § 22-2016 (2015)). Washington makes rules concerning the movement of GE organisms within the state, and can create in-state quarantines to protect state interests (Wash. Rev. Code §§ 17.24.011 and 17.24.041). Both Illinois and Wisconsin may base permit-reviewing comments to APHIS on technical reviews, public comments, and informational meetings (430 ILCS 95/5 (2015); WI Stat § 146.60 (2015)). Nebraska may rely on APHIS or other experts before they issue their permit (NE Code § 2-10,113 (2015)). Hawaii's Advisory committee on plants and animals (HI Rev Stat § 150A-10 (2015)) assists the Hawaii Department of Agriculture on issues related to the release of plants, animals, and microorganisms based their expertise in island biogeography. These illustrative examples show the range of state approaches to regulating the movement and release of GE organisms within state boundaries.

Seed Certification

States set seed certification requirements, and generally, either the state department of agriculture, the states' Cooperative Extension Service, or grower-controlled crop

improvement associations control their administration. The process for certifying seed varieties is beyond the scope of this discussion, except to note that the primary criteria for states to certify seed are genetic purity and identity, and they often certify seed quality standards (such as percent germination). At the state level, seed certification usually includes requirements for the labeling, packaging, sale, storage, transportation, and distribution of seed regardless of whether development of the variety was through conventional breeding or GE techniques. States may expressly prohibit county or local regulation of seed, for example Georgia (Ga. Code § 2-11-35 (2015)) and Pennsylvania (3 Pa.C.S.A. § 7120 (2015)).

State seed certification programs frequently use distance requirements to create isolation zones that are free of contaminating pollen. For example, in the certification of forest reproductive material, Texas requires 400 feet surrounding an orchard to be free of all trees producing contaminating pollen (4 Texas Admin. Rule § 10.29), and Washington creates districts for seed and planting stock certification programs (Wash. Admin. Code 16-325-005 potato seed; 16-319-030 forest tree seed). A transgenic-specific example of an isolation zone occurs by providing a physical separation sufficient to prevent cross-pollination between conventionally-bred and GE varieties of bentgrass in Jefferson County, Oregon (Or. Admin. Rule 603-052-1240). Other examples include isolation in field crops grown for seed when transgenic crops are also grown in the area (N.D. Admin. Code 74-03-01-08 (2015)), and oversight of sampling procedures for verification of transgenic seed use (S.D. Admin. R. 12:36:07 (2015)).

Organic Production

The National Organic Program (NOP) (authorized by the Organic Foods Production Act of 1990 codified at 7 U.S.C. §§ 6501-6523 Organic Certification; regulations at 7 CFR part 205) created standards for organically-produced agricultural products. Agricultural products represented as organic must be produced and handled according to program requirements (§ 205.201). Excluded methods include, "…cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology)" (§ 205.2).

States with an organic program generally adopt 7 CFR part 205 by reference and may codify provisions. For example, Iowa (Iowa Code 190C.1-190C.26), Puerto Rico (5 L.P.R.A. §§ 131 to 141 (2013)), Oklahoma (Okla. Admin. Code §§ 35:37-15-1 to 35:37-15-11), Texas (Texas Agric. Code Ann. § 18 (2015)), and Utah (Utah Admin. Code r. R68-20 (2016)). When a state adopts the NOP prohibitions on excluded methods, then organic producers cannot not use GE seed unless an exception in 7 CFR § 205.204 applies.

4.8.5 Other Aspects of State Biotechnology Regulation

States also issue legislation on a variety of biotechnology related topics outside the purview of 7 CFR part 340. This section considers state legislation unrelated to 7 CFR part 340, but related to agricultural biotechnology in general.

Many states have statutes that provide protections for research and commercial crops and use various means to do so. Examples of states with laws that protect research crops grown in

association with governmental entities include Arizona (AZ Rev Stat § 3-114 (2015)); California (CA Food & Agri Code § 52100 through 2015 Leg Sess. providing double damages); Florida (FL Stat § 604.60 (2015) civil action providing treble damages); Oregon (Oregon Rev. Stat. § 164.889); Pennsylvania (42 Pa. Consolidated Stat. Ann. § 8313 (2015) providing up to treble damages), South Carolina (S.C. Code Ann. § 46-1-75) and South Dakota (S.D. Codified Laws Ann. § 21-60-1 to 21-60-3 (2015) providing for double damages but not if destruction was by emergency vehicles). Examples of states that protect personal or commercial crops include North Dakota (N.D. Cent. Code § 32-03-53 (2015) providing double damages) and Oregon (Or. Rev. Stat. § 164.887 (2015) misdemeanor), but it is a felony to steal crops from the field in South Carolina (S.C. Code Ann. § 46-1-20 (2015)). None of these examples differentiates or excludes GE crops; consequently, it is reasonable to assume continued applicability of these provisions to GR crops under all of the Alternatives.

The labeling of foods and food products that are derived in whole or in part from GE plants lead to the proposal and discussion of many bills in various state legislatures. With the passage of Public Law 114-216 during July 2016, food for humans in interstate commerce will need to meet a federal disclosure standard with respect to its status as genetically engineered. States are preempted from creating different standards. Congress determined that the USDA will develop regulations in this area.

4.8.6 State Regulations and Analysis of the Alternatives

The revision of 7 CFR part 340 would not affect APHIS partnerships with states in the oversight of GE organisms, specifically in regulation of interstate movement and environmental releases. Under all the Alternatives considered, APHIS would continue working with states to ensure states are aware of authorized movements and environmental releases taking place within their jurisdiction, how the releases are performed and confined, and provide states the opportunity to request additional restrictions be placed on the release to mitigate plant pest and noxious weed risks.

Under the Preferred Alternative APHIS would likely be issuing fewer permits for the environmental release, importation, and interstate movement of GE organisms. In response to the expected reduction in the number of permits issued by APHIS, some states may decide to enact legislation to impose state level regulation on GE organisms. For states that currently have statutory requirements these state requirements would continue to apply, although they may need slight modification to ensure consistency with any revisions to 7 CFR part 340.

Alternative 3 would result in APHIS serving as a wide-scale permitting authority, overseeing certain aspects of agricultural production in almost all states. Under Alternative 3, APHIS would increase its oversight over GE organisms. Consequently, in response to this Alternative, states would not be expected to enact legislation to impose state level regulation on GE organisms, as APHIS would permit the field testing and cultivation of most commercial GE crops in all states. State level participation in inspections might increase as federal oversight over GE organisms increases under this Alternative

For the most part, the range of state legislation addressing agricultural biotechnology, namely in the way of permitting, crop protection, seed regulation, and economic development, is unlikely to change as a result of the adoption of any of the Alternatives considered. APHIS

expects that states would be required to adjust to minor programmatic and procedural changes under the Preferred Alternative and Alternatives 3. For all of the Alternatives considered, states would be required to ensure current and future statutes are consistent with federal requirements under the PPA and 7 CFR part 340

4.9 Additional Required Analyses

NEPA implementing regulations at 40 CFR part 1502.16 - Environmental Consequences, require agencies to specifically address adverse environmental effects which cannot be avoided; the relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and any irreversible or irretrievable commitments of resources which would be involved in the proposed action and alternatives. These topics are discussed throughout Chapter 4, and this section reiterates key issues to ensure these requirement are clearly addressed.

4.9.1 Potential Unavoidable Adverse Environmental Impacts

Potential unavoidable direct impacts related to APHIS regulatory actions under the Alternatives considered would be those associated with APHIS authorized interstate movement, importation, field testing, and compliance inspection activities. APHIS cannot avoid issuing a determination of non-regulated status for GE organisms that are not subject to regulation. In this sense, those potential environmental impacts associated deregulated GE organisms could be considered indirect unavoidable impacts. Unavoidable impacts related to the Alternatives considered would include the following:

- Air quality impacts due to emissions from agency activities, authorized field testing, and commercial crop production
- Gene flow among GE and non-GE crops, and socioeconomic impacts
- Development of PIP resistance in target plant pests and pathogens
- Development of herbicide resistant weed populations
- A potential increase in use of pesticide and fertilizers commensurate with population increase and demand human food, animal food, and fiber

Air Quality

The Clean Air Act requires the EPA to establish National Ambient Air Quality Standards (NAAQS) for six pollutants considered harmful to public health and the environment: carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, and sulfur dioxide. APHIS authorizations for importation, movement, and environmental release would result in the unavoidable emission of NAAQS pollutants from vehicles and machinery involved in these activities. Crop production practices can generate NAAQS pollutants and contribute to challenging regional NAAQS. Agricultural emission sources include: smoke from agricultural burning, fossil fuel combustion associated with equipment used in tillage and harvest (CO_2, NOx, SOx), soil particulates from tillage, and soil nitrous oxide (N_2O) emissions from the use of fertilizers. Field testing of GE organisms would utilize pesticides and may result in aerosolization of pesticides in minor quantities. Compliance and inspection activities would also result in unavoidable NAAQS pollutant emissions.

Gene Flow

While managed to preclude or limit, gene flow among commercial GE and non-GE cropping systems will occur to some degree. Where there is the unintended presence of GE plant material in a conventional or organic crop or crop product, this will likely have adverse economic effects on the producer of the non-GE crop, and perhaps consumers if market impacts are incurred. International trade could also be disrupted if the low level presence of GE plant material is detected in a U.S. export commodity derived from conventional or organic cropping systems.

PIP Resistance

Wide-scale commercial cultivation of insect and disease resistant GE crop plants will, over time, result in development of populations of target insect pests and plant pathogens resistant to the PIPs. This is a natural and expected process that will occur wherever an insecticide, fungicide, or any other selection agent is used. For example, resistance to Bt based insecticides will occur in both conventional and organic cropping systems where Bt based insecticides are used. For a crop plant comprised of PIPs, resistance development would be localized to the areas where these crops are grown. This would not necessarily constitute an adverse environmental impact; however, there would likely be economic impacts as a result of loss of PIP efficacy, and relative increase in the cost of plant pest and disease management where PIP efficacy was lost. For example, where the efficacy of a PIP is lost, growers would be required to return chemical and cultural means to control plant pests and diseases, which may increase the cost of production, to some degree. This cost would be equivalent to the cost of non-GE crop production, and hence increase in cost relative to any cost savings that were derived from the GE PIP based crop. Where there is a risk for resistance development, most cropping systems implement insect resistant management (IRM) programs to mitigate development of resistance. This is not only an EPA requirement for some GE crops, but in the farmer's best interest. Hence, it is expected most cropping systems will practice IRM where there is the risk for development of resistance.

Herbicide Weed Resistance

As with PIP resistance, development of herbicide resistant weed populations is a natural and expected process that will occur anywhere herbicides are used. This will occur regardless of whether APHIS determines a particular GE crop plant is subject to regulation, or not. Where APHIS does make a determination of non-regulated status, herbicides will be used on that crop plant if it is approved by the EPA and produced commercially. As such, the potential for development of weed populations resistant to herbicides exists. As with managing PIP resistance, most cropping systems implement IWM programs to mitigate development of weed resistance.

Pesticide and Fertilizer Use

Subject to EPA and state requirements, a potential increase in use of pesticides and fertilizers may occur commensurate with increases in domestic and global populations and the demand human and animal food, and fiber. This would occur regardless of whether APHIS determines a particular GE crop plant is subject to regulation, or not. Where APHIS does make a determination of non-regulated status, pesticides used on that crop would be subject

to EPA registration and use requirements. Some GE crop plants may require less insecticide, fungicide, and fertilizer use, and hence, could offset some of the expected increases.

4.9.2 Potential Irreversible and Irretrievable Commitment of Resources

An irreversible and irretrievable commitment of resources is related to the use of non-renewable resources and the effect that the use of these resources would have on future generations. Irreversible and irretrievable use of resources applies to APHIS' use of nonrenewable fossil fuels, and electricity derived from fossil fuels. Under all the Alternatives AHIS activities would involve the use of fossil fuels as part of normal business operations, as typical of many federal regulatory activities.

4.9.3 Relationship between Short-term uses of the Environment and the Maintenance and Enhancement of Long-term Productivity

APHIS authorizes environmental releases for field testing of GE organisms. These trials are on average round 20-30 acres, and span from around 1 to 3 years. As described in Chapters 3 and 4, there are no known, nor expected, adverse effects on the long-term use of the environment in these areas that would derive from APHIS authorized field trials.

5 Cumulative Impacts

A cumulative impact is defined in the National Environmental Policy Act (NEPA; 40 CFR § 1508.7) as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such actions. Cumulative impacts can result from individually minor, but collectively significant actions taking place over a period of time."

5.1 Introduction

Selecting one of the Alternatives described in this dPEIS will comprise a rulemaking decision to revise the regulatory framework under 7 CFR part 340. Hence, it regards the adoption of regulations that will guide future Agency programs, decisions, and actions, such as those governing the future permitting of the interstate movement, importation, and environmental release of regulated GE organisms. Future Agency decisions and actions will be those related to compliance with and enforcement of 7 CFR part 340, and determinations of which GE organisms are subject to 7 CFR part 340 regulation. The current environment that may be affected by the Alternatives being considered was reviewed in Chapter 3. The possible environmental consequences of the Alternative were reviewed in Chapter 4. Possible cumulative impacts are reviewed and analyzed in this chapter.

Interstate Movement and Importation

None of the effects related to the importation or interstate movement of GE organisms that were analyzed in Chapter 4 for of each of the three Alternatives were considered to have significant impacts. The types of actions involve standard shipping practices used to move GE organisms (e.g., seeds, microorganisms) from one location to another. Regulated organisms must also be shipped in accordance with the regulations in 49 CFR part 178. There are no reasonably foreseeable cumulative impacts that could derive from the repeated conduct of these activities.

Environmental Release

Field testing of certain GE-trait combinations may present risks to the human environment. These risks are evaluated by APHIS on an individual basis when authorization for an environmental release is requested. The parameters evaluated and criteria for environmental releases are described in 7 CFR part 340, and revisions to the requirements and criteria for future releases under regulations are described in Chapter 2. For future APHIS actions conducted under any of the Alternatives considered, NEPA analyses will continue to be conducted on a case-by-case basis, as applicable, to examine the potential environmental impacts of APHIS decisions and actions in the regulation of GE organisms. As part such NEPA analyses, APHIS would evaluate potential cumulative impacts.

APHIS will consider the collective authorization of field trials over space and time. For example, APHIS authorizes multiple field trials across all U.S. states and territories, which collectively comprise on an annual basis around 400,000 acres. The potential for cumulative impacts from field trials are those to physical and biological resources, human and animal health, and also require consideration of the socioeconomic aspects of crop production. The

measures imposed on field trials are designed to confine the GE organism to a particular area and thereby reduce risk by limiting exposure of the GE organism to the environment.

The potential for adverse cumulative impacts from field trials is from multiple unintended or unauthorized releases of GE organisms. In some cases, unauthorized releases of GE plants could persist in the wild as weeds. Unauthorized releases in the future are possible and are reviewed in this chapter (examples are discussed in the sections on socioeconomics). Industry has monitoring measures to detect seed resources for unintended GE traits to better track and trace GE materials, and to implement quality management systems for handling GE materials. In certain situations, such as field testing of perennial plants that may persist in the environment, APHIS has determined that prescriptive permit conditions are more appropriate than the performance standards for confinement currently imposed under the notification procedure (7 CFR part 340.4). Consequently, for the Preferred Alternative and Alternative 3, APHIS has proposed to eliminate the use of the notification procedures for field testing, authorizing environmental releases only under permitting procedures.

Determinations of Regulatory Status

APHIS considers cumulative impacts in NEPA analyses for Agency determinations of non-regulated status. Potential cumulative impacts could derive form the combined effects of repeated determinations of non-regulated status for GE organisms that may be used for commercial purposes (wide-scale plantings). As described for environmental releases, for future APHIS actions conducted under any of the Alternatives considered, NEPA analyses will continue to be conducted on a case-by-case basis, as applicable, inclusive of the potential cumulative impacts of APHIS determinations of regulatory status.

5.2 Cumulative Impacts: Acreage and Area of Lands Used for Agriculture and Forestry

5.2.1 Environmental Release

The potential for APHIS authorized environmental releases to contribute to cumulative impacts on land uses for agricultural production is negligible because acreage for these uses is not expected to change in the foreseeable future.

5.2.2 Determinations of Regulatory Status

While the planting of GE crops increased by 68 percent between 2000 and 2005, and by another 45 percent between 2005 and 2013, the total acreage and areas used for production of major U.S. crops did not change significantly. The current acreage for these uses is expected to remain constant for the next 10 years (Westcott and Hansen 2015).

None of the Alternatives considered are expected to cause any significant changes in the total acreage or areas of U.S. crop production, or commercial forestry lands. Under the No Action and Preferred Alternative, additional GE crops are expected to be developed and adopted and the percentage of acreage devoted to GE crops is expected to increase. This trend may cause socioeconomic impacts (discussed further in the socioeconomic impacts section), but is not expected to result in any cumulative impacts with regard to land use. Under Alternative 3, there could be a decline in some GE crops, or certain GE crops would supplant traditionally

bred crops under conventional or organic cropping systems. There could also be a decline in crop acreage where required buffer areas/separation distances were required. In this instance, there could be some cumulative impacts on land use from the required buffer zones between GE and non-GE crops. The land use change is difficult to predict because as the number of farms adopting GE crops decreases, the pressure to alter land use for buffer zones also diminishes. Furthermore, it is not possible to estimate the extent that these buffer regions will be planted with non-GE crops. None of these changes in choice of cropping system are expected to contribute to any significant cumulative impacts on the total acreage and area used for crop production.

5.3 Cumulative Impacts: Physical Environment

5.3.1 Soil Resources

5.3.1.1 Environmental Release

The potential for APHIS authorized environmental releases to contribute to cumulative impacts on soils is negligible.

5.3.1.2 Determinations of Regulatory Status

Availability of GE crops for commercial use influences how agricultural communities decide to implement certain management practices, such as crop rotations, tillage, and use of cover crops, all of which affect soil erosion and quality.

Most cumulative effects on soils involve tillage, cover crop selection, crop rotation, and irrigation practices used in conjunction with the particular type of crop and cropping system. These contribute to cumulative impacts on water quality, discussed in the following section. These practices can beneficially or adversely affect the quality and erosional tendencies of soils.

Conservation tillage has been widely adopted because of the availability of effective herbicides for weed control. Although conservation tillage was increasing prior to the adoption of GE crops in the mid-1990s, the most commonly used herbicides at the time were ALS (acetolactate synthase) inhibitors, and they rapidly selected for weed resistance. The increasing trend in the adoption of conservation tillage was expanded and maintained when ALS inhibitor herbicides were replaced by glyphosate used on glyphosate resistant (GR) crops. A National Academy of Sciences (NAS) review (NAS 2016b) concluded that: “Both GE crops and the percentage of cropping area farmed with no-till and reduced-till practices have increased over the last two decades. However, cause and effect are difficult to determine.”

A second evaluation by the USDA-Economic Research Service (ERS) (Fernandez-Cornejo, Hallahan et al. 2012) found that “most empirical evidence points to a two-way causal relationship between the adoption of herbicide resistant (HR) crops and conservation tillage. Farmers using conservation tillage practices are more likely to adopt HR crop varieties than those using conventional tillage, and those adopting HR crop varieties are more likely to change to conservation tillage practices than those who use non-HR cultivars.”

Where HR weeds have become a problem (for example in cotton grown in the Southeast), conventional tillage has increased and conservation tillage has diminished. Surveys of regional tillage patterns and expert assessments indicate that problem weeds are at least partially responsible for increases in conventional tillage and declines in conservation tillage. These conclusions were especially applicable in the mid-south states.[199] As discussed above in the section on HR weeds, GE innovation is expected to maintain the effectiveness of herbicide use for weed management, which is expected to maintain the use of conservation tillage. Under the No Action and Preferred Alternative, innovation is expected to continue and the positive cumulative effects from practicing conservation tillage are also expected to continue. Under Alternative 3, innovation in the use of genetic engineering is expected to diminish. Herbicides are expected to become less effective in weed management, as HR weeds become increasingly prevalent. In the absence of effective weed management with herbicides, conservation tillage is expected to decrease as seen in the Southeastern United States, so adverse cumulative impacts from increasing amounts of tillage are expected.

While farmers have shown increasing interest in the use of cover crops as a way to control weeds and promote soil conservation, their use has not become popular in the United States (Wallander 2013). Therefore, it is not reasonably foreseeable that use of cover crops will increase under the No Action Alternative or Preferred Alternative. There may be an increase in the use of cover crops under Alternative 3, where other methods become necessary to compensate for the reduced effectiveness of herbicides.

5.3.2 Water Resources and Quality

5.3.2.1 Environmental Release

APHIS-authorized environmental releases could potentially contribute to cumulative impacts on water quality through agronomic inputs such as pesticides, fertilizers, and tillage. Because field trials are small in size (averaging about 20 acres), and total authorized acreage comprises about 400,000 acres per year, compared to the total amount of U.S. cropland (~340 million acres in 2015), contributions to cumulative impacts under all of the Alternatives on water quality, if any, would be minor. Cumulative impacts on surface water and groundwater supplies would also be minor.

5.3.2.2 Determinations of Regulatory Status

Under current 7 CFR part 340 regulatory practices (No Action Alternative) cumulative impacts on water quality are already occurring. It is well recognized that the cumulative impacts of the many U.S. cropping systems in United States on water quality can be substantive. The EPA National Water Quality Assessment indicates that agricultural nonpoint source (NPS) pollution is the leading source of impacts on surveyed rivers and streams, the third largest source for lakes, the second largest source of impairments to wetlands, and a major contributor to contamination of surveyed estuaries and groundwater. Sediment and nutrients are the second and third leading sources of impairment to water

[199] See Monsanto FEIS for petitions 10-188-01p and 12-185-01p (determinations of non-regulated status for dicamba resistant soybean and cotton varieties), Appendix 9 - Monsanto tillage Report; https://www.aphis.usda.gov/brs/aphisdocs/dicamba_feis_appendices.pdf

quality nationwide, pesticides the sixteenth. These are mostly attributable to crop production. The cropping systems in the central United States have significant cumulative impacts on Gulf of Mexico water quality and fisheries. The Gulf of Mexico dead zone, which occurs on an annual basis after spring planting, is the second largest in the world, averaging about 6,000 mi^2.

After 20 years of production, there is no evidence GE crop plants require or result in increased pesticide or fertilizer use. Insect and disease resistant GE crop plants, where adopted, would likely require less pesticide use across all acres where these crops are grown, reducing runoff of synthetic chemicals. Based on data compiled from 1996 through March 2014, global cultivation of GE HR and IR crop plants has reduced chemical pesticide use by 37% (Klümper and Qaim 2014). Similar reductions have been reported by Brooks and Barfoot (2014) for 1996-2012. During this period, they estimated that GE crops reduced global pesticide use by 503 million kg (an 8.8% decline), decreasing the potential environmental impacts associated with herbicide and insecticide use on commercial crops (Barfoot and Brookes 2014). Pesticide reductions are larger for IR crops than for HR crops, and likewise vary among HR crops of corn, soybean, cotton, canola, and sugar beets. After 20 years of production, there is no evidence GE crop plants require or result in increased pesticide or fertilizer use. GE IR and disease resistant crops, where adopted, would likely require less pesticide use across all acres where these crops are grown, reducing potential runoff.

Another interpretation is that the development of weed resistance to herbicides may necessitate an increase in herbicide use or more aggressive tillage practices, which could have potential adverse effects on aquatic ecosystems. Management practices in GE glyphosate resistant cropping systems contributed to an increase in HR weeds, which have resulted in the use of a greater variety of herbicides, some of which are more toxic than glyphosate.

GE HR crops influence the types of herbicides growers choose. If certain GE HR crops allow growers to use herbicides that have the lowest environmental impacts, this would be beneficial to water quality relative to current conditions. The degree of water quality impacts are not necessarily a function of the amounts of herbicide applied; the toxicity of the active ingredient is equally or more important. The greater the toxicity of the herbicides used in crop production, the greater the likelihood of adverse cumulative effects on water quality.

Among the GE traits that have been field tested in recent years are those that increase the efficiency of nitrogen and/or phosphorus use by crops. It is expected that crops possessing these or similar traits will require fewer fertilizer inputs, which will reduce impacts from runoff. In both instances, the cumulative effects on water quality as a result of use of such crop varieties across U.S. croplands could be substantial.

APHIS anticipates that more GE crop plants will be developed that use water more efficiently. These crops could have positive cumulative effects on water abundance, but could also acquire water so efficiently that the crop has adverse impacts on water flow and abundance. Surface water quality could be positively affected by reduced runoff corresponding to reduced irrigation requirements for such crops.

Under all the Alternatives, innovation in crop development using genetic engineering is expected to continue. As such, it is expected that crops with traits that use nitrogen, phosphorous, and water more efficiently will be developed and adopted. As described in the section on pests and disease, crops with traits for improved disease resistance and IR are also expected to be developed under these Alternatives. GE crop plants engineered with such traits are expected to have positive cumulative effects on water quality by reducing pesticide and fertilizer inputs. GE HR crops would provide similar benefits to water quality through reduced tillage and soil sediment loading in waterways. While innovation in GE crop plant development is expected to continue under all Alternatives, under Alternative 3, innovation, development, and GE crop cultivation may not be as robust as that under the No Action Alternative or Preferred Alternative.

5.3.3 Air Quality

5.3.3.1 Environmental Release

Under each of the Alternatives, environmental releases resulting from APHIS-authorized actions related to GE organisms would have minor effects on cumulative air emissions because they are derived from tillage and fossil fuel combustion from mechanized agriculture equipment. As explained in the sections that follow, there would be little difference in the magnitude of the cumulative impacts associated with each of the Alternatives.

5.3.3.2 Determinations of Regulatory Status

Under each of the Alternatives considered, all of these factors discussed below would have cumulative impacts on emissions of National Ambient Air Quality Standards (NAAQS) pollutants. Where APHIS determinations of regulated status result in subsequent non-federal actions that will directly result in emissions, APHIS' determinations do affect decisions by agricultural communities to produce (or not produce) crops that may become the source of impacts. The collective actions of all growers related to crop and production practices selected (such as rotation crops, tillage choices, fertilizer use, pesticide use, and the timing associated with these practices) affects air emissions.

At the local level, certain GE crops have the potential to reduce air emissions depending upon the variety of GE crop produced. Conservation tillage practices associated with GE HR crops, and reductions in insecticide use with GE IR crop varieties, reduce air emissions by reducing the use of internal combustion engines used in tillage and insecticide application. Conservation tillage and no-till practices also reduce particulate matter (PM) emissions.

In contrast, croplands with HR weeds can increase the use of herbicides and conventional tillage, which increases drift of herbicides, soil borne PM, and vehicular NAAQS emissions.

The Preferred Alternative would likely facilitate the development and use of GE crop plants, relative to the No Action Alternative. For Alternative 3, there may be a reduction in GE crop plant use. Increased oversight under Alternative 3 would increase the need for compliance inspections and enforcement activities, which would increase NAAQS pollutant emissions from transport of inspectors to and from the sites of inspection. However, the extent to which farmers would adopt GE crops instead of conventional or organic crops, and the additional impacts this would have on air quality, is undetermined. Fewer inspections would

likely be required under the Preferred Alternative. The contribution of compliance actions to emissions would be minor.

5.4 Cumulative Impacts: Biological Environment

5.4.1 Soil Biota

5.4.1.1 Environmental Release

Agronomic practices commonly used for cultivation of GE crops are the same as those used for non-GE cropping systems (e.g., tillage, herbicide, insecticide and fertilizer applications, and irrigation). These practices can potentially affect soil biota in both beneficial and detrimental ways. Although the types of methods used are the same, the intensity of these agronomic inputs are likely to differ depending on the type of cropping system used (i.e., GE-, non-GE conventional and organic). Under the No Action Alternative, currently used practices are not likely to change, so cumulative impacts on soil biota are not expected to change. Under the Preferred Alternative, the ratio of plantings of GE to non-GE crops will likely increase. This is likely to result in less reliance on tillage, which would reduce cumulative impacts on soil biota. Adoption of Alternative 3, could result in greater overall reliance on non-GE crops, which could have the opposite effect: increased cumulative impacts compared to the No Action Alternative. These differences are reviewed in more detail in the remainder of the section.

As reviewed in Chapter 4, the primary sources of potential impacts on soil biota that would derive from field testing of GE plants would be from the use of pesticides (Locke and Zablotowicz 2004, Jänsch, Frampton et al. 2006, Gupta, Neate et al. 2007), and tillage (Gupta, Neate et al. 2007, Roger-Estrade, Anger et al. 2010). Soil biota are typically tolerant of pesticides when they are applied at recommended rates, with only minor, transient effects on soil populations (Locke and Zablotowicz 2004).

In addition to pesticide inputs, the potential impact of GE plants on soil microbial communities has also been of interest (e.g., see (Locke and Zablotowicz 2004, Lynch, Benedetti et al. 2004, Naranjo 2009, Turrini, Sbrana et al. 2015)). To date, there is disparity in the scientific literature regarding the potential effects of GE HR crop plants on composition and diversity of soil biota (Duke, Lydon et al. 2012, Hannula, de Boer et al. 2014, Turrini, Sbrana et al. 2015). In light of the inconsistency in some of the findings reported in the scientific literature (Icoz and Stotzky 2008), assessment of the potential impacts of GE plants on soil biota will remain ongoing (Icoz and Stotzky 2008, Turrini, Sbrana et al. 2015). Because the amount of acreage devoted to field testing of GE organisms is negligible compared to overall U.S. acreage of GE crops, testing conducted under any of the Alternatives will not result in any significant cumulative impacts on soil biota.

There has been particular interest among the public and scientific community in regard to the effects of PIPs on soil biota. In the field testing of GE plants comprised of a PIP, the EPA regulates and issues Experimental Use Permits (EUPs) for the field testing of PIPs - the

insect or disease resistant gene and gene product.[200] The regulations at 40 CFR part 172.4 contain the requirements for applications for EUPs. EPA regulations (40 CFR 172.2) provide that any person wishing to accumulate information necessary to register a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) may apply for an EUP. The EPA requires that a pesticide product, including PIPs and GE microbial pesticides, undergo extensive chemical, toxicological, and field-testing before being registered as a pesticide. Some testing is done under field conditions to fully understand pesticide properties, safety, and efficacy. Because testing undertaken as part of the registration process necessarily involves an unregistered product or is for a use not previously approved in the registration of the pesticide, the EPA sometimes must first authorize the distribution and sale for testing purposes by means of an EUP under FIFRA. For future field trials, the potential impacts of a particular type of PIP or other introduced trait on soil biota would be evaluated on a case-by-case basis as GE organisms were presented to EPA for permitting of field trials. Cumulative impacts as a result of field testing of PIPs are considered unlikely under any of the Alternatives.

5.4.1.2 Determinations of Regulatory Status

The potential for cumulative impacts on soil biota would comprise the same considerations described above under environmental releases. Use of pesticides, including GE PIPs and GE microbial pesticides, are regulated by the EPA as discussed above. APHIS generally evaluates potential cumulative impacts to soil biota in its NEPA analyses, as required, when evaluating petitions for determination of regulatory status. Hence, such impacts are evaluated on a case-by-case basis.

5.4.2 Invertebrates

5.4.2.1 Environmental Release

For invertebrate populations, the potential for adverse impacts is largely limited to GE plants that express PIPs, GE microbial pesticides, and chemical pesticides commonly used to control agricultural and forestry pests and disease. Invertebrate populations will always be affected by commercial scale agricultural production systems both GE and non-GE. To date, significant adverse effects on non-target invertebrate communities that are singularly attributed to the commercial use of GE IR and HR crop plants have not been identified (Naranjo 2009, Carpenter 2011, NAS 2016b). As described above, use of PIPs, GE microbial pesticides, and chemical pesticides is regulated by the EPA. Under the No Action Alternative, currently used agronomic practices are not likely to change, so cumulative impacts on invertebrates are not expected to change. Under the Preferred Alternative, the ratio of plantings of GE to non-GE crops may increase. This is likely to result in less reliance on tillage, insecticides and herbicides, which would reduce cumulative impacts on invertebrates. Adoption of Alternative 3, could result in greater overall reliance on non-GE crops, which could have the opposite effect: increased cumulative impacts on invertebrates compared to the No Action Alternative.

[200] Current and previously registered plant-incorporated protectant registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

5.4.2.2 Determinations of Regulatory Status

Wide-scale adoption of GE crops by growers has occurred during the past 20 years. By 2015, GE crops accounted for more than 400 million acres worldwide. To date, no ecological effects, such as disruption of animal populations and plant communities, have been reported in the literature (Icoz and Stotzky 2008, Wolfenbarger, Naranjo et al. 2008, Naranjo 2009, NAS 2016b). A recent report by the National Academy of Sciences for a review of data collected during the past 20 years for different types of GE crops concluded that there is no evidence of a cause-and-effect relationship between GE crops and environmental problems (NAS 2016b). The development of insect pest populations resistant to PIPs represent a cumulative impact likely to occur under each of the Alternatives. The intensity and significance of the impact is not likely to differ under each Alternative because EPA-required resistance-management practices will remain in place regardless of which Alternative is selected.

5.4.3 Wildlife

5.4.3.1 Environmental Release

As with invertebrate populations, most of the cumulative impacts on wildlife from GE plants are related to those expressing PIPs and/or resistance to certain herbicides. Under the No Action Alternative, currently used agronomic practices are not likely to change, so cumulative impacts on wildlife are not expected to change. Under the Preferred Alternative, the ratio of plantings of GE to non-GE crops may increase. This is likely to result in less reliance on tillage, insecticides and herbicides, which would reduce cumulative impacts on wildlife. Adoption of Alternative 3, could result in greater overall reliance on non-GE crops, which could have the opposite effect: increased cumulative impacts on wildlife compared to the No Action Alternative.

5.4.3.2 Determinations of Regulatory Status

Pesticides are used on both commercial GE and conventional crops and can potentially harm wildlife both directly and indirectly, when improperly used. GE IR and disease resistant crops can reduce the use of pesticides. Conversely, the widespread use of herbicides on either GE or non-GE crops when improperly applied can present risks to wildlife. Further development of HR weeds can potentially lead to an increased use of herbicides. The EPA has initiatives to help manage development of herbicide weed resistance and minimize pesticide spray drift. In general, pesticides applied following the EPA label requirements will present minimal risk to wildlife. The EPA considers impacts on wildlife as part of its ecological risk assessment, registration, and establishment of pesticide use requirements. Risk assessments evaluate the toxicity of a pesticide and its breakdown products (degradation products) to various terrestrial and aquatic animals and plants that the pesticide is not intended to kill.

As reviewed and analyzed in Chapter 4, while the interests of agriculture and wildlife can be competing, there are no adverse impacts on wildlife attributable to commercial cultivation of GE crops. A recent review of the scientific literature by the NAS found little evidence to connect GE crops with adverse agronomic or environmental problems (NAS 2016b). Consequently, the risk for potential adverse cumulative impacts on biological resources is

considered negligible. Certain traits, such as insect and disease-resistance, and nitrogen and phosphorous use efficiency are expected to have positive cumulative effects on biological resources. Varieties of GE plants incorporating these traits are more likely to be developed, and more widely cultivated under the No Action and Preferred Alternatives than under Alternative 3.

5.4.4 Cumulative Impacts: Pest and Disease Management

5.4.4.1 Environmental Release

The potential for APHIS-authorized environmental releases under each of the Alternatives to contribute to cumulative impacts from plant pest and disease management practices is considered negligible because of the small scale of these releases. Details about how APHIS considered these potential impacts are reviewed in the following section.

5.4.4.2 Determinations of Regulatory Status

Similar to that described above for HR crops, there are beneficial cumulative impacts derived from GE IR and disease resistant crops that are similar to those previously reviewed. However, there are also cumulative adverse effects. The source of these impacts are the same as those described in Chapter 4, but with effects intensified by repeated occurrences that are manifested as cumulative effects. GE IR and disease resistant crops reduce reliance on pesticides used to suppress plant pests and pathogens. The beneficial effects are both direct on the target crop, and indirect on crops adjacent to the one treated because of an overall localized reduction of the pest population. For example, Bt crops reduce insecticide use and reduce populations of insect pests of corn, soybean, and cotton benefitting growers of non-GE crops in the same locality. In some instances, these types of crops promote eradication of plant pests. One example is how virus-resistant papaya has benefited the Hawaiian papaya industry by reducing virus pressure on non-GE papaya in Hawaii.[201] The continued review and approval of such GE crop plants by APHIS will increase the choices available to growers in managing plant pests and disease, with the same benefits on the environment, the agricultural industry, and the consumer.

Crops that incorporate Bt resistance to insect pests in a PIP may cause cumulative impacts from the widening spectrum of crops (such as corn, soybeans and cotton). As APHIS finds that more GE IR and disease resistant crop plants are not subject to regulation, these will likely be utilized in commercial crops, subject to EPA registration and use requirements as appropriate. If used for human or animal food, these would be subject to the FDA's recommended biotechnology consultation for food safety (US-FDA 1992, US-FDA 2006). With more varieties of GE IR and disease resistant crop plants becoming available and adopted for commercial use, there is an increase in the potential for development of resistance to the introduced traits. This would apply to any agent used for control of pest insects and diseases, as chronic exposure of any insect pest or pathogen population to a control agent creates selection pressure that selects for individuals in the population resistant to that agent.

[201] Virus resistant (VR) papaya has benefited the Hawaiian papaya industry by reducing virus pressure

Under Alternative 3, there would be fewer new GE crop plants approved for cultivation as not regulated by APHIS. This might result in a decline in the pest and disease management efficiencies that can be afforded by GE IR and disease resistant GE crop plants. In contrast, the issue of development of pest and pathogen resistance to such GE traits would decline. These factors considered, when PIP-based strategies for pest and disease management are not utilized, APHIS expects that more synthetic chemical use will ensue. As with the PIPs, the issue of development of pest and pathogen resistance to chemical agents would continue. In general, it is expected that effective management of plant pests and disease will require integration of agricultural biotechnology approaches with various chemical and cultural mechanisms (i.e., crop rotations, tillage, cover crops), as well as biological controls.

Cumulative effects under the No Action and Preferred Alternative are expected to be about the same. Cumulative beneficial effects on the agricultural industry would be expected via increased efficiencies in the management of plant pests and diseases with less insecticide use in the production of human foods, animals foods, and fiber nationwide. These benefits would likely be more pronounced under the Preferred Alternative.

In response to development of resistance to Bt-based PIPs, the EPA instituted insect resistance management (IRM) requirements for Bt crops.[202] The EPA has recently developed a broader effort to mitigate the development of pesticide resistance by developing a Pesticide Registration Notice (PRNs): "Guidance for Pesticide Registrants on Resistance Management Labeling." This notice updates an existing PRN (2001-5) and recommends additional resistance management information for pesticide labels.[203]

5.4.5 Cumulative Impacts: Agricultural Weeds and Noxious Weeds

5.4.5.1 Environmental Release

The potential for APHIS authorized environmental releases to contribute in a cumulative manner to the development of HR weed populations is considered negligible due to the small scale of releases. The average release (test) site is about 20 acres, and the annual total acreage of such sites in the United States is around 450,000 acres or less. In comparison, the U.S. acreage devoted to cropland was about 325 million acres in 2015, most of which was treated with herbicides.[204]

5.4.5.2 Determinations of Regulatory Status

For GE HR crops that are no longer subject to regulation by APHIS and commercially cultivated, there would be both potential beneficial and adverse cumulative impacts on the development weed resistance to herbicides under each of the alternatives.

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[202] Introduction to Biotechnology Regulation for Pesticides: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides#resistance

[203] Draft Guidance on Managing Pesticide Resistance, June 7, 2016: https://www.epa.gov/pesticides/draft-guidance-managing-pesticide-resistance

[204] USDA 2012 Census of Agriculture: https://www.agcensus.usda.gov/Publications/2012/Online_Resources/Highlights/Farms_and_Farmland/Highlights_Farms_and_Farmland.pdf

APHIS notes that crops with HR traits that have been widely adopted, such as those conveying resistance to glyphosate, glufosinate, 2,4-D, and dicamba, will continue to be used and introduced into new GE crop varieties under each Alternative. This trend and the continued authorization by APHIS, EPA and/or FDA will increase the number of varieties of GE HR crop varieties available to growers. Where these crops are adopted by growers for commercial use, more herbicides will be applied. This will increase the selection pressure for greater herbicide resistance in weeds. In the United States, at least 155 weed species are resistant to one or more herbicide modes of action (MOAs). Weed resistance is a notable example of a cumulative impact that is not exclusively related to the development and widespread adoption of GE HR crops. Weed resistance has been occurring since the 1950s; it began soon after wide scale adoption of herbicides in U.S. agriculture.

Many of the newer GE HR crop plants are stacked-trait varieties resistant to two or more herbicides (e.g., 2,4-D and glufosinate-resistant soybeans and cotton). These are intended to allay development of resistant weeds by allowing for rotation of herbicides with different MOAs in an integrated weed management (IWM) program. Such stacked-trait varieties can delay the selection of resistant weeds in no-till and conventional cropping systems from pre-plant to post-emergent treatment, offering growers flexibility in the control of weeds. In this respect, stacking HR traits helps manage resistant weed populations.

While there have not been herbicides released with new modes of action in at least 30 years,[205] there are still opportunities to find resistance traits to existing herbicide chemistries that can be inserted into new GE HR crop varieties. This offers a strategy that will expand the options for better management of HR weeds. There is also an opportunity to manage herbicide resistant weed populations with gene drives to maintain the susceptibility to the least expensive herbicides that have the least impact on the environment (NAS 2016a).

Integrated weed management (IWM) is a practice widely promoted by weed scientists, agronomists, and USDA extension services. These practices must be consistently implemented to avert the future development of resistant weed populations. IWM practices include using a variety of herbicides with different MOAs, rotation of herbicides, and crop rotation.

The EPA has recently embarked on a more widespread effort in combating and slowing the development of pesticide resistance, developing a Pesticide Registration Notice (PRNs): "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship," which focuses on the overall strategy to manage herbicide resistance during registration and registration review. Other EPA actions include specific registration use requirements. For example, EPA required as a condition of registration that Enlist Duo, which is designed for use on 2, 4-D/GR corn and soybean, can only be used by growers who incorporate an herbicide resistance management plan into their agronomic practices

APHIS anticipates that the EPA will implement such measures with respect to weed resistance management and associated registration of pesticides used on GE crop plants.

[205] EPA's Perspective on Resistance Management with a Focus on Herbicides and Bt Crops: https://www.epa.gov/sites/production/files/2016-05/documents/session_8_resistance_management.pdf

State extension agents, seed providers, herbicide suppliers, and other professionals such as researchers affiliated with the Weed Science Society of America (WSSA), will also provide advice and training to growers, who are becoming aware of the needs for sustainable weed management and therefore, are more likely to implement best management practices. The overall success in allaying or preventing weed resistance will depend on the IWM practices implemented and adherence to EPA guidance by individual growers.

Under all the Alternatives considered, APHIS notes that more growers are likely to implement recommended management practices that reduce selection for weed resistance, in response to concerted outreach by weed scientists, extension services, the EPA, and USDA; a trend that has been documented by recent polls (Prince, Shaw, Givens et al. 2012).

5.4.6 Gene Flow and Weediness

5.4.6.1 Environmental Release

One of the more commonly expressed concerns among stakeholders is that GE plants may escape areas of field testing or cultivation and persist in the environment as weeds or invasive species. Sexually compatible plant species can hybridize. For GE plants this can be a concern where sexually compatible wild relative or weedy species exist (Warwick, Beckie et al. 2009, Ellstrand, Heredia et al. 2010, Ellstrand 2012). The likelihood and success of gene flow from GE plants is dependent on numerous factors such as the proximity of sexually compatible species; the species of GE plant or other organisms field tested; the GE trait; outcrossing rate for plants; pollen type; pollen and seed dispersal pathways; seed dormancy characteristics; management practices used in cultivation of GE plants; and environmental conditions and events where the GE plant is used. For plants, the particular species of GE plant and occurrence and proximity of sexually compatible species is the primary factor in evaluating the risk of gene flow (for more details see the review in Section 3.4.2). The Preferred Alternative and Alternative 3 encompass a broader scope of regulation over GE organism-trait combinations and the potential risks they may present, so consequently they include more protective measures for managing the potential risks of gene flow. Hence, in terms of potential cumulative impacts, under the Preferred Alternative and Alternative 3 the risks for cumulative impacts are expected to be less than that under the No Action Alternative.

5.4.6.2 Determinations of Regulatory Status

In considering the Alternatives to regulation, there is potential for gene flow under all the Alternatives. However, as reviewed and analyzed in Chapter 4, the potential risk of such gene flow is expected to be greater under the No Action Alternative which limits the scope of GE organisms considered to those that pose a plant pest risk.

As described for field testing, the Preferred Alternative and Alternative 3 encompass regulation over a broader scope of GE organism-trait combinations and the potential risks they may present. Consequently these Alternatives are considered more protective in managing the risks that may be presented by potential gene flow. Hence, in this respect, the potential for cumulative impacts from gene flow would be less under the Preferred Alternative and Alternative 3, than under the No Action Alternative.

5.4.7 Biodiversity

5.4.7.1 Environmental Release

The median size of an approved field trial is approximately 5 acres, and the average size is about 20 acres. Collectively, authorized field trials in the United States encompass approximately 450,000 acres or less each year. Potential impacts on biodiversity that may result from authorization of field trials are dependent on the species of GE organism (e.g., annual or perennial plant, occurrence of sexually compatible species in the area of field testing, extent of domestication), the trait (e.g, insect or herbicide resistance), the management practices involved in field testing of the GE organism (e.g., tillage, pesticide use), and the environment in which the field trial is conducted (e.g., proximity to wilderness areas, wildlife refuges, critical habitat). These would be considered on a case-by-case basis as authorization requests are received by APHIS. In general, because of the relatively small scale and transient nature of field trials, there is limited potential for adverse cumulative effects on biodiversity.

Field trials of GE organisms are subject to all federal and state regulations governing protections of wildlife, habitat, and biodiversity. Any GE organism field tested would be subject to U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Services (NMFS) authorities for protection of T&E species under the Endangered Species Act (ESA) of 1973,[206] EPA regulations protecting air and water quality, and various State requirements for protection of wildlife and T&E species. APHIS authorizations for notifications and permits require applicants to identify whether the proposed release site and/or area to be monitored is within or in close proximity to designated critical habitat for a listed T&E or within habitat proposed for designation under the ESA. These requirements would not change under any of the Alternatives. APHIS notes that actions made by growers using GE crops that are no longer regulated by the Agency are still subject to the ESA and growers are responsible for ensuring ESA compliance under those circumstances (see Chapter 6 for further details about ESA compliance requirements).

5.4.7.2 Determinations of Regulatory Status

In general, species abundance and diversity is less on and around agricultural lands, relative to undisturbed/unmanaged habitats. Highly managed landscapes, such as croplands, impact biodiversity by loss of habitat, fragmentation of habitat, and conversion of unmanaged environments to highly managed ones. Various studies over the last 10 years have investigated the differences in the biological diversity among GE and non-GE crop fields, particularly those GE crop plants that are resistant to insects (e.g., *Bt* crops) or to certain herbicides. Some studies have found negligible to modest decreases in biological diversity or abundance attributed to GE IR or HR crops; other studies have found no effects (e.g., see (NRC 2010a, Carpenter 2011, NAS 2016b)). Since 2008, over 360 original research articles have been published examining the non-target effects of Bt crops, in particular, on invertebrate (mostly arthropod) organisms (Naranjo 2009).

[206] By example, see http://www.fws.gov/endangered/laws-policies/regulations-and-policies.html, and https://www.fws.gov/permits/ltr/ltr.html

A recent review of over 360 research articles on the potential impact of GE crops on biodiversity indicated that commercial GE crops can reduce the impacts of agriculture on biodiversity through promoting adoption of conservation tillage practices, reducing insecticide use, and encouraging the use of less toxic pesticides (Carpenter 2011).

Commercial crop production, including non-GE conventional, organic and GE systems, rely on agronomic practices that will always have some cumulative effect on biodiversity in and around crop fields. None of the Alternatives considered would alter this, or the relationship between commercial crop production and biodiversity.

As analyzed in greater detail in Chapter 4, various federal and state programs serve to support biodiversity and sustainability in commercial agriculture. Sustainable agriculture was addressed in the 1990 Farm Bill (Food, Agriculture, Conservation, and Trade Act of 1990 [FACTA], Public Law 101-624, Title XVI, Subtitle A, Section 1603).[207] Under FACTA, the term sustainable agriculture means "an integrated system of plant and animal production practices having a site-specific application that will, over the long term: satisfy human food and fiber needs; enhance environmental quality and the natural resource base upon which the agricultural economy depends; make the most efficient use of nonrenewable resources and on-farm resources and integrate, where appropriate, natural biological cycles and controls; sustain the economic viability of farm operations; and enhance the quality of life for farmers and society as a whole."

The USDA recognizes that conservation by farmers, ranchers, and forest owners is required for sustaining agriculture for the future and provides various programs that support biodiversity and sustainability, such as landscape-scale conservation initiatives and the Conservation Reserve Program.[208] The USDA funds the Sustainable Agriculture Research & Education (SARE) program (http://www.sare.org/), which provides grants to farmers, ranchers, researchers, educators, and community groups;[209] and a SARE-supported network of sustainable agriculture educators in every state and island protectorate—comprised of expert farmers, ranchers, and agriculture professionals.

5.5 Cumulative Impacts: Human Health

There have been concerns among some stakeholders that human and animal foods derived from GE crop plants are unsafe for human or animal consumption (e.g.,(Smith 2007)). Numerous peer reviewed studies, and reviews of these studies by domestic and international scientists and regulatory bodies, have concluded that human and animal foods derived from GE crops currently in commercial production are as safe for consumption as their non-GE counterparts (see section 4.4 for more details about this topic).

In 2016, the U.S. National Academy of Sciences (NAS) evaluated the relationship between foods derived from GE crop plants and human health, and found that "the research that has been conducted in studies with animals and on chemical composition of GE food reveals no differences that would implicate a higher risk to human health from eating GE foods than

[207] USDA - Sustainable Agriculture: https://afsic.nal.usda.gov/sustainable-agriculture-information-access-tools-1
[208] USDA - Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation
[209] SARE- Sustainable Agriculture Grants: http://www.sare.org/Grants

from eating their non-GE counterparts." The NAS review also found that: "In addition to experimental data, long-term data on the health and feed-conversion efficiency of livestock that span a period before and after introduction of GE crops show no adverse effects on these measures associated with introduction of GE feed. Such data test for correlations that are relevant to assessment of human health effects, but they do not examine cause and effect" (NAS 2016b). Considering the existing domestic and international regulatory review and authorization processes for food safety (summarized in sections 3.8 and 4.4 – Human Health), and the efficacy of these review and authorization processes in ensuring the safety of foods, there are no potential adverse cumulative impacts on human health associated with any of the Alternatives considered, nor with the public consumption of current or future foods derived from GE crop plants.

5.6 Cumulative Impacts: Animal Food and Welfare

One of the major applications of GE corn and soybean is for use in animal food.[210] Corn is the primary U.S. feed grain, accounting for more than 95% of total feed grain production and use in the United States. As with human foods derived from GE crops, there have been concerns among some stakeholders that animal foods derived from GE crops may adversely affect animal health. The 2016 NAS study found that "In addition to experimental data, long-term data on the health and feed-conversion efficiency of livestock that span a period before and after introduction of GE crops show no adverse effects on these measures associated with introduction of GE feed. Such data test for correlations that are relevant to assessment of human health effects, but they do not examine cause and effect" (NAS 2016b). The NAS review also found that: "The design and analysis of many animal-feeding studies were not optimal, but the large number of experimental studies provided reasonable evidence that animals were not harmed by eating food derived from GE crops. Additionally, long-term data on livestock health before and after the introduction of GE crops showed no adverse effects associated with GE crops."

Considering the human and animal health data reviewed and analyzed in Chapters 3 and 4 and of this dPEIS, there are no adverse cumulative impacts on animal health and welfare that are expected under any of the Alternatives. The FDA will continue to oversee the safety of human and animal food, including the consideration of data used to compare food derived from GE plants with their conventional counterparts, under its voluntary plant biotechnology consultation program. The EPA will continue to regulate and establish tolerance limits for pesticides used on human and animal food crops.

Modification of crop plants to improve the nutritional value of animal food is an emerging area of research where beneficial cumulative impacts may be realized. For example, a low lignin form of alfalfa was recently developed that improves the digestibility of alfalfa.[211] Similarly, a phytase-modified corn has been developed that shows efficacy in reducing the need to supplement chicken feed with phosphorous (Gao, Ji, Zhao et al. 2013). Phytase-modified corn is also expected to improve phosphorous assimilation by pigs. Not only is this

[210] USDA-ERS: http://www.ers.usda.gov/topics/crops/corn/background.aspx

[211] Dupont-Pioneer, Reduced-Lignin Trait Could Revolutionize Alfalfa: https://www.pioneer.com/home/site/us/silage-zone/alfalfa_feed/reduced-lignin-trait/

considered a nutritional improvement, it could reduce the amount of phosphate in manure, thereby decreasing environmental phosphate loads that can adversely impact water quality, as described in sections 3.5.2 and 4.2.2.

The ever expanding aquaculture industry is also an area seeing increased application of plant biotechnology for provision of feed. Globally, fisheries are at or beyond their exploitable limits and cannot satisfy the growing demand for fish and seafood. Consequently, around 50% of seafood is now farmed (FAO 2014b). From 2000 to 2012, farmed seafood production worldwide doubled from 32.4 million to 66.6 million metric tons.[212] All fish, wild and farmed, have dietary requirements for omega-3 fatty acids, which are typically met in fish farms by feeding meal derived from small fish and marine algae. The need for sustaining feedstock has spurred innovation in developing plant based diets for farmed fish. Today the main ingredient in fish feed continues to be soybean meal. GE plants modified to provide a nutritional profile more tailored to the specific needs of the fish, such as omega-3 fatty acids, could serve to help sustainably provide the feeds required for aquaculture, which otherwise are primarily obtained from small fish and marine algae (Betancor, Sprague, Usher et al. 2015). Most recently, a genetically engineered camelina has proved to be a feasible source of omega-3 fatty acids, which could effectively substitute for fish in aqua-feeds, and provide levels of these fatty acids in farmed fish that could maintain their nutritional quality for the human consumer (Betancor, Sprague et al. 2015).

Under the No Action and Preferred Alternatives, it is likely that a greater variety of GE plants will be developed and commercially produced that have improved characteristics as animal feed, relative to Alternative 3. Alternative 3 is not expected to promote the development of new GE crop varieties to the degree the other alternatives would. Hence, as for cumulative impacts on animal food and welfare, APHIS determinations of regulatory status for GE plants under the No Action and Preferred Alternative would likely better serve the agricultural biotechnology sector, the animal food industries, and consumers of animal derived food products.

5.7 Cumulative Impacts: Climate Change

5.7.1 Potential Impacts of Agriculture on Climate Change

Because a multitude of small individual sources contribute to global greenhouse gas (GHG) concentrations that collectively affect climate change, all emissions have a cumulative effect. As CEQ has emphasized, statements such as “emissions from the proposed action represent only a small fraction of global emissions” provide no meaningful information.

The volume of GHGs released as a result of field trial activities would be limited to an area of less than 450,000 acres per year; the collective annual sum of field trials authorized for release. In recent years, the collective annual acreage of authorized field trials has been around 350,000 to 450,000 acres. The most significant source of GHG emissions from cropping systems is soil based N_2O. CO_2, and CO would also be released during use of farm

[212] For example, Yale University e360 Digest: https://e360.yale.edu/digest/in_booming_aquaculture_industry_a_move_to_plant-based_food_for_fish/4523/

equipment and transport of products, growers, scientists, and APHIS officials to and from field sites.

APHIS determinations of regulatory status are not federal actions that will directly result in GHG emissions and climate change impacts, but rather, APHIS' decisions affect the agricultural community's decisions to produce (or not produce) GE crops, which may become the source of air emissions. The collective actions of all those individuals planting the GE crop and their production practices (such as rotation crops, tillage choices, fertilizer use, pesticide use, and the timing associated with these practices) affects GHG emissions. Such actions are based on pest and disease pressures, the prevalence and variety of weed species, soil quality, and market forces. Consequently, predicting how grower choices will contribute in adverse or beneficial ways to climate change would be highly speculative, although the sources of GHG emissions and potential impacts can be evaluated.

In 2014, GHG emissions from agriculture accounted for approximately 9% of total U.S. GHG emissions. GHG emissions from agriculture have increased by approximately 11% since 1990, primarily because of a 54% increase in combined CH_4 and N_2O emissions from livestock manure management systems. Emissions from soil management activates in cropping systems increased by about 5% since 1990.

Agricultural soil management practices such as fertilizer application and tillage are the largest source of N_2O emissions in the United States, accounting for 78.9 percent.[213] Agricultural soils produce the majority of N_2O emissions in the United States; about 318 million metric tons in 2014. N_2O emissions from croplands tend to be higher in the Corn Belt (Illinois, Iowa, Indiana, Ohio, Southern and Western Minnesota, and Eastern Nebraska), where a large portion of the land is used for growing highly fertilized corn and nitrogen-fixing soybean crops. Minimizing fertilizer applications by using only the amount of nitrogen required would reduce N_2O because increased fertilizer application can lead to higher N_2O emissions. Crop residue is also burned on some farms, and burning is a source of CH_4, N_2O, CO, and NOx.

Reduced tillage and fertilizer use would serve to reduce N_2O emissions. Newly developed GE crop plants with improved nitrogen or phosphorous use efficiencies could facilitate reduction in fertilizer needs. As discussed in this section, conservation tillage is associated with GE HR cropping systems, a trend that would be expected to continue. GE crops with pest resistant traits require fewer pesticide applications thereby saving fuel and reducing GHG emissions. Under the No Action and Preferred Alternative, there would likely be a greater variety of GE crop plants with such traits available for commercial production, as well a greater number of GE crop plants produced. These types of crops could contribute to reduction in the cumulative emissions of GHG from U.S. agriculture. As APHIS determines such plants are unlikely to pose any plant pest or noxious weed risk, and they are cultivated for commercial purposes, subject to review and approved use by the EPA, and voluntary consultation with FDA, such GE plants are expected to help reduce GHG emissions.

[213] EPA - Climate Change: https://www3.epa.gov/climatechange/Downloads/ghgemissions/US-GHG-Inventory-2016-Chapter-5-Agriculture.pdf

5.7.2 Potential Impacts of Climate Change on Agriculture

Climate change will beneficially and adversely affect crop production in the United States. Hence, challenges are presented. Crop production is influenced by complex relationships with temperature, precipitation, carbon dioxide concentrations, weeds, pests, and disease – all of which are respondent to climate change. More severe weather events are likely as climate warms. Climate change projections indicate increased variability in temperature and precipitation. Extreme events including sustained droughts, and heat waves, can have large effects on crops. Hail can also be damaging. As temperatures increase, crop production areas may shift to regions where the temperature range for optimal growth and yield have moved, though production in any given location will be more influenced by available soil water during the growing season.

Many weeds, pests, and pathogenic fungi and bacteria thrive under warmer temperatures, moister climates, and increased CO_2 levels. The ranges of weeds, and plant pests and pathogens, are likely to expand Northward. This would cause new problems for farmers of crops in areas previously unexposed to such plant pests and diseases. The potential magnitude of these effects is not well understood. For example, while some insect pests thrive under warmer climates, warming temperatures may force certain pests out of their current geographical ranges. Weed control costs currently total more than $11 billion a year in the United States. These costs are expected to rise with increasing temperatures and carbon dioxide concentrations. Moreover, increased use of pesticides and fungicides may be required to effectively manage pests and diseases in some areas.

By mid-century, when average temperatures are projected to increase 1.8°-5.4°F and precipitation extremes are expected to intensify, yields of major U.S. crops and farm profits are expected to decline. There have already been detectable impacts on production caused by increasing temperatures (Hatfield, Takle et al. 2014). Research indicates that U.S. cropland agriculture will be fairly resilient to climate change in the short term, with expansion of irrigated acreage, regional shifts of crop acreage, and other adjustments partially compensating for yield effects caused by changing climate patterns (Walthall, J. Hatfield, P. Backlund et al. 2012). The degree of impact will vary regionally, with producers in some areas of the U.S. potentially benefitting and others suffering losses as a result of yield changes, adjustments to prices, and increased risk and economic variability. This short-term balance will likely be followed by net losses in the longer term as temperatures continue to increase and other changes in climate become more pronounced (Walthall, J. Hatfield et al. 2012). There remains, however, much uncertainty about weather extremes, and potential changes in plant pest and pathogen populations.

In consideration of the variable of effects of climate change on crop production, one factor will not change: human food, animal food, and fiber demand is expected to continue to increase as the global population increases. An increase in demand means that more of these agricultural commodities must be produced, produced more efficiently, and this must occur under more variable climate conditions.

Adaptation strategies available to U.S. producers include shifts in the timing of farming operations, selection of specialized crop varieties (inclusive of traditionally bred and GE

varieties), pesticide use, technology, and other sustainable practices to increase resiliency. In the short term, these strategies are expected to provide substantial adaptive capacity, protecting domestic producers and consumers from the market effects of climate change, although the occurrence of protracted extreme events, such as drought, could have significant effects. In the long-term, adaptation in the U.S. crop production system may be more difficult, and costly, as crop plant physiological limits are exceeded more frequently; plant pest, disease, and weed shifts become more variable; and cropping system productivity become less predictable (Walthall, J. Hatfield et al. 2012).

Meeting the demand for human food, animal food, and fiber will require technological advances in crop production; inclusive of plant biotechnologies, and on farm technologies that provide greater efficiencies in resource utilization. In addition to traditionally bred cultivars, there will be additional reliance on genetic engineering to develop crop plants that confer tolerance to drought, heat, and salinity, and resistance to pest and disease populations (Walthall, J. Hatfield et al. 2012, Lybbert and Sumner 2015). Genetic engineering provides for modification of crop plants for resilience to biotic and abiotic stresses in a more precise, and timely, manner; relative to traditional breeding. Hence, genetic engineering is expected to facilitate implementation of strategies to meet changes in regional climate, associated shifts in weeds, and plant pests and disease. This will enable producers to more readily adapt to climate change.

The No Action Alternative and Preferred Alternative are expected to support U.S. agricultural responses and adaptation to climate change by fostering an environment for the development and commercial introduction of GE crop plants with traits that meet producer needs under changing climate and environmental conditions. Alternative 3 is not expected to facilitate GE crop plant variety development, or cultivation, to the degree the other alternatives would.

5.8 Cumulative Impacts: Socioeconomics

5.8.1 Domestic Markets

5.8.1.1 Environmental Release

The unauthorized release of GE crop plants can have an adverse socioeconomic impact on trade. For example, the unauthorized release during field testing of GE alfalfa resulted in the unintended presence of GE alfalfa material in non-GE alfalfa.[214] Unauthorized releases of GE wheat have occurred in Oregon and Montana, although no GE wheat has been detected in commercial seed or grain.[215] Under the Preferred Alternative, the cumulative socioeconomic impacts of such unauthorized releases would likely diminish, as the only GE crop plants that would be subject to regulation would be those that posed a plant pest or noxious weed risk. Revision to permitting and reporting requirements, in tandem with compliance requirements, are expected to reduce the possibility for unauthorized releases of regulated GE organisms.

[214] Monsanto Company v. Geertson Seed Farms, Docket No. 09-475: http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/09-475.htm
[215] USDA-APHIS Factsheet: https://www.aphis.usda.gov/publications/biotechnology/2014/faq_ge_wheat.pdf

One consideration is that, if APHIS determines a GE crop plant intended for human or animal food is not subject to regulation, and that GE plant obtains regulatory review and authorization by the EPA, and the developers consult with the FDA, as appropriate, this could, over the long-term, potentially result in an increase in the variety of GE crop plants in commerce and available for export. In this scenario, there would need to be authorizations of such GE crop plants in foreign countries prior to export to preclude instances of LLP. If there is an increase in regulatory authorization and commercial production of new GE crop plants in the United States that have not been reviewed and authorized by foreign countries, then there is a potential increase in the risk of LLP for certain commodities, such as corn and soybean. However, under the Preferred Alternative, it is unlikely that there will be a significant increase in the rate of commercialization of GE crops, as EPA regulatory requirements will remain unchanged, as will the safety assessment needed for human or animal food which would be the basis for a voluntary consultation with the FDA. Neither the pace of commercialization nor volume of GE crop plants commercialized is expected to significantly change, as the FDA and EPA will still have oversight of most GE crops plants that are intended for commercial uses. Developers of GE crops plants would remain subject to the FFDCA, FIFRA, and all other laws and regulations providing human health and environmental protections, and required to comply these laws and implementing regulations, as under the No Action Alternative.

Under Alternative 3, if the regulatory burden deters growers from adopting GE crops, cumulative economic impacts associated with unauthorized releases could potentially decline. On the other hand, if the agricultural biotechnology sector remains innovative and production of GE crops sustains, despite the increased regulatory burden under Alternative 3, socioeconomic impacts might actually increase, as the vast majority of GE crop plants, and their planting, would be regulated and require an APHIS permit for cultivation.

5.8.1.2 Determinations of Regulatory Status

APHIS determinations of regulatory status under these Alternatives would affect the agricultural community's decisions in regard to the particular GE and non-GE cultivars of crop plants they will grow. The cumulative impacts of these determinations, and subsequently grower decisions in crop cultivation, would result from coexistence of GE and non-GE cropping systems (i.e., conventional, and organic systems). Coexistence is a well-understood industry requirement under all the Alternatives, although the degree to which coexistence practices will need implementation will vary.

Both the organic and "non-GMO" verified sectors are burgeoning, as is the GE crop sector. Hence, there is and will be increasing need for coexistence and ensuring segregation of these cropping systems and their post-harvest processing chains in supplying agricultural commodities to commercial markets.

Under the No Action and Preferred Alternative, beneficial cumulative impacts would be expected to be seen in the GE market sector by way of a continued expansion and increased variety of GE crop plants available to the commercial market. However, under the Preferred Alternative less regulatory burden on developers would be expected, so there would be a possible increase in research and development in the agricultural biotechnology sector, and

therefore, more options available to growers to meeting market demand for food and fiber. University researchers have often commented that the cost of regulation thwarts their ability to use modern methods to innovate and improve crop varieties. The Preferred Alternative would lower the cost of conducting field trials and completing regulatory approvals through APHIS. The greater innovation that may occur across the public and private sector could yield cumulative benefits in the way GE organisms are developed. This may ultimately benefit growers, consumers, and the environment (e.g., less reliance on synthetic chemicals). In contrast, Alternative 3, as a result of comprehensive regulation by APHIS, would be expected to be a disincentive to research and develop GE organisms.

Under the Preferred Alternative, farmers catering to the non-GE market (growers of organic and "non-GMO" crops), who have had no neighboring GE crops, could be affected if these Alternatives contribute to increasing the number and variety of GE crops grown in the United States. The non-GE crops most likely to be negatively impacted are grain crops such as wheat, rice, barley, sorghum, and oats, for which no GE varieties have been commercialized to date, which are handled as commodities subject to commingling, and which are primarily grown for grain which is susceptible to the introduction of GE traits during fertilization.[216] Other crops such as hops and peanuts, could also be affected.[217] If the Preferred Alternative facilitates the development and adoption by growers of new GE varieties that lead to incidences of unintended presence of GE plant material in non-GE crops, the non-GE producers could be negatively affected. Because organic crops and other non-GE commodities can always be sold as conventional commodities, the price premium above the conventional price represents a measure of the value affected by the unwanted presence of GE trait material in a non-GE commodity.

Bearing these considerations in mind, because many of the new GE crop plants are expected to be developed through genome editing techniques, these may not be easily detectable in the resulting modified plants unless the specific genetic changes are clearly known or distinguishable from traditionally bred crop varieties. Hence, the expected future modifications may present a new challenge in regard to what comprises unintended presence, or even the ability to identify unintended presence if it has occurred (detect the genetic medication).

Under Alternative 3, a decline in the number of GE crops is expected, and non-GE crop producers would benefit in terms of the risk of unintended presence. In contrast, GE crop producers would be highly regulated and the rate of innovation and development in the agricultural biotechnology sector would likely lag compared to how it would respond under the other Alternatives.

[216] A variety of GE rice has been deregulated but not commercialized.

[217] The extent to which some crops are harvested after flowering affects how much of the crop would be potentially affected by the unwanted presence of biotechnology traits.

5.8.2 International Trade

5.8.2.1 Environmental Release

In some cases, unauthorized releases of GE crop plants have led to low level presence (LLP) but wide scale introduction of unauthorized GE trait material in seed used for commercial crop production. This occurred most notably in the case of LibertyLink rice and resulted in a significant adverse economic impact to the rice industry.[218] Unauthorized releases during the field testing of GE alfalfa also led to LLP in alfalfa seed intended for non-GE markets. Economic fallout from the alfalfa LLP was not as widespread as in the rice example. In the case of LibertyLink rice, there was a large economic cost even though the unauthorized rice was virtually identical to another event that was deregulated by APHIS, and considered to be harmless by virtue of its low level presence (3 seeds in 10,000 seeds).[219] In regard to the international trade, under the Preferred Alternative the cumulative socioeconomic impacts of such unauthorized releases are expected to diminish, as APHIS would be regulating fewer numbers of GE crop plants, with more stringent field testing requirements for those GE crop plants APHIS did regulate. Under Alternative 3, cumulative socioeconomic impacts from unauthorized releases would likely increase, as the vast majority of GE crop plants, and their planting, would be regulated by APHIS.

5.8.2.2 Determinations of Regulatory Status

Developers of GE crop plants and crop producers have made significant contributions to increasing global production levels of commercial crops such as corn, soybeans, and cotton, resulting in economic gains for farmers in both developing and developed countries. The export of GE organisms determined to have non-regulated status by APHIS has largely been limited to commercial crop commodities such as corn, soybeans, and cotton, and their products. The export of these GE agricultural commodities is expected to continue. It is also expected that a greater variety of GE crop commodities will be exported in the future because of increased use of GE crops in agricultural production.

The Preferred Alternative represents a change from the current regulatory process, and this change could have either positive or negative impacts on international trade. For example, international regulatory agencies from a number of countries have been exploring how to regulate new plant breeding technologies and whether such modifications should be included within the realm of genetic engineering (Schuttelaar&Partners 2015). One possibility is that other international regulatory bodies will either follow all or some of the changes being proposed by APHIS. Another possibility is that international regulatory bodies will accept the decisions made by APHIS in individual cases. Either case should lead to a reduction in regulatory obstacles and facilitation of international trade.

Another possibility is that changes proposed by APHIS would not be acceptable to the international community in which case international trade would be hindered because, prior

[218] For example: Bloomberg - Bayer Will Pay $750 Million to Settle Gene-Modified Rice Suits, http://www.bloomberg.com/news/articles/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice

[219] FDA - U.S. Food and Drug Administration's Statement on Report of Bioengineered Rice in the Food Supply U.S. Food and Drug Administration's Statement on Report of Bioengineered Rice in the Food Supply

to exporting a GE product, international approval of a commercialized GE product must occur to minimize trade disruptions. Even the trace presence of a GE trait material in U.S. exports to markets for which it has not been approved can result in market disruptions and corresponding income loss for exporters and importers, as has happened with exports of corn, soybeans, and alfalfa. Consumers in importing countries also could face higher domestic commodity prices when imports are deterred or directed to another trading partner (see Section 3.10.3 for more details). APHIS will be conducting briefings with international regulatory agencies after the publication of the proposed rule and the outcome from such briefings will inform the Agency direction in rule revision. Under Alternative 3, GE crops could only be commercialized after international approvals in key markets were granted. This measure would decrease the number of asynchronous approvals relative to the other Alternatives. However, it would mean that other countries could hinder U.S. competitiveness by arbitrarily withholding authorizations.

Hence, cumulative effects could be seen across the international regulatory community because of APHIS' adoption of one of the Alternatives. This could influence how other countries regulate GE organisms, particularly in regard to trade, as harmonization of regulatory criteria is desired, as is reductions in the potential for AA and LLP.

5.9 Summary of Cumulative Impacts

Under the Preferred Alternative and Alternative 3, the revision of 7 CFR part 340 is designed to expedite the identification of new GE organisms that are unlikely to pose plant pest or noxious weed risks, while ensuring appropriate regulation of those that do pose such risks. Because the general concepts of the regulatory revisions were developed in consultation with the other federal agencies that regulate GE organisms, it is not anticipated that these revisions would increase the potential for adverse cumulative impacts. Under the Preferred Alternative and Alternative 3, the increased regulatory scope and stringency of the regulations are expected to further the environment protections provided under the No Action Alternative, both incrementally and cumulatively. In implementing any new regulations, APHIS will continue to work closely with the other agencies to ensure that its revised regulations do not duplicate or conflict with those of other agencies in a way that would result in adverse cumulative impacts. NEPA analyses prepared in conjunction with case-by-case decision-making at APHIS will continue to be used, as required, to examine the potential cumulative impacts of Agency decisions regarding GE organisms.

APHIS also has established working relationships with state regulatory officials and strives to keep them informed regarding introductions of GE organisms under its oversight. APHIS anticipates that the proposed regulatory revisions under the Preferred Alternative and Alternative 3 will not result in any significant changes to potential cumulative impacts as a result of APHIS regulation, and regulation at the state or local levels.

6 Endangered Species Act

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species – and the ecosystems on which they depend – as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other federal, state, and local agencies, tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, one of the Services (NMFS or USFWS) must first add it to the federal list of threatened and endangered wildlife and plants. Threatened and endangered (T&E) species are plants and animals at risk of becoming extinct throughout all or part of their geographic range (endangered species) or species likely to become endangered in the foreseeable future throughout all or a significant portion of their ranges (threatened species).

The Services add a species to the list when they determine it is endangered or threatened because of any of the following factors or a combination thereof:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overuse for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; or
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, in accordance with the ESA, protective measures apply to the species and its habitat. These measures include protection from adverse effects of federal activities.

This dPEIS section is an evaluation for an entire regulatory program to ensure that APHIS addresses – as required by the ESA – anticipated, project-level actions. The program is nationwide in scope, including territories and commonwealths of the United States – such as Puerto Rico. Because of the broad geographical area and wide range of habitat types where effects might occur, this section addresses potential effects at a programmatic level. For specific project-level actions carried out under the regulations, APHIS will conduct an assessment of the potential effects on a listed species and critical habitat and consult with the Services as required by Section 7 of the ESA when appropriate. In such cases, APHIS may develop a Biological Assessment and submit it to the Services. In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, and APHIS' NEPA implementing procedures. APHIS may develop an EA or EIS and solicit public involvement along with an endangered species assessment.

6.1 Requirements for Federal Agencies and APHIS' Authority

Section 7(a)(1) of the ESA requires all federal agencies, in consultation with the Services and with the assistance of the Secretary of Interior and/or Secretary of Commerce, to use their authorities in furtherance of the purposes of the Act by carrying out programs to conserve threatened and endangered species.

Section 7(a)(2) of the Endangered Species Act requires that each federal agency, in consultation with the Services and with the assistance of the relevant Secretary, ensure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of a listed T&E species, or result in the destruction or adverse modification of designated critical habitat. You can find implementing regulations in 50 CFR part 402, Interagency Cooperation Regulations.

When analyzing potential effects of a proposed regulatory action on T&E species and critical habitat, under Section 7(a)(2), agencies must use the best available scientific information to consider direct, indirect, interrelated, interdependent, and cumulative effects as defined in the implementing regulations of the ESA (50 CFR §402.02):

> Direct Effects – Direct effects are immediate. An example of a direct effect would be a plant genetically engineered to produce a pesticide in an area of a susceptible listed species, and the species would be expected to be exposed to the genetically engineered (GE) plant. Another example would be the clearing of woodland to plant a GE row crop in an area known to have a listed species that would find the original habitat suitable.
>
> Indirect Effects – Indirect effects are caused by or resulting from the proposed action and are later in time, but are still reasonably expected to occur. An example would be the release of a plant genetically engineered to produce a pesticide in an area of a susceptible species that is preyed upon by a listed species also known to be in the area. As a result, the prey base for the listed species may be affected.
>
> Interrelated Effects – Interrelated effects result from an action that is part of a larger action and depend on the larger action for their justification. An example would be the construction of an access road to the release site of a GE organism, where the construction of the roadway affects habitat suitable for a listed species known to be in the area.
>
> Interdependent Effects – Interdependent effects result from actions having no independent utility apart from the proposed action. An example would be the construction of a facility to process a plant that is genetically engineered to produce proteins of pharmaceutical interest.
>
> Cumulative Effects – The ESA defines cumulative effects as effects from future state or private activities -- not involving federal activity -- that are reasonably certain to occur within the area of the federal action. If an agency anticipates any future state or private activities in the action area that when combined with the federal action could affect listed or proposed T&E species or critical habitat, the agency must consider these actions during the effects analysis.

An effects analysis results in either a "may affect" or "no effect" determination. "May affect" is an appropriate determination when an action may have an effect on any individual(s) of a listed species or designated critical habitat. A "no effect" determination is appropriate when an action will have no effect on any individual(s) of listed species or designated critical habitat. In accordance with Section 7 of the ESA, APHIS consults with the Services for any "may affect" determination. The ESA does not require consultation with the Services for "no effect" determinations.

When actions may affect listed or proposed T&E species, or designated or proposed critical habitat, agencies must prepare biological assessments (BAs). A BA analyzes potential effects and describes any protective measures an agency proposes to use to protect affected species and/or their habitats. The agency submits findings of a BA for review by the appropriate Service. This review is followed by a consultation process between the participating agencies to formalize limitations on allowable effects on T&E species and establish protective measures to mitigate effects.

If the federal agency reaches a "may affect" determination, it must determine whether the action is likely or not likely to adversely affect the listed species or designated critical habitat.

> A ***"may affect, not likely to adversely affect"*** determination is appropriate when effects on listed species or designated critical habitat are expected to be discountable, insignificant, or completely beneficial. If the determination is "may affect, not likely to adversely affect," the agency initiates an informal consultation with the Services. Failure to obtain the Services' concurrence with this determination requires formal consultation.
>
> A ***"may affect, likely to adversely affect"*** determination is appropriate when the agency does not expect effects on listed species, or designated critical habitat to be discountable, insignificant, or completely beneficial; the overall effect is beneficial, but is also likely to cause some adverse effects; or if the agency expects a "take" to occur as a result of the action. If the determination is "may affect, likely to adversely affect," the agency initiates a formal consultation with the Services. The formal consultation process ends with a decision by the Services (usually written in a Biological Opinion) on whether the action will result in jeopardy/non-jeopardy to the continued existence of the species if the action will adversely modify designated critical habitat.

6.2 ESA Analyses under Current APHIS Regulatory Procedures

Releases, Interstate Movement, and Importation of Regulated Articles

APHIS currently regulates the introduction (environmental release, interstate movement, or importation) of GE organisms that may be plant pests or for which there is reason to believe are plant pests. The agency authorizes introductions after considering the organism, the nature of the genetic engineered modification, and the ways in which the GE organism is likely to interact with the environment. As part of the authorization process, applicants must submit required information (7 CFR § 340.3, and 7 CFR § 340.4) for the agency to evaluate

the environmental risks, including risks to T&E species and critical habitat, posed by the introduction. The applicant must also submit confinement and mitigation procedures/methods to minimize environmental risks. In addition, APHIS evaluates all introductions according to our NEPA implementing regulations (7 CFR part 372). If the proposed introduction does not meet APHIS' criteria for a categorical exclusion, APHIS completes an EA for public review and comment prior to making a decision on whether to approve its introduction.

Based on the lack of new issues posed by the types of plants which qualify for notification, environmental releases under notification meet the criteria for categorically excluded actions under our NEPA implementing regulations (7 CFR § 372.5).

Any plants that do not meet the notification criteria are subject to the permitting process. [220] APHIS uses the permitting process for introductions of plants genetically engineered to produce pharmaceutical or industrial compounds, other GE plants including those that don't qualify under the notification process, and GE non-plant organisms (e.g., insects or microbes) if they meet the definition of regulated article in 7 CFR part 340. Confinement conditions and standard operating procedures are tailored on a case-by-case basis to maintain confinement of the GE organism throughout the course of the field trial.

To ensure that notification and permit holders maintain regulatory compliance, APHIS provides guidance and compliance procedures that include violation-prevention efforts, inspections, documentation of compliance infractions, and mitigation and enforcement actions to address any regulatory infractions. APHIS also requires all notification and permit holders to submit reports and notices that include information about the field trial, data collected, and any known adverse environmental effects that may have occurred. When necessary, APHIS remedies issues of noncompliance through required remedial actions.

In 2002/2003 APHIS met with USFWS to discuss a proposed decision tree on whether Section 7 consultation with USFWS is triggered for "plants under permit that are genetically engineered to express a pharmaceutical product or which are infected with a virus genetically engineered to express a pharmaceutical." This decision tree described the types of plants and viruses being engineered for such purposes, the types of genetic modifications, the types of information that APHIS requires and reviews, and the conditions under which the agency authorize such field tests. The effects analysis focused on: 1) the potential for outcrossing to a T&E species plant; 2) the potential of the pharmaceutical product to harm a T&E species listed in the county of release based on the level and route of exposure; and 3) the stability, digestibility, toxicity and biological activity of the pharmaceutical protein being produced. APHIS used this decision tree until the agency implemented a new process and Memorandum of Understanding (MOU) in 2007.

Beginning in 2005, APHIS revisited the ESA effects analysis process used to determine whether or not to issue a permit for the release of GE plants and to find ways to further the purposes of the ESA. Similarly, APHIS also reviewed its policy for ESA effects analysis for environmental releases under notification. The primary intent was to determine if it is

[220] See 7CFR § 340.4 and http://www.aphis.usda.gov/biotechnology/guidance.shtml for more information about permits.

possible to describe criteria for environmental releases of GE organisms in such a way that it becomes evident which environmental releases are likely to pose little or no risk to T&E species and critical habitat. If applications for environmental release (under permit and notification) met specific criteria, these applications could receive an expedited effects analysis, while still considering all possible effects to T&E species and critical habitat. APHIS first addressed potential criteria and processes for environmental releases of GE plants and held numerous discussions with USFWS as we worked on these processes, criteria and refinements. As a result, both parties decided that an MOU between APHIS and USFWS would be appropriate; both parties signed the MOU in May 2007.

The MOU (Appendix 4) helped define and clarify policies and procedures APHIS would use for effects determinations for all environmental releases of GE plants under regulation, including plants producing pharmaceutical and industrial compounds, and also for interactions between APHIS and USFWS for ESA consultations. APHIS also uses a modified version of these procedures when evaluating environmental releases of GE organisms other than plants (Article 4 of the MOU).

Petitions for Non-regulated Status

After a developer has sufficient information about a regulated GE organism to demonstrate that the organism is not a plant pest, the developer may submit a petition containing such information (found in 7 CFR § 340.6) to support a "determination of non-regulated status" for the organism. APHIS may determine the GE organism has non-regulated status if it concludes that the GE organism is unlikely to pose a plant pest risk. Once APHIS has determined that the GE organism has non-regulated status under 7 CFR part 340, it may be moved, planted or released into the environment without the requirement of 340 permits/notifications. APHIS may also extend non-regulated status to other GE organisms if it is determined they are similar to organisms previously found to have non-regulated status. APHIS prepares the appropriate NEPA documents (EA or EIS) for these extension and petition processes which includes a T&E species and critical habitat effects analysis. When appropriate, APHIS will also prepare a Biological Assessment and consult with the Services.

For its analysis of effects on T&E plants and critical habitat, APHIS focuses on: the agronomic differences between the regulated article and other varieties of the crop currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing.

For its analysis of effects on T&E animals, APHIS focuses on the implications of exposure to the modified proteins expressed in the plant as a result of the transformation, and the ability of the plants to serve as a host for a T&E species.

6.3 ESA Analyses under the Preferred Alternative and Alternative 3

The major change in regulation under the Preferred Alternative and Alternative 3 is that certain organisms, particularly plants, derived from genetic engineering would be evaluated using an "analyze first" approach. As in other actions under 7 CFR part 340, APHIS would give full consideration to completing an appropriate analysis of effects on T&E species and critical habitat. Procedures and factors used to analyze effects under the current regulations

would be applied to this "analyze first" action, as well as any other regulatory action. APHIS would continue to seek advice and assistance from the Services when necessary and consult when appropriate.

In addition to this "analyze first" approach, there are several types of actions that APHIS may carry out under the Preferred Alternative and Alternative 3 that require ESA consideration once an organism is deemed "regulated" by APHIS. These include:

- Issuance of permits for environmental release, importation, and interstate movement.
- Decisions on requests for determinations of regulatory status.
- Compliance, enforcement and remedial actions.

Below is a description of the categories of regulatory actions and procedures APHIS uses to analyze potential effects on T&E species and critical habitat for each type of action. Note that regulatory actions taken under the proposed rule will not result in any changes to the ESA processes APHIS uses for conducting T&E species effects analyses for similar actions under the current rule. Also, eliminating the notification process under the Preferred Alternative may have a beneficial effect. Under a permit, APHIS could require that the applicant take steps that may benefit T&E species, and APHIS would enforce these supplemental permit conditions. The notification process does not allow for supplemental permit conditions.

It is impossible to predict all species of recipients and donors of genetic material, or phenotypes that may be submitted to APHIS in the future. When necessary, APHIS will work with the Services to assess and improve its ESA evaluation procedures.

6.3.1 How APHIS Evaluates the Effects on T&E Species and Critical Habitat from Regulated Environmental Releases of Genetically Engineered Plants

APHIS has determined, based upon the nature of the recipient plant and inserted genetic material, that the regulated environmental release of many GE plants would have no effect on any T&E species or critical habitat regardless of their presence. APHIS uses the multiple step process described in the 2007 MOU with USFWS to make this 'no effect' determination on a case-by-case basis. Steps include:

1. APHIS determines if the GE plant meets specific exclusionary criteria agreed upon in Article 2 of the MOU (Appendix 4). If the plant meets these criteria, we determine that the environmental release has no effect on T&E species or critical habitat.
2. APHIS further evaluates environmental releases that do not meet these specific criteria using a 4-step process described in Article 4 of the MOU to determine the appropriate level of ESA consultation.

Shortly after the MOU was signed in 2007, APHIS added a step to the ESA review process. APHIS recognized that activities associated with the environmental release of a regulated GE plant, regardless of genetic transformation, may have potential direct or indirect effects on listed species or species proposed for listing by altering their habitat. To analyze these potential effects, APHIS requests site-specific information about the historic use of the

release site and distance from critical habitat. APHIS uses this information to determine if actions associated with the environmental release may affect the baseline habitat of any listed or proposed species as well as designated or proposed critical habitat. If there are any concerns about the activities that take place when conducting the environmental release, APHIS analyzes the effects, and, as needed, consults with the Services. If APHIS determines there are no threats posed by the characteristics of the GE plant, and there are no anticipated effects expected from the activities associated with the environmental release, the agency would determine the action has no effect.

The proposed revisions to regulations under the Preferred Alternative and Alternative 3 do not result in any changes to the ESA effects analysis process APHIS uses to analyze potential effects of regulated environmental releases of GE plants.

6.3.2 How APHIS Evaluates Effects on T&E Species and Critical Habitat from Regulated Environmental Releases of Genetically Engineered Organisms other than Plants

APHIS occasionally receives applications for authorization of environmental releases of non-plant GE organisms that are plant pests, such as insects or microbes, currently representing less than 1% of requests. To analyze the ESA effects of non-plant GE organisms, APHIS uses the decision tree developed for the MOU (Appendix 4), but modified as needed in consideration of the GE organism to be released. For example, the evaluation of an environmental release of a regulated GE insect would consider, among other issues, the sexual-compatibility of the GE insect with T&E insects, potential effects on insect pollinators of T&E plants, or the likelihood that a T&E species may interact with the GE insect. Evaluation of environmental releases of GE microbes would consider the likelihood that the GE microbe may infect T&E species, or if there are indirect effects of the GE microbes in food webs for T&E species (e.g., if the GE microbe may cause disease in a pollinator of a T&E plant). For field releases of non-plant GE organisms, the analysis for the effects on critical habitat is the same as for GE plant releases.

The proposed revisions to regulations under the Preferred Alternative and Alternative 3 do not result in any changes to the ESA effects analysis process APHIS uses to analyze potential effects of regulated environmental releases of GE organisms other than plants.

6.3.3 How APHIS Evaluates Effects on T&E Species and Critical Habitats from Permits for Importation and Interstate Movement

APHIS regulates the importation and interstate movement of regulated GE organisms. APHIS requires that regulated GE material be securely shipped in containers such that the regulated material does not interact with the environment when it is moved interstate or imported. Under the proposed regulations, there will be no changes to this requirement.

Under the current regulations, APHIS requires that permittees follow specific measures, including specific prescriptive packaging requirements, before a regulated GE organism can be imported or moved interstate. Under the proposed regulations, the requirements are performance-based and APHIS will assess them for each permit on a case-by-case basis.

Effects are possible in the event of an unauthorized release during shipment. Evaluation of remedial actions that would take place if this were to occur are described in the next section.

The proposed revisions to regulations under the Preferred Alternative and Alternative 3 do not result in any changes to the ESA effects analysis process APHIS uses to analyze potential effects from the importation and interstate movement of regulated GE organisms.

6.3.4 How APHIS Evaluates Effects on T&E Species and Critical Habitats from Remedial Actions

When an unauthorized release occurs, applicants are required to notify APHIS within 24 hours of the incident or discovery. Once notified, APHIS analyzes the possible effects on T&E species and critical habitat, either due to the GE organism itself, or to the action(s) taken during remediation, and contacts the Services as appropriate. APHIS takes into consideration the characteristics of the GE organism, the engineered trait, and any other information known about the regulated organism. APHIS also factors in the remedial activities associated with the unauthorized release, such as clean-up activities, monitoring activities, and how and where the material will be disposed. The agency uses these factors when defining the action area. If APHIS determines that exposure to the GE organism or any of the activities associated with the action may affect listed and proposed species, designated critical habitat, or habitat proposed for designation, APHIS contacts the Services for advice on measures to minimize the effects of the response. As soon as practicable, APHIS will initiate formal consultation with the Services if listed species or critical habitat have been adversely affected.

The Preferred Alternative and Alternative 3 will not change the process, considerations, or actions that APHIS will use concerning the effect of remedial actions on T&E species and critical habitat.

6.3.5 How APHIS Evaluates Effects on T&E Species and Critical Habitat from Decisions on Regulated/Non-regulated Status

Under current regulations, when a developer of a GE organism that is currently regulated has sufficient information to demonstrate the GE organisms is not a plant pest, it may submit a petition requesting non-regulated status. The basic standard for a determination of non-regulated status of a GE organism has been related to plant pest risk. In the proposed rule, APHIS would apply a similar basic standard, namely, whether the GE organism is unlikely to be a plant pest or noxious weed, when considering and evaluating requests to change APHIS' decision regarding regulatory status of a GE organism. Although APHIS slightly revised the proposed standard, the effects analysis for non-regulated status will remain the same under the proposed rule.

If APHIS determines that a GE organism is unlikely to pose a plant pest risk and determines that the GE organism has non-regulated status, the GE organism could be grown or released anywhere in the United States and its territories. In such instances, the action area for the effects analysis is likely anywhere in the United States and its territories where the organisms can be planted or released. To help facilitate this review process, APHIS, in consultation

with the USFWS, developed a decision tree document to determine when a consultation with the USFWS is appropriate (Appendix 5).

APHIS uses the considerations outlined in the decision tree, along with any other appropriate criteria identified in the request regarding regulatory status, to analyze potential effects to T&E species and critical habitat. Under NEPA, APHIS reviews all petitions for non-regulated status, often through the development of an EA or EIS, along with the appropriate level of public involvement. The NEPA documents include a discussion of possible effects to T&E species and critical habitat.

In certain instances, GE plants may include plant incorporated protectants that have insecticidal properties. In these cases, as part of APHIS' regulatory decision making process, APHIS will also continue to coordinate with EPA, which performs risk-based analyses that evaluate potential effects on T&E species and critical habitat.

The proposed revisions to regulations under the Preferred Alternative and Alternative 3 do not result in any changes to the ESA effects analysis process APHIS uses to analyze potential effects from determining the regulatory status of a GE organism. When necessary, APHIS will work with the Services to identify all relevant concerns and consider them in any effects analysis. APHIS will consult with the Services when reaching a 'may affect' determination to discuss ways of minimizing effects and to ensure that the action does not jeopardize the continued existence of any listed or proposed species or result in the destruction or adverse modification of designated or proposed critical habitat.

6.4 Amendments to the Rule

In the future, if APHIS decides to further amend the rule, APHIS will review the amendment for possible effects it would have on the agency's ability to comply with the ESA. If appropriate, APHIS will consult with the Services on any proposed amendments.

6.5 Effects Determination

In reaching an effects determination for the Preferred Alternative and Alternative 3, APHIS considered all actions that may be taken during application of the rule that could affect T&E species and/or critical habitat. These actions include consideration of: evaluation of GE organisms during the "analyze first" process; issuing permits for environmental release, importation, and interstate movement; remedial actions that may be required; decisions on requests for determinations of regulatory status; and, future amendments to the rule. APHIS has determined that under the current regulations, it has sufficient authority to impose restrictions and take measures sufficient to ensure that, in consultation with the Services, its actions are unlikely to jeopardize the continued existence of a listed or proposed species or result in the destruction or adverse modification of designated or proposed critical habitat.

The proposed revisions to regulations under the Preferred Alternative and Alternative 3 do not differ materially from the existing regulations regarding effects on T&E species and critical habitats. It also does not change the processes APHIS would use to analyze these effects. APHIS will continue to use the processes that they developed over the years in consultation with the USFWS.

Changes to the regulations under the Preferred Alternative and Alternative 3 will enhance APHIS' ability to take measures on individual actions to reduce the potential for effects on listed species and critical habitat and improve compliance with Section 7 of the ESA. These enhancements include:

- Discontinuing the notification process for releases in § 340.2 would improve the ability to comply with the ESA because it will allow APHIS to require permit conditions beyond the approved design protocol system currently used for notifications. Under the permit system, APHIS can require supplemental permit conditions. This change will provide APHIS the flexibility to require actions that may benefit species or habitat and to implement reasonable and prudent measures that the Services request as a result of consultation.
- Changing the container requirements in § 340.8 will provide APHIS greater flexibility to set appropriate requirements rather than develop a general standard, providing APHIS the ability to make container requirements appropriate to the level of risk reducing the possibility of an accidental release that could affect T&E species and critical habitat.

USDA Regulation 9500-004, Fish and Wildlife Policy, states: "Agencies of the Department will not approve, fund or take any action that is likely to jeopardize the continued existence of threatened and endangered species or destroy any habitat necessary for their conservation unless exemption is granted pursuant to subsection 7(h) of the Endangered Species Act of 1973, as amended." In addition to compliance with this policy, APHIS will take steps to identify and, in consultation with the Services, mitigate effects of actions when possible.

It is important to note that the adoption of either the Preferred Alternative and Alternative 3 alone would not result in direct or indirect impacts to T&E species. However, individual decisions made while implementing either alternative could impact T&E species. APHIS will consider these actions appropriately using the current ESA effects analysis process to analyze potential effects on T&E species. If APHIS determines that an action may affect T&E species or critical habitat, APHIS will consult with the Services as required by the ESA.

Considering the sum of the information above, APHIS has determined that revisions to regulations under the Preferred Alternative and Alternative 3 will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, neither consultation under Section 7(a)(2) of the Act nor the concurrences of the Services is required.

7 Federal Statutes, Regulations, Executive Orders, Memoranda, Standards, and Treaties Related to the Proposed Revisions to Regulations

During the planning and implementation of program actions, to include actions authorized under 7 CFR part 340, APHIS must comply with applicable federal statutes, regulations, executive orders (EO), federal memoranda, and international standards and treaties. The most relevant laws, regulations, EOs, standards, and treaties are summarized in the sections that follow.

7.1 Environmental Statutes

The most important and far-reaching environmental statutes considered by APHIS, when analyzing the environmental consequences of it actions, include the National Environmental Policy Act of 1969 (NEPA), the Clean Water Act of 1972 (CWA), the Safe Drinking Water Act of 1974 (SDWA), the Clean Air Act of 1970 (CAA), the Endangered Species Act of 1973 (ESA), and the National Historic Preservation Act of 1966 (NHPA).

7.1.1 The National Environmental Policy Act

During planning and implementation of its programs and actions, APHIS complies with NEPA, the regulations promulgated for NEPA by the Council on Environmental Quality (CEQ), and the USDA APHIS NEPA implementing regulations. NEPA is designed to ensure transparency about possible environmental effects of federal actions prior to implementation. It requires federal agencies to document, in advance and in detail, the effects of their actions on the human environment to ensure that there is a complete understanding of possible environmental impacts of federal actions by both the decision-makers and the public. For proposed actions, federal agencies must evaluate and document:

- the significance of possible and actual environmental impacts that may result;
- unavoidable adverse effects that may result;
- alternatives to proposed actions; the relationship between local and short-term uses of the human environment versus the maintenance and enhancement of long-term productivity; and
- any irreversible and irretrievable resources that will be committed if they are implemented.

NEPA and its associated regulations provide guidance about how to: identify the environmental components that may be affected by proposed actions; analyze and evaluate the significance of the effects identified; and identify the practices that must be used to obtain and ensure public involvement. This draft programmatic environmental impact statement (dPEIS) is prepared specifically to comply with the requirements of NEPA (42 United States Code (U.S.C) 4321, et seq.).

7.1.2 The Endangered Species Act

Threatened and endangered (T&E) species are plants and animals at risk of becoming extinct throughout all or part of their geographic ranges (endangered species) or species likely to become endangered in the foreseeable future throughout all or a significant portion of their ranges (threatened species). Species can be listed under the ESA, or under parallel state laws, or both. To date, no direct or indirect adverse effects on T&E species, species proposed for listing, or designated critical habitats have been identified as resulting from regulatory decisions made by APHIS for genetically engineered (GE) organisms it regulates under 7 CFR part 340.

Compliance with the ESA requires an analysis of the impact of federal programs and actions upon listed species. Federal agencies that propose programs and actions that could have an effect on T&E species that are listed or proposed to be listed, or on designated or proposed critical habitat must prepare biological assessments (BAs). A BA analyzes potential effects and describes any protective measures an agency proposes to use to protect affected species and/or their habitats. The findings of a BA are submitted for review by the U.S. Department of Interior, Fish and Wildlife Service (FWS) and/or the U.S. Department of Commerce, National Marine Fisheries Service (NMFS). This review is followed by a consultation process between the participating agencies; this consultation formalizes limitations on allowable effects on T&E species, and establishes protective measures to mitigate effects.

APHIS' determinations of non-regulated status for a GE plant may result in it being planted without any restrictions anywhere in the United States. APHIS will consult with the FWS and/or the NMFS if Agency regulatory actions under 7 CFR part 340 (whether revised in accordance with one of the proposed Alternatives or not [no-action alternative]) affect T&E species. In certain instances, GE plants may include plant incorporated protectants that have insecticidal properties. In these cases, as part of the Agency's regulatory decision-making process, APHIS will also continue to coordinate with the EPA, which performs risk-based analyses that, in part, evaluate possible effects on T&E species. Additional discussion about APHIS' compliance with the ESA is located in Chapter 6.

7.1.3 The Clean Air, Clean Water, and Safe Drinking Water Acts

The CAA, CWA, and SDWA are environmental statutes that authorize the EPA to regulate discharges of pollutants to air and water. APHIS will continue to consider and evaluate possible effects of regulatory decisions under the proposed revised regulations of 7 CFR part 340, and consult and coordinate with the EPA, when necessary, to ensure compliance with all federal statutes governing air quality, and ground and surface waters.

7.1.4 National Historic Preservation Act

The National Historic Preservation Act of 1966 (NHPA) and its implementing regulations (36 CFR 800) require federal agencies to determine whether activities they propose constitute undertakings that have the potential to cause effects on historic properties. If they do, agencies must evaluate the effects of such undertakings by consulting with the appropriate persons and/or organizations as defined by the Act (i.e., State Historic Preservation Officers, Tribal Historic Preservation Officers, the Advisory Council on Historic Preservation, etc.).

APHIS will continue to consider and evaluate possible effects of regulatory decisions authorized under the proposed revised regulations of 7 CFR part 340 on historic properties, and consult and coordinate with the appropriate governing authorities of sites affected, as needed to ensure NHPA compliance.

7.1.5 The Regulatory Flexibility Act of 1980

The Regulatory Flexibility Act of 1980 requires federal agencies to review regulations for their impact on small businesses, small organizations, and small governmental jurisdictions, and consider less burdensome alternatives. In compliance with these requirements, APHIS conducted a Regulatory Impact Analysis (RIA) and Initial Regulatory Flexibility Analysis of the proposed rule and Alternatives (USDA-APHIS 2016c).

7.1.6 Other Environmental Statutes

APHIS considers and complies with the regulations of several other environmental statutes, including the following:

- Migratory Bird Treaty Act
- Bald and Golden Eagle Protection Act
- Federal Insecticide, Fungicide, and Rodenticide Act
- Toxic Substances Control Act
- Resource Conservation and Recovery Act
- Comprehensive Environmental Response, Compensation, and Liability Act of 1980
- Food Quality Protection Act

APHIS will continue to consider and evaluate possible effects of regulatory decisions authorized under the proposed revised regulations of 7 CFR part 340 with respect to these laws and to all state statutes corresponding to these laws.

7.2 Executive Orders and Memoranda

7.2.1 Memoranda

Memorandum for Heads of Food and Drug Administration, Environmental Protections Agency, and Department of Agriculture - Modernizing the Regulatory System for Biotechnology Products, July 2, 2015: The White House Office of Science and Technology Policy (OSTP), Office of Management and Budget (OMB), the U.S. Trade Representative, and CEQ issued this memorandum (memo) in 2015, directing the three federal agencies with jurisdiction over products of biotechnology, the EPA, FDA, and USDA to update the Coordinated Framework. The memo initiated a process whereby agencies will (1) clarify EPA, FDA, and USDA roles and responsibilities in the regulation of products of biotechnology; (2) formulate a long-term strategy to ensure that the federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and

predictability, and reducing unnecessary costs and burdens; and (3) commission an external, independent analysis of the future landscape of biotechnology products.

7.2.2 Executive Orders

EOs issued by the U.S. President have the force of law, and are generally used to direct federal agencies in their execution of congressionally established statutes or U.S. policies. As part of APHIS's revision of 7 CFR part 340, there are several EOs that require consideration during the decision-making process, as well as in implementation of any revised 7 CFR part 340. Applicable EOs are summarized in the following sections.

EO 12866 – Regulatory Planning and Review and EO 13563 – Improving Regulation and Regulatory Review: EOs 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). EO 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. In compliance with these requirements, and in addition to this dPEIS, APHIS conducted a Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the proposed rule and Alternatives (USDA-APHIS 2016c).

Executive Order 12988 - Civil Justice Reform: This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All state and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court.

EO 12898 - Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations: This was the first major federal action on environmental justice in the United States and requires federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income populations, and federally recognized Indian tribes from being subjected to disproportionately high and adverse human health or environmental effects.

EO 13045 - Protection of Children from Environmental Health Risks and Safety Risks: Children may be disproportionately, relative to adults, more sensitive to environmental health and safety risks because their neurological, immunological, digestive, and other bodily systems are still developing. This EO, to the extent permitted by law and consistent with the agency's mission, requires each federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

Currently, the EPA is proposing to revise the existing Worker Protection Standard, at 40 CFR part 170, to reduce the incidence of occupational pesticide exposure and related illness among agricultural workers (workers) and pesticide handlers (handlers) covered by the rule. The EPA is proposing to strengthen the protections provided to agricultural workers and

handlers under the Worker Protection Standard by improving elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies.

The EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public. This regulation, in combination with other components of EPA's pesticide regulatory program, is intended to prevent unreasonable adverse effects of pesticides among pesticide applicators, workers, handlers, the general public, and vulnerable groups, such as minority and low-income populations.

EO 13175 - Consultation and Coordination with Indian Tribal Governments: Executive departments and agencies are charged with engaging in consultation and collaboration with Indian tribal governments; strengthening the government-to-government relationship between the United States and Indian tribes; and reducing the imposition of unfunded mandates upon Indian tribes. The EO emphasizes and pledges that federal agencies will communicate and collaborate with representatives of all potentially affected U.S. tribal lands on matters related to domestic issues of proposed federal actions.

APHIS has assessed the potential impact of the proposed rule on tribes and determined that the proposed rule does have tribal implications that require tribal consultation under E.O. 13175. If a tribe requests consultation, APHIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

EO 13112 - Invasive Species: Invasive species are a significant issue in the United States, causing both adverse economic and environmental impacts. This EO directs federal agencies to use their programs and authorities to prevent the spread or to control populations of alien species that cause economic or environmental harm, or harm to human health.

EO 13186 - Responsibilities of Federal Agencies to Protect Migratory Birds: Federal agencies taking actions with a measurable negative effect on migratory bird populations are directed by EO 13186 to develop and implement a Memorandum of Understanding (MOU) with the FWS that promotes the conservation of migratory bird populations. On August 2, 2012, APHIS and FWS signed a MOU to facilitate the implementation of this EO.

7.3 International Standards and Treaties

Regulatory authorities and phytosanitary practices in the United States and other countries will continue to be applied under the proposed revised version of 7 CFR part 340. Any international trade in organisms developed using biotechnology will continue to be fully subject to national phytosanitary requirements of the country of import. Importing countries will continue to apply their regulatory procedures, which typically include risk or safety assessments pertaining to human and animal food, and the environment.

7.3.1 World Trade Organization: The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

The United States is a member of the World Trade Organization (WTO), which deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably, and freely as possible. The Agreement on the Application of Sanitary and Phytosanitary Measures (1995), also known as the "SPS Agreement," is a subsidiary agreement under the WTO. Under the SPS agreement, the WTO sets the rights and responsibilities on members' measures. These relate to impacts of international trade on food safety concerns (e.g., bacterial contaminants, pesticide residues, inspection, and labelling practices). They also relate to animal and plant health issues (e.g., risk of importing pests and diseases). One of the primary objectives of the SPS Agreement is to minimize impacts of SPS measures on trade, while recognizing the rights of member countries to protect their interests (plant, animal, human health). Regulations governing importation of organisms developed through biotechnology are considered SPS measures. Annex B of the SPS Agreement, entitled, "Transparency of Sanitary and Phytosanitary Regulations," includes a WTO notification procedure whereby countries will inform and answer questions from other member countries about changes to regulations. APHIS will notify the WTO about proposed revisions to 7 CFR part 340 consistent with the requirements of the Agreement.

The SPS agreement recognizes three international organizations/frameworks that have established standards and guidelines related to SPS measures including the Codex Alimentarius Commission (food safety), World Organization for Animal Health (OIE) (animal health and diseases), and the International Plant Protection Convention (IPPC) (plant health).

7.3.2 World Trade Organization: International Plant Protection Convention (IPPC)

The IPPC is the standard-setting organization for plant health for the WTO's SPS Agreement. The United States and 181 other contracting parties currently adhere to the IPPC. The stated objective of the IPPC is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control (IPPC, 2010). The IPPC is designed to protect natural flora and plant products from damage caused by weeds, and direct and indirect injury from pests.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention. In April 2004, a standard for pest risk analysis of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard (International Standard for Phytosanitary Measures No. 11 [ISPM-11], Pest Risk Analysis for Quarantine Pests). The standard acknowledges that not all LMOs present a pest risk, and recognizes the importance and need for swift pest risk analyses of LMOs proposed for importation. APHIS' pest risk assessment procedures for GE organisms are consistent with this guidance, and will remain so if 7 CFR part 340 is revised as proposed.

7.3.3 International Venues Related to Biotechnology Information Exchange in Support of Harmonization

U.S. exporters must comply with the importing countries' regulations pertaining to biotechnology; therefore, harmonization of such regulations supports international trade. Regulations are applied in the context of multiple factors, including laws and other regulations, trade agreements, and other international agreements and arrangements to which a country is party. APHIS continues to promote harmonization of biosafety and biotechnology policies through development of technical consensus documents and guidelines within the Organization of Economic Cooperation and Development (OECD), specifically the Working Group on the Harmonization of Regulatory Oversight in Biotechnology. The mission of the OECD is to promote policies that will improve the economic and social well-being of people around the world. Governments of 34 democracies with market economies work with each other, as well as with more than 70 non-member economies, including developing countries, to promote economic growth, prosperity, and sustainable development. The United States is a member of the OECD. The objective of the Working Group on Harmonization of Regulatory Oversight in Biotechnology is to ensure that the information used in environmental risk/safety assessment of organisms developed using modern biotechnology, as well as the methods used to collect such information, is as similar as possible among countries. This is to improve mutual understanding, increase the efficiency of environment risk/safety assessment, avoid duplication of effort and reduce barriers to trade. As an active member of the OECD Working Group, APHIS has continued to promote harmonization of biotechnology practices and policies, and will continue to do so under the revised 7 CFR 340.

8 Glossary

A

Agent: A person who is authorized to act on behalf of the responsible person to maintain control over a regulated organism during its movement and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States.

Animal and Plant Health Inspection Service (APHIS): An agency within the United States Department of Agriculture. APHIS protects and promotes U.S. agricultural health, regulates genetically engineered organisms, administers the Animal Welfare Act, and carries out wildlife damage management activities.

B

Bald and Golden Eagle Protection Act: The Act prohibits anyone, without a permit issued by the Secretary of the Interior, from "taking" bald eagles, including their parts, nests, or eggs. The Act provides criminal penalties for persons who "take, possess, sell, purchase, barter, offer to sell, purchase or barter, transport, export or import, at any time or any manner, any bald eagle ... [or any golden eagle], alive or dead, or any part, nest, or egg thereof." The Act defines "take" as "pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb."

Best Management Practices (BMPs): A collection of effective measures that provide protection of environmental resources during land management activities.

Biodiversity: Refers to the variety and abundance of biota and their functions in ecosystem dynamics. In an agricultural setting, growers are concerned with biodiversity to the extent that it supports species conducive to crop production. Such species include pollinators (i.e., bees and butterflies), species that control insect pests (i.e, beneficial avian species), and some members of the plant community.

Bioenergy: Renewable energy derived from biological resources, primarily plants.

Biotechnology: Laboratory-based techniques to create or modify a genome that result in a viable organism with intended altered phenotypes. Such techniques include, but are not limited to, deleting specific segments of the genome, adding segments to the genome, directed altering of the genome, or direct injection and cell fusion beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers.

Buffer Zone: An area of land that lies between two other areas of land. The middle area of land serves to provide distance between the two sites to protect against potential environmental impacts, or conflicts that may arise from different uses. Buffer zones are used to isolate GE, conventional, and organic cropping systems.

C

Clean Air Act: The Clean Air Act (CAA) is the comprehensive federal law that regulates air emissions from stationary and mobile sources. Among other things, this law authorizes EPA to establish National Ambient Air Quality Standards (NAAQS) to protect public health and public welfare and to regulate emissions of hazardous air pollutants.

Clean Water Act: The Federal Water Pollution Control Act of 1948 was the first major U.S. law to address water pollution. Growing public awareness and concern for controlling water pollution led to sweeping amendments in 1972. As amended in 1972, the law became commonly known as the Clean Water Act (CWA). The CWA established the basic structure for regulating pollutant discharges into the waters of the United States.

Comprehensive Environmental Response, Compensation, and Liability Act: Commonly known as Superfund, was created a tax on the chemical and petroleum industries and provided broad federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment.

Contained Facility: A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the enclosed organisms. Examples include laboratories, growth chambers, fermenters, and containment greenhouses.

Conventional Tillage: A tillage system using disking, plowing, and other means for seedbed preparation and weed control. Conventional tillage is the most intensive form of tillage, leaving less than 30 percent ground cover. Residue burning after harvest is common. Conventional tillage produces the most runoff and erosion.

Cumulative Effects (with respect to ESA): The ESA defines cumulative effects as effects from future state or private activities -- not involving federal activity -- that are reasonably certain to occur within the area of the federal action.

D

Direct Effects (with respect to ESA): Direct effects are immediate. An example of a direct effect would be the clearing of woodland to plant a GE row crop in an area known to have a listed species that would find the original habitat suitable.

Disturb (Bald and Golden Eagle Protection Act): Any activity that can result in injury to an eagle or cause nest abandonment or decrease in productivity by impacting breeding, feeding, or sheltering behavior.

E

Endangered Species Act (ESA): Provides for the conservation of species that are endangered or threatened throughout all or a significant portion of their range, and the conservation of the ecosystems on which they depend.

Environmental Impact: Any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organization's activities, products or services.

Eutrophication: Excessive nutrients in a body of water which causes a over-growth of plant life; typically in reference to algae. Subsequently, over-growth of plant life can result in a reduction or depletion of dissolved oxygen in water bodies, adversely affecting fish, invertebrates, and other aquatic biota.

Executive Orders: Issued by the President, have the force of law, and are generally used to direct federal agencies in their execution of congressionally established statutes or U.S. policies.

F

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): The federal statute that governs the registration, distribution, sale, and use of pesticides in the United States.

Federal Register: A daily publication of the U.S. federal government that issues proposed and final administrative regulations of federal agencies.

Field Testing/Trial: To test GE organisms in the environment in which it will be used.

Food and Agriculture Organization (FAO): An agency of the United Nations that leads international efforts to defeat world hunger.

Food Quality Protection Act (FQPA): The FQPA standardized the way the Environmental Protection Agency (EPA) would manage the use of pesticides and amended the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food Drug and Cosmetic Act.

Fuel Crops: A crop used to produce biofuels.

G

Genetic Engineering: Techniques that use recombinant or synthetic nucleic acids to create or modify a genome. For the purposes of this dPEIS, genetic engineering does not include traditional breeding techniques (including marker-assisted breeding) or chemical or irradiation-based mutagenesis.

Genetically Engineered Organism (GE organism): An organisms developed using genetic engineering.

Greenhouse Gas: Emitted from natural processes and human activities and consist of water vapor, carbon dioxide, methane, nitrogen oxides, ozone, and chlorofluorocarbons.

Ground Water: The supply of freshwater found beneath the Earth's surface (usually in aquifers), which often supplies drinking wells and springs. Because ground water is a major source of drinking water, there is growing concern over areas where leaching agricultural or

industrial pollutants or substances from leaking underground tanks are contaminating ground water.

H

Herbicide Resistant Weeds: The inherent ability of a weed to survive and reproduce after herbicide treatment.

I

Import (importation): To move into, or the act of movement into, the territorial limits of the United States.

Indirect Effects (with respect to ESA): Are caused by or resulting from the proposed action and are later in time, but are still reasonably expected to occur. An example would be the release of a plant genetically engineered to produce a pesticide in an area of a susceptible species that is preyed upon by a listed species also known to be in the area.

Inspection: An official visit to a farm by a person who possesses sufficient specific education, training, and experience in order to ensure compliance with all relevant provisions of the regulations, including authorizations under the permitting and notification procedures.

Inspector: Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

Interdependent Effects (with respect to ESA): Interdependent effects result from actions having no independent utility apart from the proposed action. An example would be the construction of a facility to process a plant that is genetically engineered to produce proteins of pharmaceutical interest.

Interrelated Effects (with respect to ESA): Interrelated effects result from an action that is part of a larger action and depend on the larger action for their justification. An example would be the construction of an access road to the release site of a GE organism, where the construction of the roadway affects habitat suitable for a listed species known to be in the area.

Interstate: From one state into or through any other state or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Interstate Movement: To move from one state, territory, or possession of the United States to another. The use of any means of conveyance or facility in connection with the movement of regulated organism.

Isolation Distances: The minimum separation required between two or more varieties of the same species for the purpose of keeping seed pure.

L

Livestock: All farm-raised animals, including poultry and fish.

M

Microorganism: Living organisms, usually so small that individually they only can be seen through a microscope.

Migratory Bird Treaty Act (MBTA): Is a United States federal law for the protection of migratory birds between the United States and Canada. The Act makes it illegal for anyone to take, possess, import, export, transport, sell, purchase, barter, or offer for sale, purchase, or barter, any migratory bird, or the parts, nests, or eggs of such a bird except under the terms of a valid permit issued pursuant to federal regulations.

Move (moving, movement): To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.

Mycotoxin: Any toxic substance produced by a fungus.

N

National Ambient Air Quality Standards (NAAQS): Standards established by EPA under the Clean Air Act. The standards provide protection to public health, including "sensitive" populations such as asthmatics, children, and the elderly. The standards also provide protection against decreased visibility and damage to animals, crops, vegetation, and buildings.

National Environmental Policy Act (NEPA): A United States environmental law that promotes the enhancement of the environment and established the President's Council on Environmental Quality (CEQ).

National Historic Preservation Act (NHPA): Legislation intended to preserve historical and archaeological sites in the U. S. The National Historic Preservation Act of 1966 (NHPA) and its implementing regulations (36 CFR 800) require federal agencies to determine whether activities they propose constitute undertakings that have the potential to cause effects on historic properties.

National Pollution Discharge Elimination System (NPDES) Permits: Permits granted by EPA or individual States that control regulated point source discharge into waters of the United States.

Noxious Weed: Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Nucleic Acid: Long chains of nucleotides that comprise DNA and RNA. Each nucleotide consists of a nitrogen-containing base (adenine (A), guanine (G), cytosine (C), thymine (T), and uracil (U)) attached to five-carbon sugar, which is in turn attached to a phosphate group.

P

Pathogen: A bacterium, virus, or other micro-organism that can cause disease.

Permit: A written authorization, including by electronic methods, by the Administrator to move regulated organisms and associated articles under conditions prescribed by the Administrator.

Pesticide: With certain exceptions, a pesticide is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, or desiccant, or any nitrogen stabilizer.

Plant: Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed.

Plant Pest: Any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

Plant Pest Risk Assessment: An assessment evaluating whether a GE organism is a plant pest.

Plant Product: Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of a plant or any manufactured or processed plant or plant part.

Plant Protection Act of 2000 (PPA): Provides APHIS authority to issue regulations that serve to prevent or mitigate plant health risks, including those presented by a wide array of plant pests and noxious weeds.

Product of Biotechnology: An organism developed using biotechnology.

R

Recipient Organism: The organism whose nucleic acid sequence will be altered through the use of genetic engineering.

Records: A piece of evidence in writing or some other permanent form about a regulated organism that was imported or moved interstate under a permit.

Regulated Organism: Any GE organism that is regulated pursuant to 7 CFR § 340.0. This definition would replace the definition of "regulated article."

Regulatory Flexibility Act: An act which require federal agencies to review regulations for their impact on small businesses, small organizations, and small governmental jurisdictions, and consider less burdensome alternatives.

Regulatory Sequence: A sequence of nucleic acids capable of increasing or decreasing the expression of specific genes within an organism.

Release into the Environment (Environmental Release): The use of a regulated organism outside the constraints of physical confinement that are found in a contained facility.

Reporting: Regarding any activities associated with environmental release of a regulated organism is a general permitting condition.

Resource Conservation and Recovery Act (RCRA): The Resource Conservation and Recovery Act (RCRA) gives EPA the authority to control hazardous waste from the "cradle-to-grave." This includes the generation, transportation, treatment, storage, and disposal of hazardous waste. RCRA also set forth a framework for the management of non-hazardous solid wastes.

Responsible Person: The person who has control and will maintain control over a regulated organism during its movement and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part.

S

Secondary Pollutant: Caused by a chemical reaction between two primary pollutants forming nitrate and sulfate compounds.

Secure Shipment: Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

Soil Biota: A collective term that encompasses all the organisms that spend a significant portion of their life cycle within a soil profile, or at the soil-litter interface.

State: Any of the several states of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, the Virgin Islands of the United States, or other Territories or possessions of the United States.

Tribal or State Regulatory Official: Officials with responsibilities for plant health, or any other duly designated state or Tribal official, in the state or on the Tribal lands where the importation, interstate movement, or environmental release is to take place.

T

Take: To “pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb” [Bald and Golden Eagle Protection Act].

Threatened and Endangered (T&E) Species: Plants and animals at risk of becoming extinct throughout all or part of their geographic ranges (endangered species) or species likely to become endangered in the foreseeable future throughout all or a significant portion of their ranges (threatened species).

Tillage: A fundamental method by which growers prepare land to control weeds and aerate soil.

Toxic Substances Control Act (TSCA): The Toxic Substances Control Act of 1976 provides EPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides.

W

Watershed: An area of land that contributes water to a river or stream.

Weed: Any plant growing where it is not wanted; particularly plants that tend to overgrow or outcompete more desirable plants. Weeds can be native or non-native, invasive or noninvasive, and noxious or not noxious.

Weed Risk Assessment (WRA): An assessment to evaluate whether a GE plant is a noxious weed.

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Appendix 1: Stakeholder Meetings and Public Outreach

In a stakeholder message sent on February 27, 2015, and a Federal Register notice published on March 4, 2015, APHIS announced the withdrawal of its 2008 proposed rule that would have amended 7 CFR part 340, and plans for new stakeholder engagement regarding APHIS regulation of GE organisms.

Stakeholder engagement and outreach began in April 2015 when APHIS announced the opportunity for stakeholders and the public to provide initial feedback with written comments on the future of biotechnology regulation during a 90-day public comment period. APHIS sought input on the following questions:

1. Should APHIS regulate based on the characteristics of biotechnology products and the potential risks they may pose, or by the process by which they were created? In either case, what criteria should be used to determine what APHIS regulates? Are there products and processes APHIS should not regulate?

2. The Plant Protection Act gives APHIS the authority to protect plant health through regulatory programs. APHIS has implemented the plant pest authority as part of their biotechnology regulations. Should APHIS add noxious weed provisions to their to biotechnology regulations and if so, how? What protection goals should APHIS consider?

3. Are there legal authorities given to USDA outside the Plant Protection Act that APHIS should examine to regulate or oversee the products of biotechnology? What are they, and how would they be used?

4. What non-regulatory solutions or policy alternatives could or should be considered to complement APHIS's regulatory program?

APHIS received 196 submissions representing over 220,000 public commenter. A variety of stakeholders provided comments, including non-governmental organizations, trade associations, industry, and the academic community. The comments received on this docket (APHIS-2015-0036) are available at https://www.regulations.gov/docket?D=APHIS-2015-0036.

Verbal comments were also taken during a series of webinars APHIS held during May 2015. The May 2015 public meeting documents, recordings, and transcripts are publicly on APHIS' website.[221] APHIS-BRS met with developers, trade associations, and non-governmental organizations from September to December 2015 to discuss the proposed revisions to 7 CFR part 340. On November 18, 2015, APHIS-BRS held its annual stakeholder meeting where a question and answer session took place on a the proposed new rule that APHIS is currently considering and subject of this dPEIS. As part of the stakeholder meeting, APHIS-BRS leadership held 8 one-on-one meetings with stakeholders to continue to answer questions.

[221] May 2015 Public Meeting Documents, Recordings and Transcripts: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/6_documents

Transcripts and related materials from the 2015 stakeholder meeting are also available on the APHIS website.[222]

As described in Chapter 2, on February 5, 2016, APHIS-BRS published a notice in the Federal Register to inform stakeholders and the public of its plan to develop and publish this dPEIS. The notice also provided more information on the alternatives that was considering for analysis in this dPEIS, as well as other issues.

APHIS sent a letter to Tribal leaders (dated February 8, 2016) informing them of the NOI. APHIS-BRS held two Tribal Nations conference calls on February 26 and March 22, 2016 to provide information and answer questions regarding the development of this dPEIS. It is APHIS' intention to further communicate publication of the proposed rule and dPEIS to Tribes during the rulemaking process.

[222] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/stakeholder-meetings/brs+2015+stakeholder+meeting

Appendix 2: Public Comments – NOI

Members of the public were invited to participate in the scoping process for this dPEIS through an announcement of a notice of intent (NOI) to prepare a programmatic environmental impact statement (EIS), which was published in the Federal Register (FR) (Federal Register, Vol. 81, No. 24, p. 6225, Friday, February 5, 2016). The notice solicited public involvement in the form of written comments, which were accepted on an extended public comment period through April 21, 2016. APHIS received 125 submissions from the public, including 2 petitions with 11,693 and 20,271 signatures, respectively, and a collection of nearly 9,644 form letters. The submissions were from individuals from academic organizations (14), professional organizations (5), trade groups (33), industry (11), NGOs (20), and unspecified individuals (42). Full text of the comments are available online at: https://www.regulations.gov/#!docketDetail;D=APHIS-2014-0054.

Representative comment excerpts are listed below and grouped into the following subject areas:

- Biotechnology Definition
- Review Criteria
- General Considerations/Process
- Noxious Weed Authority
- Weed Risk Assessment
- Exceptions/Exemptions
- Permits
- Elimination of Notifications and Petitions
- Regulation of Plant Made Pharmaceutical and Industrial Compounds (PMPI)
- NEPA
- Communication and Transparency
- Issues to be analyzed in the dPEIS
- Alternatives considered in revision of 7 CFR part 340

Biotechnology Definition

1. Broad definitions for biotechnology, product of technology and regulated organisms are needed to ensure adequate regulation.
2. Biotechnology definition should not exclude chemical and radiation mutagenesis.
3. All breeding methods need to be treated equally. If biotech crops need to undergo special regulation, so should mutagenic crops and artificially selected ones. All have the same risks involved. Regulate all or none.
4. Simple genome editing, as defined in this APHIS Notice of Intent as gene edits resulting in "nucleotide deletions, single base pair substitutions or other modifications that could

reasonably be expected to be obtained through mutagenic techniques," should not be included in the definition of biotechnology.

5. APHIS should use genetic engineering as the trigger for APHIS regulation. APHIS should regulate all GE organisms as posing potential "plant pest risks" or "noxious weed risks" so all products of biotechnology are regulated organisms. "Genetically engineered" means produced from an organism or organisms in which the genetic material has been changed through the application of: Vector-based recombinant deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) techniques; direct introduction of DNA or RNA into cells, protoplasts, or organelles; or other in vitro nucleic acid techniques. For the purposes of this definition, "in vitro nucleic acid techniques" means preparation of DNA or RNA outside of organisms and then introduction of the prepared nucleic acid into a recipient cell, protoplast, organelle or organism in such a way that the genetic material of the recipient is changed.
6. The APHIS proposed definition for "regulated organism" should be an "organism developed using biotechnology," deleting the rest of the proposed definition. The APHIS proposed definition of "regulated organism" would allow the agency not to conduct the detailed EIS required to understand the "ecological consequences of a gene drive," to say nothing of the documented and potential off-target effects alterations of the genome and gene regulation.
7. Several commenters suggested using the definition of modern biotechnology from Cartagena Biosafety Protocol under the Convention on Biological Diversity and adopted in Codex Alimentarius. A new APHIS definition also runs counter to the current internationally accepted definition developed through the Codex Alimentarius Commission.
8. Commenters objected to the phrase Laboratory based techniques to create or modify a genome, create additional genomes" in the definition of biotechnology because it overlapped with techniques safely used in traditional breeding for decades and even in varieties grown under the organic standard. For example, dihaploid or tetraploid plants generated by colchicine treatment are used in many carrot, cabbage, cucumber, eggplant, pepper, and seedless watermelons. Embryo rescue is used in wide crosses. Other techniques that could be interpreted to fall under the regulation include somatic embryogenesis and protoplast fusion. Marker assisted breeding might fall under the definition but is not an excluded method in organic production. The proposed change in the definition will create confusion for the public and jeopardize the acceptance of non-GE products by the consumer.
9. Commenters objected to the phrase "intended altered phenotypes" as though it differs from a similar mutation made by unintended alteration as happens in mutagenesis. They raised the question whether the regulation would apply to one and not the other.
10. The fact that regulations apply to certain products of biotechnology but not to the identical organism created by a "traditional" method falsely suggests that the practice of biotechnology has an inherent impact on the risk assessment.
11. The definition is process, not risk based. It should be product based and regulation should extend to any product that poses a risk independent of how it was created.
12. The definition leaves open the possibility that other techniques might be considered creating uncertainty.

13. On what basis is the taxonomic family considered to be a significant limit for the use of genetic diversity the implication being that taxonomic limits as proposed here to be politically rather than biologically based.
14. To create a broad definition and then state that it does not include what it clearly does encompass is arbitrary and confusing.
15. Limit the scope of the proposed legislation to plants in which their genetic material has been altered beyond what is possible naturally by mating or natural recombination. This can either be achieved by using a definition of biotechnology that also contains criteria for the end product and is not based on a purely process-based regulatory trigger. Another possibility is to have a rather wide general scope of the legislation, but introduce specific exemptions.
16. The term "biotechnology product" means a plant (A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding.
17. The definition of biotechnology should be limited to transgenes to enable gene editing techniques and cisgenics and to promote public acceptance of organisms modified with these techniques.
18. A broad definition of biotechnology will stifle innovation in medium and small companies
19. "Biotechnology" equals Genetically Modified (GM), Genetically Modified Organism (GMO), and Genetically Engineered (GE). Any attempt to re-define the term will be complicated and lead to confusion, as the current consumer understanding of the term is widespread.
20. APHIS's proposed new definition of biotechnology could significantly complicate oversight of microbes by further expanding oversight into areas already adequately covered by one (or more) APHIS and EPA programs. This overly expansive definition of laboratory-based techniques would regulate nearly every microbial agricultural product regardless of the phenotype or lack of risk to plant health or the environment. Microorganisms that are plant pests or biocontrol agents, including those developed by gene editing, are already regulated by PPQ under 7 CFR Part 330. Therefore, the plant pest risks of any agricultural microorganism are already being addressed. Certain GE and other microorganisms are subject to regulation for non-plant pest related risks by several other agencies, such as EPA, CDC, and other programs in APHIS, such as Veterinary Services. It appears that this NOI is intended to address GE crops rather than microorganisms (GE or non-GE). For example, it is unclear how Alternative 3 relates to microorganisms.
21. It is not necessary for APHIS to define "biotechnology" or "products" thereof to define what is or is not a regulated article. The PPA provides very clear instruction on what organisms they have regulatory authority over, being plant pests and noxious weeds. APHIS can and must continue to regulate the introduction and movement of any organism that *is* a plant pest, whatever its origin, and of any organism that *is* a noxious weed by adding it to the federal noxious weed list and including it in its oversight
22. To avoid duplicate regulation, clarify APHIS's jurisdiction over biological control organisms subject to regulation by USDA under part 340 vs Part 330 and by EPA under FIFRA.

23. We are also concerned that APHIS applies a heavy regulatory burden on biotechnology techniques which are used to make a microbial strain safer and serve to protect health and the environment
24. Biotechnologically-Derived Genetically Modified Organisms are "Organisms derived from somatic cell fusion or direct insertion of a gene construct, typically but not necessarily from a sexually-incompatible species, using recombinant DNA techniques and any genetic transformation technology."
25. We note that there are potential problems in applying the new potential definitions to all four of the regulatory alternatives under consideration. First, it appears that the new definitions cannot be applied to the first alternative (the No Action Alternative), as they are not all used in current APHIS regulations. Secondly, the definition of "regulated organism" appears to be most closely aligned with the two-step process set forth in Alternative 2 (analysis first, followed by determination to regulate), but it is harder to see how this definition is consistent with Alternatives 3 and 4, which do not appear to include such a process. Finally, biotechnology-specific definitions seem to be inconsistent with Alternative 4, as the process by which the products have been developed appears to have no bearing on the decision to regulate under existing plant pest and noxious weed regulations (7 CFR parts 330 and 360).

Review Criteria

1. The APHIS proposal explicitly abandons the risk-based trigger for oversight codified in the regulations at 7 CFR 340 adopted in 1987 and revised in 1992, replacing it with a trigger that is undeniably process-based. Such a move is explicitly foreclosed under the Coordinated Framework and would entail abandoning its bedrock virtue of being science based. APHIS does not have the independent authority so profoundly and unilaterally to depart from the ruling policy laid out in the 1986 Coordinated Framework and reaffirmed by OSTP in 2015.
2. A new plant variety should undergo regulatory review by APHIS if;
    a. There is stable gene insertion into the host plant; and
    b. There is no sexual compatibility between the host plant and donor organism; and
    c. The same result can only be achieved via biotechnology (as we have defined above). Under this alternative set of criteria, only biotechnology products with traits that go *beyond* the range and variability found in nature or able to be produced through the breeding of new plant varieties will meet the regulatory review criteria and be assessed for plant pest or noxious weed risk.
3. APHIS Should Propose a Regulatory Program that Regulates GE Organisms Based on Science- and Risk-Based Criteria and Not Whether a GE Organism is a Potential Plant Pest or Noxious Weed. The process of the GE seed developer collecting data on whether the crop is a plant pest, submitting a petition for non-regulated status, and APHIS granting the petition is a waste of time and resources by the developer, APHIS, and the interested public. As APHIS considers how best to regulate the potential risks that might arise from certain GE organisms, it would be best to establish a system that is science- and risk- based. Under such a system, the potential risk of the particular GE product would determine if it is regulated, not whether it meets a narrow or broad reading of a "plant pest" or a "noxious weed." a better regulatory system for GE crops would be to assess whether the product could have impacts to the

environment or agricultural interests (such as development of resistant weeds) and determine, based on those impacts, whether oversight is needed. If APHIS can't develop a regulatory alternative that is science- and risk-based and covers GE crops with potential risks to the environment or agriculture, then it should request Congress to provide such authority. Only a science-based system will safeguard the environment and agriculture and also garner the support of the public.

4. APHIS permit requirement for field testing of GE strains developed using intrageneric donors is not consistent with EPA's TSCA requirements, EPA's BPPD requirements, or FDA's GRAS requirements. The proposed APHIS regulations appear to create additional regulatory requirements.
5. Plant pest trigger should be refined so it does not include vectoring DNA, disarmed *Agrobacterium*, or regulatory sequences from a plant pest.
6. Common sense dictates that near identical products pose near identical risks, and should be regulated and managed similarly. But transferring an Xa21 disease resistance gene into rice using both traditional crossing and rDNA results in one being commercialized without any regulated safety assessment, while the other is so heavily regulated and scrutinized it will never see commercial release.
7. Make Genetic Engineering the Trigger for Regulation. At least 30 GE organisms have been exempted from APHIS regulatory review because, although genetically engineered, they did not involve the use of plant pests. The NRC committee had recommended that USDA regulate all GE plants, because those that did not involve use of plant pests could also cause harm to public health or the environment, and because there is no scientific basis on which to forecast which ones might pose risk. Besides offering a greater degree of environmental protection, a simple GE trigger is also more transparent than the current system, in that it conforms to the public's and many GE crop, insect, and tree developers' expectations that USDA regulates GE organisms. Using genetic transformation as the trigger for regulation would also be more efficient administratively, eliminating the ad hoc, individual correspondence and evaluation that presently occurs when GE organism developers (often confused by the current, byzantine system) seek APHIS determinations on whether their GE organisms fall under the scope of regulation. Despite the many advantages a GE trigger would have over the current system—namely, closing what APHIS itself has long characterized as a "regulatory gap" and providing superior environmental protection and greater transparency and efficiency—APHIS inexplicably fails to incorporate it in any of the four alternatives discussed in its scoping notice. Absent following the NAS's recommendation and its own past views, if it fails to include any alternative in which GE is the trigger for regulation, APHIS has failed to provide sufficient regulatory alternatives for responsible future regulation of GE organisms.

General Consideration/Notes on Process

1. Small scale field trials can take place without APHIS notification as long as the test follows accepted performance standards, perhaps subject only to a simple online registration. APHIS might decide it would be prudent to institute a simple online registration form, under which an applicant would provide APHIS and the applicable state Department of Agriculture with basic information about the institution(s) carrying out the trial and about the trial itself (e.g. identity of the plant species to be tested, and the acreage, location and duration of the trial),

perhaps accompanied by an attestation that the test would be carried out in accordance with specified standards. If such a registration were implemented, no particular advance notice would be needed, and it could also include the requirement to inform APHIS of any significant risk-related issues that may arise during the trial, and to submit a notification upon its completion.

2. We believe that the body of knowledge specifying appropriate procedures and safeguards for the conduct of small research-scale field trials is sufficient for APHIS to determine that there would be no adverse risks to the environment if such trials were allowed to proceed with a minimum of Agency oversight.
3. To streamline consider closely related sequences in a single risk assessment
4. Consider adaptive approaches –stage or limited deregulation- for example, for example, a particular product of biotechnology might be safely released in certain regions (e.g., where wild relatives for outcrossing are not present). With monitoring, the necessary factual data to support a larger release could then be gathered without imposing an excessive burden on the investigators
5. USDA should make it easier for University researchers to comply with regulations by including
    a. targeted outreach and accommodations for university research
    b. improvements to intra-agency coordination within USDA-APHIS,
    c. improvements to interagency coordination within the federal government.
    d. USDA should assign an outreach liaison to each university system to provide compliance assistance for university stakeholders and communicate the needs of academia back to the USDA
6. USDA-APHIS and NIH OBA each have different (and sometimes conflicting) guidance on transparency and availability of public information. Specific requirements for indoor containment of genetically-modified plants are also different between USDA and NIH. This inconsistency can lead academic institutions to delay research authorization or implement arbitrary requirements that unnecessarily impact research without effectively achieving compliance with USDA-APHIS regulations
7. Extend U.S. Federal Coordinated Framework to oversight of indoor research. formal integration of regulations and guidelines for outdoor and indoor work could accelerate university research
8. It should not be necessary for developers to consult with APHIS for every new plant variety under evaluation. There should be a self-determination step based on clear criteria in either regulation or policy statements that make it known which organisms APHIS may need to oversee. This distinction could be accomplished with a definition, but could also be illustrated by a decision tree based on product characteristics, or an appropriately detailed, yet flexible, exemptions list. For those plant varieties for which it is either not clear if they fall outside APHIS authority, or, for those that do fall within its scope, there should be an early consultation process by which developers could receive advice on the status of their plant variety prior to beginning initial field testing. The timing of this consultation is critical due to the volume of candidate plant varieties under evaluation during early development. Criteria

for consulting with APHIS should be clarified. The extent of characterization data required should recognize the stage of development and should be determined based on a reasonable hypothesis of risk to plant health.

9. Several commenters expressed concern that the alternatives were not reviewed by state regulatory agencies, agricultural community, other federal Agencies, and International Regulatory Agencies.
10. The breadth of the proposed definition of biotechnology could lead to a regulatory bottleneck through the upfront assessment proposal.
11. We believe it is premature and ill-timed for APHIS to propose an expansive new definition for "biotechnology," particularly given ongoing global discussions that are occurring regarding the pre-market regulatory scope that may apply to new breeding techniques. It also risks undercutting current efforts to build a more harmonized and rational, and less cumbersome and costly, regulatory system for addressing gene editing and other new non-transgenic breeding techniques
12. This definitional approach also poses a risk of signaling to competent regulatory authorities in other countries that the United States is expanding – rather dramatically– the potential scope of its regulatory review, thereby contravening ongoing and potentially productive international efforts to do just the opposite
13. Increased risk of litigation, challenging the decisions of the USDA.
14. How does the Agency anticipate phasing in and actively communicating such changes to the process, both domestically and internationally?
15. We strongly encourage the agency to explicitly prepare and (in any forthcoming notice of proposed rulemaking that follows) publish a detailed and robust account of the clear and compelling public need for revising its regulations; to identify the specific problems in current regulations that the agency intends to address; and to develop regulatory alternatives narrowly targeted to address those issues
16. How will such field trials be enabled on a crop/trait combination before a RA is complete? One possible method to manage the RA process is the concept of a notification, where product developers would notify APHIS of their new plant variety or crop/trait combination, and the Agency would respond to the developer by a certain time if the Agency has any questions. If there is no Agency response, this means the Agency has no questions. Once a RA is completed for a crop/trait combination meeting the two-trigger standard, is a similar plant automatically the same status as the original? If so, how would this determination be communicated to the regulated community and would developers of similar or same crop/trait combinations still need to contact BRS for a RA. How will developers know when to come to BRS? How will self-determination of regulated status be enabled?
17. APHIS will need to provide unequivocal guidance on "phenotypic similarity" and a mechanism by which developers can consult on individual cases.

Noxious Weed Authority

1. APHIS should use its broad noxious weed authority to regulate for indirect impacts such as herbicide resistant weeds
2. APHIS should apply the full scope of its statutory authority under the PPA to GE organisms
3. Noxious weed authority should include the potential to select for HR weeds via application of inputs that utilize the engineered traits; and that this definition be included in the regulatory review criteria that will trigger an APHIS review process.
4. APHIS should restrict the application of its authority to regulate plant pests.
5. USDA has legitimate statutory authority to protect U.S. farmers and agricultural economies, and should move swiftly to exercise it. Adding noxious weed provisions to USDA's biotechnology regulations would enable USDA to:
    - Impose isolation distances,
    - Require regulatory restrictions,
    - Establish/mandate management practices,
    - Establish geographic restrictions, or
    - Impose conditions to reduce impact to organic farmers.
6. All the alternatives should include noxious weed authority. If Alternative 1 does not, APHIS should analyze the impact of not including this legal authority.
7. Opposes bringing unspecified aspects of 7 CFR 360 under the 7 CFR 340 umbrella as this likely would create broad and subjective evaluation of plant products due to the tremendously flexible interpretation and possible application under 7 CFR 340
8. The definition of a noxious weed must be applied consistently across the agency with one standard for the identification and management of a noxious weed regardless of its origin or the process by which it is developed. USDA clearly outlines a process through the Noxious Weed Regulations (7 CFR Part 360) under PPA through which specific plants are named "noxious weeds to prevent their introduction into the United States or their dissemination within the United States." Generally, this determination is made at the taxonomic rank of species to clearly define broad differences of risk among plant species within the same genus. Cultivated crops, like sorghum, are the result of considerable selective breeding and even though they may be a conspecific of a potential weedy relative, they are purposely planted and highly managed. Crops like sorghum and rice can be successfully managed for concerns of gene flow through the development and implementation of stewardship practices. However, broad interpretations of the term noxious weed and potential onerous stewardship requirements that may not be practical on-farm will disadvantage any crop that has a weedy relative with outcross potential. Additionally, noxious weed provisions of PPA should in no way be used to protect the economics of markets sensitive to genetically engineered products. These provisions should remain focused on their intended purpose under APHIS authority and be limited to actual invasive and damaging weeds that are difficult to control. The expansive use of noxious weed provisions with its reference to, "plant or plant product that can directly or indirectly injure or cause damage," leaves open a huge array of possible interpretations that would not be solely at the discretion of USDA but also groups that are

anti-modern agriculture. Judges, inevitably, will be forced to construe and guide USDA on how to interpret this authority. Finally, without the inclusion of benefits, it is very possible that any level of risk would be too great for regulatory approval in a legal challenge. The separation of 7 CFR 340 and 360 allowed for a very clear and defensible case (referring to litigation on Roundup Ready Alfalfa). If the noxious weed provisions at that time had been incorporated in part into 7 CFR 340, there is a very good chance the 9th Circuit would have come to a different conclusion. The subjectivity and uncertainty of linking 7 CFR 340 and 360 would threaten the diversity of crops grown in the U.S. and could limit our competitiveness in the global marketplace.

9. Using the noxious weed authority, the Agency should include protection against:
    a. Market disruptions, including conflicts involving other agricultural markets, such as organic, non-GE, and other sensitive marketing channels;
    b. Increased herbicide and pesticide use, and resulting damages associated with usage, including weed and pest resistance;
    c. Enhanced weediness of existing GE crops;
    d. Impacts to beneficial non-target organisms, including pollinators;
    e. Damage to biodiversity, including soil microorganisms;
    f. Animal and human health impacts; and
    g. Gene flow and other routes of seed and crop contamination.

Weed Risk Assessment

1. No description of how, when, or what information would go into a risk assessment
2. No consideration of *benefits* in the evaluation process;
3. APHIS is urged to eliminate event-by event de-regulation. Refocusing risk assessments on product phenotype rather than genotype is more scientifically defensible than is the current policy.
4. GE trees, which may involve techniques (such as the grafting of GE budwood to existing rootstock in the field) require different approaches to testing and cultivation than those scenarios that involve GE seed produced in a contained facility for subsequent distribution to growers for planting. Any new proposal should take these fundamental distinctions into consideration.
5. The risk assessment model to be used by the Agency to determine to regulate should be published and thoroughly vetted by all stakeholders before implementation. The parameters, and weight placed on each parameter, used for risk assessment should be clear. The decisions based on the models output, to regulate or not to regulate under the PPA, must also be clear. There should be a level of transparency to the model such that a developer will have a reasonable expectation, prior to submitting its product to the Agency for analysis, of what the result will be. Where the output of the model directs the Agency to regulate, there should be a mechanism for a developer to have its product reassessed should data and experience with the product show that the level of risk identified by the model is not demonstrated in reality.

6. The agency should establish clear and objective criteria that would define how the conclusions of a risk assessment model would be used to reach regulatory determinations. APHIS should publish its decision-making criteria for public review and comment in advance of, or in conjunction with, any proposed rule or draft environmental analysis
7. APHIS should utilize the new model to identify broad categories of products that do not pose a risk to plant health, and therefore could be excluded or exempted from regulation
8. For products that are not regulated organisms, the Agency should facilitate a streamlined process by which developers can, upon request, be provided with a letter confirming such status. Confirmation of Agency assessment may be essential for developers as part of other regulatory processes with other domestic and/or international regulatory authorities.
9. If the scope of regulation is defined entirely by the output of a risk assessment model and subsequent agency decision— as opposed to clear, up-front criteria or standards— such a system would provide little if any transparency, clarity, or predictability about what is actually subject to regulation; developers would have no way of knowing the regulatory status of their products without first approaching the agency and asking.
10. Disparate conclusions reached using the same tool/protocol are ready reminders of the potential subjectivity in risk assessments and further strengthen the need for USDA-APHIS to have a transparent and collaborative approach to developing the biotechnology risk assessment model
11. APHIS should include known impacts of GE organisms, including increased herbicide use, herbicide-resistant weeds, impacts to non-target organisms, contamination of organic and other non-GE crops, among others, in risk assessments, and the agency should apply its regulatory authority to monitor, mitigate, and prevent negative impacts associated with GE organisms
12. The "analyze first" step of this alternative contains no requirement for the collection of sufficiently robust experimental data gathered by independent scientists. Such data is necessary to make an accurate determination of potential direct or indirect harms that would trigger the second step of regulatory review. This leaves the decision-making process prior to the regulatory review step highly vulnerable to subjective or less than rigorous assessment and potential over-reliance on industry supplied data or recommendations.
13. A straight-forward process for exempting negligible-risk categories of GMOs for environmental release is easily defined, however difficult to implement: 1) convene expert groups, 2) review the evidence, 3) define exempted categories, 4) publish in the Federal Register, 5) evaluate feedback, 6) implement. It is critical that an unbiased group of individuals with deep expertise in agriculture/aquaculture and in genetic modification be brought together for the present purpose. This means avoiding the trap of constituting a committee balanced with regard to its pro- and anti-GMO belief systems or individuals deemed to be unbiased by virtue of having little or no relevant expertise and experience. Moreover, the expert committee(s) should be the nexus of inter-agency coordination to minimize the generation of multiple, potentially conflicting regulatory schemes in each agency. The process should be convened as a standing committee under the auspices of the National Academies of Science, but involve all three regulatory agencies. This "expert" process is very vulnerable to being gamed even in the (laudable) interest of broad representation, so it is essential that membership be based on the expertise, scientific stature

and relevant practical experience of each member, not on the individual's beliefs about or stance on GMO issues.

14. The term *benefits* and its use in the evaluation process are not included in the NOI. When elements of a regulatory process insert considerable subjectivity into the evaluation and the potential inclusion of and only risks are considered, the argument for approval or non-regulatory status is very difficult to make. Risk is inherent in everything we do. However, risk should be evaluated and balanced by the perceived or expected benefits. Without the inclusion of benefits in the USDA process and only the assessment of risk, particularly with a broader scope of regulation, those more inclined to precautionary approaches are in a strengthened position to challenge the USDA's decisions
15. APHIS should make its decision-making clear enough that developers are, for the most part, able to make a self-assessment of similarity with confidence

Exceptions or Exemptions

1. Because of the safety of the breeding selection process, and the ability of new breeding techniques to generate far more precise variation than currently accepted breeding practices we propose that plant varieties/products developed using these new breeding techniques should NOT be subject to GMO (Genetic Modified Organism)- level regulation if they meet the following criteria:
    a. When plant varieties could be obtained by crossbreeding;
    b. When plant varieties have been or could be obtained by mutagenesis of crossable or highly related plants;
    c. When no exogenous heritable material is introduced into the progeny.
2. Whole categories of applications, such as precisely targeted gene inactivation or the transfer of disease resistance genes from both closely and not-so-closely related organisms, to long-used crop plants, pose negligible risks to human health and the environment.
3. The agency should articulate the kinds of products which could cause risk. Examples of traits which create risk could include:
    a. Herbicide resistance genes which encourage greater use of herbicide and thus increase noxious weeds resistance to the herbicide (a similar problem to antibiotic use)
    b. Toxic genes known to be damaging to other life forms (including beneficial organisms) but which have not yet shown to be safe
    c. Genes which confer a known selective advantage on the plant and which could therefore increase the plants weediness (note that the selective advantage mechanism should be known and clearly articulated to require regulatory action, and the base plant should probably already have some potential for weediness to be considered a risk)
    d. Products using 'Gene Drive' technology due to it's potential to change an entire population which could have unknown consequences for propagating in the wild
    e. Products which are known to affect human health (eg proteins known to be allergenic or plants containing pharmacologically active molecules)
    f. Coding region's on the 'select agent' list maintained by DNA synthesis companies

   g. Other traits/examples which USDA has previous experience of causing problems

4. Examples of things which should not be regulated include the following:
   a. Gene editing technologies, such as CRISPR, which allow more precise genetic changes with lower off-target effects than chemical/radiation mutagenesis
   b. Regulatory elements, independent of the donor organism
   c. Plants engineered with agro-bacteria
   d. Disarmed agrobacteria
   e. Well characterized coding regions not sourced from plant pests
   f. All vectors/methods currently in common use for inserting transgenes (though APHIS should monitor progress in this space in case a new method introduces novel risks to the final product)
   g. Traits included in the list of 'regulated' items which have been shown to present no risk (this would enable development of traits like BT resistance into the long tail of interesting crops not just the large cash crops where the economics support deregulation)
   h. Other traits USDA gains experience with as causing no risks
5. Interstate movement of all genetically modified plants (except federal noxious weeds) should be categorically exempt when moved between and used in containment facilities that meet defined performance standards (e.g., contained laboratories, greenhouses, and similar containment facilities).
6. Environmental release (both confined and unconfined) of all genetically modified plants (except federal noxious weeds) should be categorically exempt when its phenotype is substantially equivalent to an antecedent plant with a history of safe use or an APHIS risk assessment. This regulatory approach would be conceptually equivalent to meeting FDA standards of over-the-counter (OTC) product monographs or 5 lO(k) pre-market notification for regulated products, not the bioequivalence review schemes for generic small molecule or biological (biosimilar) drugs. Antecedent plants should include plants developed using any technique, including genetic engineering, mutational breeding, traditional breeding, or other processes.
7. APHIS should consider providing for separate procedures that outline a more streamlined and, if appropriate, expedited approach to authorize the testing, movement, and release of regulated organisms when necessary to address a crisis or emergency situation. APHIS might consider such "emergency authorizations" appropriate in connection with scenarios where the no action alternative threatens significant economic loss, significant environmental risk, significant risk to plant health, or other emergency conditions associated with plant pests or disease and for which no existing alternative practices provide effective or feasible control. While such emergency authorizations would remain fully subject to APHIS regulatory approval and control, they should be made subject to appropriately prioritized review and, where consistent with the PPA, at least temporarily exempt from otherwise applicable permitting requirements that might represent barriers to resolving emergency conditions.

8. Exclusions should not be based on method of development of a product to remain consistent with the principles of the Coordinated Framework. Nor should exclusions be dependent on a mechanism of action to achieve a particular phenotype. To be consistent with the principles of the Coordinated Framework and statutory authority under the PPA, the exclusions should be based purely on the trait or phenotype expressed by a particular product of biotechnology. The exclusion list should also be continuously expanded based on outputs of the risk assessment model. If the Agency determines not to regulate a particular product which met the triggers because the risk assessment model did not produce a risk-score requiring regulation, this decision should be clearly communicated as an exclusion to add to regulatory relief and transparency for other product developers.
9. Optimization of alleles at native loci for desired phenotype. For example: Rps1k Phytophthora locus in soybean; Viral diseases in edible beans; Shrunken 2 locus in sweet corn; Corn endosperm quality traits
10. We suggest that if the agency is considering a regulatory system in which a new risk assessment mechanism is used to inform agency determinations about scope of regulation, then the agency should consider using the same system to identify categories of organisms that should be included ("triggers") or excluded ("exemptions") within its scope. We suggest that this approach would create a logical consistency and would prevent triggers and exemptions from being created using different, and possibly inconsistent, rationales.
11. Exclude deletions from regulation
12. We propose that organisms that are similar to organisms that have previously been deregulated on the basis that they do not a plant pest risk be exempted. These exemptions would be based on plant x phenotype as described above, rather than on the biotechnology process by which the GE organisms were created, and would clearly support the Coordinate Framework tenet that regulations be product- not process-based. APHIS has discussed previously publishing along with the proposed rule a list of crop x phenotype combinations that have been analyzed and found not to pose plant pest or noxious weed risks, and subsequently adding to this list. This list could effectively consist of the exempted GE organisms and would be valuable in providing clarity and predictability to developers and the public.
13. APHIS should design the programmatic EIS so as to enable the regulation of NBT techniques to prevent the off- target mutations from resulting in "noxious weeds" or "plant pests" per the PPA.
14. Exemptions granted must not represent gaps in oversight or reduced risk assessment, thereby eroding consumer confidence.

Permits

1. APHIS did not provide information in the NOI about what the Agency considers to be risk appropriate conditions.
2. Currently though users of our kit have to apply for a permit, which in one recent example for a high school took six months to get approval – despite the bacteria posing no plant pest risk!

Elimination of Notifications and Petitions

1. We are not in agreement with the proposition that elimination of the petition process for non-regulated status under 7 CFR 340.6 is warranted because "APHIS will conduct new risk analyses consistent with the 'analyze first, regulate when necessary' [principle] when new information is made available." It seems to us that new information demonstrating that a permitted organism presents no plant pest risks would warrant a conclusion that a permit for that organism is no longer required
2. We also believe new regulations should abandon the current process for "deregulating" GE organisms, as no GE product should be completely outside regulatory review
3. In accordance to the PPA, there needs to be a petition mechanism to review such a determination when new information is available that affects the outcome of the analysis. The developer may petition APHIS to evaluate the plant pest risks of the organism, using the clearly defined, published criteria and analysis tools that are available to the public, to determine whether or not the organism is a regulated article.
4. The NOI indicates that under this alternative there would not be a petition process for developers to request that a regulated article is deregulated, but instead APHIS will conduct a new risk analysis when new information is made available. APHIS needs to describe what new information it would look for to trigger a new analysis and how it would obtain that information. Indeed, a petition process may be the most appropriate approach to changing the regulatory status of a regulated article, as required under the PPA.

Regulation of GE Plant Made Pharmaceutical and Industrial Compounds (PMPI)

1. Any agency oversight under the PPA must spring from the agency's statutory authority to regulate plant pests or noxious weeds, and that decisions about regulatory scope and level of oversight should be consistent across all organisms regardless of the process used to develop them.
2. We do suggest that small-scale field trials of plants engineered for pharmaceutical or industrial purposes could and should qualify for whatever program of reduced oversight (e.g. elimination of advance notification) that APHIS may create for other plant species: for example, our suggestion that most research field tests could take place without advance notification if best practices and appropriate performance standards are followed.

NEPA

1. Should APHIS eliminate notifications and petitions, APHIS should outline and specifically describe the expected level and timing of associated review under the NEPA for proposed agency actions to regulate or to not regulate a biotechnology product. Building NEPA review timelines into its regulatory proposals will facilitate compliance, coordination, and planning by technology developers, while contributing directly to APHIS's overall effort to increase the efficiency and precision of its biotechnology regulations. To this end, APHIS should also consider whether its proposed changes to Part 340 may warrant corresponding revisions to its related NEPA-implementing regulations under 7 C.F.R. Part 372, such that NEPA reviews inform APHIS' decisions and do not delay the overall process.

2. APHIS's new regulatory proposal should provide it with the tools and flexibility needed to adequately address the unique circumstances associated with the cultivation of GE trees, while allowing APHIS to rely upon its three decades of experience assessing and regulating the plant pest and noxious weed risks of GE organisms. APHIS may act promptly and need not "default" to an EIS under the National Environmental Policy Act (NEPA) simply because it is reviewing a GE version of a certain fruit for the first time. Rather, APHIS should bring to bear its expertise with similar GE, as well as non-GE, traits.
3. EIS should not get triggered in the first phase of analysis in the event that USDA determines a product does not pose a plant pest or noxious weed risk and will not be subject to regulatory action. The language and interpretation of the proposed new regulations should be carefully reviewed to ensure NEPA is not triggered and that this can't be subject to legal challenge by opponents of biotechnology. Furthermore in the next iteration of the proposals APHIS should clearly articulate that the first step of review will not trigger NEPA requirements as it is not a regulatory action. Perhaps to achieve this APHIS should make the first stage of analysis voluntary. As I discuss below in my discussion of option #4 it should be expected that all product developers will voluntarily submit to the first stage as it will be required by investors and customers.
4. For all but Alternative 1 (the no action alternative), APHIS would likely need simultaneously to propose accompanying revisions to APHIS NEPA implementing regulations (7 CFR 372) in order to implement changes to 7 CFR 340.

Communication/Transparency

1. The three federal agencies responsible for products of biotechnology can and should increase the visibility of their communication to consumers and other stakeholders about the decision-making used to ensure the safety of biotechnology products. We believe each of these federal agencies should continue to provide opportunity for public comment on regulatory decisions via the federal eRulemaking Portal (www.regulations.gov) as a way to foster communications. Additionally, we urge federal agencies to continue to make timely publication of their regulatory decisions, practices, and bases of decision-making on their respective Internet websites.
2. The "Am I Regulated" process is a good thing as that process is helpful to innovators. However, as I'm sure APHIS is aware, currently there are long backlogs of 'Am I regulated' letters in review that are causing delays for product developers. My understanding is that APHIS targets a 90 day review for these letters, but is not currently meeting this deadline due to lack of internal resources. For example my company submitted two Am I regulated letters in August/September 2015 and have yet to receive a response from the agency. We also have customers who have taken six months to receive permits to ship *Agrobacterium*. These delays present particular and significant challenges for small businesses with limited financial runway where the old adage 'time is money' is particularly apt APHIS should review the criteria under which products of biotechnology either trigger regulation or do not on an ongoing and regular basis. Given how fast this field is moving this should take place at least every three years and no more than five years. A critical part of this regular update should be to remove criteria where the scientific evidence suggests no risk.
3. We urge the agency to conduct a robust process to obtain input from plant breeders and agricultural producers. We believe that their input will strongly support the idea that any

changes to the current system should be minor and targeted and should allow more flexibility to utilize appropriate discretion on which new varieties require regulatory oversight.

4. Include a diversity of farmers – and particularly those most impacted by potential contamination from genetically engineered crops – and other stakeholders from agriculture, academia, and the public throughout the regulatory and review process
5. Proposing expanded definitions and other significant revisions to update APHIS' regulatory scheme should be closely coordinated with the White House-led government-wide effort to modernize the regulatory system for biotechnology products. The White House also directed the USDA, FDA, and EPA to commission a study by the National Academies of Sciences, Engineering, and Medicine to prepare an expert study on the future landscape of the products of biotechnology. We encourage APHIS to utilize the expertise of the National Academies and consider the findings of that study before making significant changes to its regulatory scope that could include the kinds of products within the scope of the study. As APHIS considers regulatory revisions, we encourage the agency to continue to work closely with the White House and other executive branch agencies—including, but not necessarily limited to, FDA, EPA, USDA's Foreign Agricultural Service, OSTP, the Office of Management and Budget (OMB), the Council on Environmental Quality (CEQ), and the Office of the U.S. Trade Representative (USTR)—to ensure that any regulatory scheme proposed by the agency is consistent with regulatory best practices.
6. To ensure that the analysis is objective and predictable, APHIS needs to first subject its analysis tools to scientific peer review and subsequently make them available for use by the public and GE organism developers. The analysis process needs to be scientific, simple and clear, and decision making as to the regulatory status of a product needs to be based solely on the outcome of that process. However, as currently described, it is unclear what the status is of GE products that meet the analysis trigger but have not gone through analysis. A publicly available analysis tool or process would allow developers to make this assessment themselves with the option of requesting confirmation from APHIS if there is uncertainty.
7. Over the course of the last several years, APHIS has published a series of letters clarifying the regulatory status of individual products. While this process has been helpful in building up a body of precedents to illustrate how the agency interprets its regulatory scope, to date the agency has not published more generalized guidance articulating how the agency determines what is or is not subject to current regulation. We encourage APHIS to develop such guidance to provide additional clarity and transparency about which products the agency believes pose a plant health risk and are subject to regulation
8. APHIS should also provide guidance on how to petition the agency to create new categories of products that are or are not subject to regulation as plant pests or noxious weeds. The PPA already authorizes such a process. This system of building exclusions could be used by the agency to gradually winnow the agency's effective scope of regulation. This would allow the agency to retain those categories of organisms with which it has little experience or familiarity, or for which there is legitimate scientific evidence to suggest they may pose a risk to plant health.
9. As it is currently conceived, APHIS' process is not capable of assessing or managing all of the risks associated with genetically engineered plants, animals or organisms. The current regulations do not adequately protect the safety of humans or the environment and they do

not ensure farmer choice, fair practices in input markets or the ability of those who do not use this technology to operate without bearing unfair economic burdens. Since the introduction of patented GE organisms, a lack of oversight has led to the unwanted presence of unapproved GE crops, contamination of organic and non-GE crops with GE content and the decision to allow certain GE crops to be sold and planted with zero regulatory scrutiny. The failures of APHIS' approach can be clearly seen in the discrepancies and contradictions in how different GE organisms are regulated, or in some cases, not regulated at all. Numerous GE plants have entered the market with no safety review including Kentucky bluegrass, switchgrass, sorghum, loblolly pines, and more recently, crops produced with CRISPR techniques. These GE organisms are allowed to enter the marketplace with no safety review not because of their indisputable safety, but merely because under the current process, APHIS does not exercise jurisdiction over them. APHIS has already approved a variety of crops engineered by RNA interference (RNAi) without looking at the full range of risks associated with the process itself. Many studies have shown that RNAi can actually suppress unintended genes that are similar to the target gene. These unintended effects may also be heritable through reproduction, which could have serious ramifications for plant and animal populations as well as cellular metabolism. APHIS should take this opportunity to do independent research on the impacts of the technology, rather than assume that the developers are doing a comprehensive analysis. CRISPR and other emerging gene editing techniques raise similar questions. In a 201 issue of *Nature*, an article on CRISPR states, "some scientists want to see more studies that probe whether the technique generates stray and potentially risky genome edits; others worry that edited organisms could disrupt entire ecosystems." Brandeis niversity molecular biologist James Haber warns, "These enzymes will cut in places other than the places you have designed them to cut, and that has lots of implications." One major issue for regulation of these gene editing technologies is that there will be relatively no way to track their presence in engineered products. As new genetic engineering techniques continue to emerge, unless there is a massive overhaul of the approval process, we can expect its limitations to allow an increased number of potentially risky, totally unregulated GE crops to enter the marketplace. This exposes consumers, the environment and the economy to potential risks and also greatly diminishes public confidence in the government's oversight of these products.

10. NASDA requests USDA undertake a more thorough and robust review, in conjunction and consultation with partner agencies responsible for regulating products of biotechnology and the agricultural community, to enhance continued alignment, agency roles and responsibilities, and improve communication between the federal, state, and agricultural stakeholders. While the current regulatory process is not perfect, it has operated successfully for decades without adverse plant health impacts to U.S. agriculture.

11. Prior to publication of a proposed rule, USDA should continue to work with the state departments of agriculture, growers, producers, scientific experts, and the regulated community to execute a more robust review of the alternatives considered under the current NOI and identify specific modifications to enhance or supplement the proposed alternatives through improving clarity, transparency, regulatory predictability, and ease of implementation. Furthermore, an enhanced review process with the state regulatory agencies and the agricultural stakeholder community will result in greater understanding of the proposed changes, enhance communication and collaboration among partners, and facilitate greater support for future implementation proposals.

12. Any changes to U.S. biotech regulatory processes – including Part 340 – should be considered only after advance, robust and thorough discussions with competent government authorities in countries that represent important U.S. export markets, during which alignment in regulatory approaches is achieved to the maximum extent possible. To our knowledge, that has not occurred to date with respect to: 1) the four proposed regulatory alternatives; and 2) the new definitions for Part 340 proposed by APHIS in this notice. We urge the agency not to proceed further with the EIS or proposed revisions to Part 340 unless and until such consultations are conducted and completed.
13. APHIS is requested to consult with EPA and FDA to ensure that its new regulations will reflect the continued alignment of roles and responsibilities and avoid non-harmonious policies and practices among all three agencies. APHIS is asked to expressly describe the relationship of its regulatory program to the Coordinated Framework and the related changes now being considered by APHIS together with EPA and FDA. Moreover, APHIS is requested to incorporate within its new regulations the flexibility that will be required to ensure that future changes that may be imposed in the context of the Coordinated Framework will not disrupt APHIS's proposed amendments or otherwise force APHIS to withdraw and reconsider key elements of its new program to reflect changed priorities or responsibilities that may subsequently be agreed to with EPA and FDA.
14. As the Agency considers revisions to its regulations, it is critical that it do so within the context of the Coordinated Framework that has functioned to the benefit of agriculture since its inception. This exploration of rulemaking should not be distinct from the ongoing review of the Coordinated Framework initiated by the White House Office of Science and Technology Policy. During this period where the USDA seeks to update its rules, it is critical that it do so in full coordination with EPA and FDA to preserve the U.S. as the example of an efficient and predictable regulatory system for the rest of the world to emulate. The USDA has made great strides in recent years to improve the timeliness of its determinations of regulatory status through the Agency's petition improvement process, with further gains possible through expanded use of the extension process. Efficiency and predictability of any regulatory framework is paramount to encouraging innovation. Prior to implementing any change to the regulatory framework, the Agency should ensure they have the capacity to maintain, and ideally improve upon, the efficiency and predictability of the current framework.
15. USDA must consult with USTR and other agencies to ensure any proposed regulatory changes align with America's stated positions on biotechnology within the context of international trade. As an example, a range of departments and agencies regularly participate in negotiations with China over imports of biotech derived grains. We want to avoid trade challenges, as exemplified by the China issue, when it comes to products developed through precision breeding tools.
16. The U.S. government and our industry are actively encouraging our foreign trading partners to adopt product-based regulatory review systems for biotech traits that are similar to our own. While progress has been slowed by asynchronous approvals in some countries, this approach remains the most viable way to move the technology forward by ensuring market acceptance. Any decision to change to a process-based system in the U.S. would cause other countries to question and possibly abandon the positive changes they are considering for their current regulatory systems. A sudden or unexpected change in our regulatory policy could

prevent the introduction of new biotech products in the U.S as well as Canada, since nearly all countries have a zero tolerance for the presence of traits they haven't approved.

17. Arguments such as importance of alignment of regulatory standards with international trading partners should be examined particularly critically as this argument is in fact a protectionist argument designed to erect regulatory barriers to startups. If an overseas country decides to inhibit competition through requiring unjustified scientific studies that is no reason for also imposing those same studies domestically.

Issues to be analyzed in the dPEIS

All data in the EIS including field data should be publicly available. Disallow any CBI for data. Impacts to Address in the EIS:

Socioeconomic

1. Agricultural production impacts, including and not limited to: the burden from GE contamination (or the risk of it) on GE-sensitive markets, such as organic, non-GE, and many export and domestic markets;
2. Other impacts to traditional agricultural production from GE crop production;
3. Socioeconomic impacts, such as: transgenic contamination and its economic effects on domestic and export markets and contaminated farmers, including both non-GE and organic farmers, as well as consumers and farmers' right of choice. Collectively, transgenic contamination has cost U.S. farmers billions of dollars in rejected sales, lost exports, and closed agricultural markets. These contamination episodes have resulted in the rejection by foreign markets of GE-contaminated supplies; farmers' loss of GE-contaminated seed stocks for planting purposes; removal of potentially hazardous GE-contaminated food items from supermarket shelves; and loss of valuable grain export markets to other nations capable of providing the GE-free supplies demanded by foreign markets. Domestic GE-sensitive markets are harmed by contamination as well: organic growers are at particularly great risk of losing their customers and markets, and potentially their organic certification, since USDA organic standards prohibit use of GE seed, and require that all inputs in organic production be 100% organic. More crucially, organic consumers buy organic specifically to avoid GE crops, and reject GE-contaminated products, costing organic growers their reputation and customers. The risk of contamination alone creates costly burdens for organic and conventional farmers and businesses, such as the need for DNA testing or crop buffer zones. As opposed to offshoring this tremendous opportunity for American farmers, we must fully account for the cumulative impacts of this technology to the sector as a whole,
4. Consequences for conducting field trials without confinement conditions imposed by APHIS. APHIS must assess the consequences of eliminating these field trial regulations on the agricultural economy, since transgenic contamination is likely to increase substantially, with increased potential for rejection of contaminated supplies by foreign and domestic buyers.
5. Changes in seed industry market concentration and its impacts;
6. Impacts on farm size through any labor-saving effects of GE crops; (An ERS report from 2013 shows that, by reducing the time and labor costs of weed management for well-capitalized farms, glyphosate resistant crops were a key factor in the latest surge of farm

consolidation and increasing farm size that has occurred over recent decades. This process deprives rural areas of a skilled workforce, and very large farms without skilled labor resources can only consider very simple and time efficient approaches to weed management. Thus, when an outbreak of herbicide-resistant weeds occurs, large-scale farmers simply do not have the time, labor, or management ability to integrate cover crops, inter-row cultivation, or perennial forages for weed control. Instead, they look anxiously to the commercialization of a new herbicide-resistance trait/herbicide package as a short-term solution.

7. Effects on the methods and costs of weed control.
8. Biotech effects on seed diversity.
9. EU countries restrict or ban GMO crops and resulting impact on trade
10. Regulation of imports-accompanying declaration for any subject of APHIS regulation
11. Analyze opportunity costs of each alternative. Consider innovation and commensurate benefit for environmental protection and consumer benefits.
12. Discuss the impact of the current regulatory scheme on small vs large companies (favors large and hinders small), the impact of this alternative on the ability of small and public-sector developers to develop and release new beneficial GE organisms, and whether the regulations favor the large multinational companies
13. Discuss the impact of regulation on exports. The EIS needs to include the impact on demand by these countries, and the specific area that may be sensitive to demand if changed. These countries need to be surveyed by APHIS and included in the EIS: Japan, Mexico, Philippines, Nigeria, Korea, Brazil & Taiwan.
14. Acknowledge that members of the public have and continue to raise social and economic concerns about agricultural biotechnology. APHIS should consider courses of action that can communicate APHIS's intentions regarding social and economic concerns about agricultural biotechnology, while remaining within the agency's statutory authority. Examples of such courses of action might include:
    - Stating explicit regret that APHIS lacks the authority and expertise necessary to address these concerns;
    - Cultivating the expertise needed to understand the full extent of social and economic concerns, so as to identify where, if at all, APHIS does actually have authority to regulate based on social and economic concerns;
    - Working with other programs at USDA and other agencies to identify government entities that do have the appropriate authority and expertise, and developing coordinated regulatory processes that allow new agricultural biotechnology products to be reviewed simultaneously on health, environmental, social, and economic grounds;
    - Organizing — possibly with other programs and agencies — non-binding deliberative forums in which government officials and citizens can discuss social and economic concerns directly. Such forums have been used extensively in Europe, and in the US most recently by NASA's Asteroid Initiative.

15. The regulatory changes being considered may not be compatible with regulatory approaches utilized by other government authorities important to U.S. export markets. Consider likelihood of trade impacts because other governing bodies will reject APHIS regulatory approach. Consumer trust in the regulatory system should be evaluated in the EIS. Technologies rejected by consumers and global customers can diminish the value of U.S. agriculture and potentially cause significant costs and disruptions in the food supply chain. Evaluate public perception of the alternatives and potential impacts on market access.
16. The international trade implications of this approach must be considered, especially if specific regulations move the U.S. regulatory system further out of synchrony with existing national biosafety systems around the world, exacerbate asynchronous approval risks, and restrict market access for U.S. manufactured foods.
17. Consider conditional deregulation and impacts on asynchronous approvals.
18. Consider the likelihood of increased state involvement in biotech regulation.
19. Consider impacts from not performing a conflict analysis.
20. Consider use of expert panels and impact on trust and streamlining deregulation.

Agronomic Practices

1. Increased use of herbicides: Effects on threatened, endangered, or other non-target species and their habitat. The herbicide resistant weed epidemic and associated economic and environmental harm. Impact of HR crop systems on sustainable weed control HR crop volunteers as weeds.
2. Feral HR crops as weeds.
3. Interplay between HR traits and Bt resistant pests
4. Herbicidal drift injury to sensitive plants and other non-target organisms. APHIS should consider the extent to which HR crops will be adopted for defensive reasons;
5. New research is showing that cover cropping and diversified crop rotation – typical of organic and other sustainable agricultural systems – have positive impacts on soil carbon storage, soil water holding capacity, and nutrient cycling and retention, which may outweigh those of systems that only use no-till without these diversified practices. GE cropping systems that rely on increased use of herbicides can restrict farmer options for diversified rotations. The scientific information and data used to assess these technologies must reflect these new findings
6. Another cultural impact the PEIS process should consider is the loss of the time-honored farmer practice of saving and selecting crop seeds

Physical Environment

1. Life cycle assessment

Biological Environment

1. Environmental impacts, including but not limited to: gene flow from GE crops to compatible varieties and any resulting increase in weediness;

2. changes in herbicide use patterns and associated harms to non-target organisms, such as reduction in floral resources for pollinators and degradation of habitat for animals; and impacts on soil health such as increased erosion from altered tillage practices, for instance to control herbicide resistant weeds Effects on threatened and endangered species, such as: effects of herbicide use on habitat; and quality of crop components as food sources.
3. Disease and pest impacts, such as increased susceptibility to diseases or pests from herbicide applications to an herbicide resistant crop.
4. Impacts on pollinators-such as glyphosate on Monarch populations.
5. Should include GE insects and livestock.

Consumer Health

1. Public health impacts, such as: effects of herbicide use, including impacts on farm workers; and safety of food products

Animal Food and Animal Health

1. Livestock health impacts, such as: effects of herbicide use; and safety of animal food.

Alternatives Considered in Revision of 7 CFR part 340

Organic and environmental groups did not like any alternatives, although Alternative 3 was preferred over the No Action, Preferred Alternative, and Alternative 4.

In the view of commenters from organic and environmental groups, 7 CFR part 340 regulations should meet the following:

1. Require independent testing.
2. Until proven safe, GE crops should not be commercialized.
3. Require environmental impact statements for each new GE crop that consider all of the risks of the product in addition to a lifecycle analysis examining the impact of the method of production of that GE crop.
4. Require full transparency and public disclosure of GE field trials, approvals and commercialization decisions.
5. Enact controls that would allow APHIS to monitor, inspect and enforce penalties for noncompliance for GE crops from field trial to post‑commercialization.
6. If there is substantial risk of harm to any sector of agriculture, markets, the environment, or non-target organisms, APHIS must have the ability to deny approval or to go back after these new rules are written and rescind an approval that is no longer justified.
7. Mandate conflict assessment before a crop is approved. If a GE crop has a high potential for contamination that should be sufficient reason for it not to be commercialized.
8. Establish liability for GE contamination that rests with patent holders.
9. Establish a fair compensation mechanism for losses caused by herbicides drifting from fields planted with herbicide‑resistant GE plants.

10. Create and enforce mandatory stewardship requirements for GE crop production to ensure that responsibility for preventing GE contamination is shared, rather than resting solely on organic and non-GE producers. These requirements should include buffer zones for GE crop fields that adjoin organic and non‑GE crop fields to reduce GE and chemical drift.
11. Commit resources to researching, tracking and analyzing incidences of contamination and associated economic losses at all levels of the supply chain.
12. Coordinate with the Grain Inspection Packers and Stockyards Administration to establish contract protections for organic and IP grain growers to ensure they have fair access to testing data and recourse if they believe testing for GE presence is incorrect. APHIS should also invest in research to develop lower-cost rapid testing technology that could be used at different points in the supply chain, including for functional traits.

Alternative 1 - No Action

For Alternative 1 : Most trade groups and some large Biotech Developers

1. Works-make surgical changes-make changes other than by rulemaking.
2. Make broader use of extension process and Am I regulated.
3. Publish guidance clarifying which products are or are not subject to the regulation.
4. Incorporate a new efficient risk assessment based mechanism for adding and removing new categories of organisms from its current scope of regulation.
5. Based on case by case regulatory status evaluations, identify categories of exemptions and use to develop applicable guidance for developers
6. Apply 360 instead of noxious weed provision into 340.

Against Alternative 1: Academics, environmentalists, small scale industry, some biotech industry, organic industry, some trade

1. Doesn’t protect conventional/organic farmers, environment or public health
2. GE organisms escape review
3. Stifles innovation.
4. Scientifically unjustifiable trigger for regulation-not risk based
5. Need streamlined less burdensome regulations for traits posing little risk
6. Expensive regulatory environment benefits large companies, prevents biotechnology from being applied to crops with small markets.
7. Contrary to principles of the Coordinated Framework, unnecessary costs and burdens, there is no basis in logic or experience for the assumption that a GE organism poses a plant pest risk and is therefore a regulated article.

Alternative 2 - Preferred Alternative

For Alternative 2: Some trade groups, small biotech developers, some large biotech developers, some academics

1. Potential to be scientific-risk based regulatory approach
2. Flexible and adaptable-able to accommodate new scientific evidence
3. Potential to efficiently focus regulatory resources on actual plant pests and noxious weeds.
4. Greatest Incentives for Private Sector Investments in Biotechnology
5. Appealing if exemptions or exclusions create equitable treatment for products with substantially equivalent phenotypes
6. APHIS should take into account the views and responsibilities of FDA and EPA.
7. More likely to be successful if phased in.
8. Triggers, exemptions, exclusions, risk assessment model need to be clear in order to give product developers clarity.
9. Positive if agency can be responsive within 90 days.
10. Elimination of the notification system is positive
11. Tools must be subject to peer review.

Against Alternative 2: Some trade groups, organic industry, environmental groups, some biotech developers

1. Any changes to 340 should be made in step with CF review
2. Concern about asynchronous approvals
3. Concern about undermining efforts for international approvals to become product based.
4. Not clear that APHIS has resources to efficiently implement
5. Vague and does not address unintended consequences
6. Based on assumption that biotechnology products necessarily present a different and elevated hazard/risk profile than the products of conventional breeding, mutagenesis
7. Identifying GE crops and animals that might be waived from the regulatory process under thi s option would likely be difficult to determine a priori.
8. No longer collecting the information in 7 CFR 340.6 would not allow potential impacts to be fully assessed.
9. Developers would no longer be under any obligation to prevent inadvertent mixing of GE organisms with other non regulated organisms
10. Developers would no longer be under any obligation to take measures to ensure the GE organism does not persist in the environment.
11. Developers would no longer be obligated to submit field test reports concerning deleterious effects of the GE organism.
12. Data would not be collected on the interactions between genes, organisms, environment, and society

13. Doesn't include independent expert review
14. If manufacturers do not have to disclose data to APHIS or the public there will be little chance for evidence of harm to become known
15. The rationale behind the need to conduct an up-front risk assessment for organisms that do not present a plausible risk to plant health;
16. The regulatory status of organisms prior to and during the up-front risk assessment process; only organisms that have a plausible risk to plant health, either as a plant pest or noxious weed should be considered for this up-front risk assessment process, should it be implemented
17. inconsistent with Codex, which are utilized by a vast majority of countries, including by competent government authorities in significant U.S. export markets thereby increasing the number of trade disruptions
18. Against the elimination of the petition and notification procedures due to the perception that the public would no longer be alerted to the agencies evaluation of plant pest and noxious weed risk for a particular biotech organism.
19. Would not address crops that have pharmaceutical and industrial traits.

Alternative 3 - Comprehensive Regulation of GE Organisms to Facilitate Coexistence

For Alternative 3: Some organic groups; some trade groups

1. In favor of GMO crop exclusion zones, isolation distances, mandatory conflict analysis, update of procedures and BMPs for preventing introgression of GE traits in plant germplasm
2. In favor of protection against premature commercialization of biotech enhanced traits
3. APHIS should be required to provide notice that a given trait is under review and solicit public comment. This would enable affected industry and producer stakeholders to meet at an early stage with technology owners/providers to assess the adequacy of their risk-management (stewardship) and risk-responsibility (liability) plans if – and during the time that – the trait is subject to conditional deregulation status. Stakeholders then could provide timely and relevant feedback to APHIS on whether the technology owner's/provider's plans are sufficient, while preserving confidential business information that may be part of such plans
4. Notes that this alternative is suitable for regulating pharmaceutical or industrial output traits without revisions to EPA and FDA regulations

Against Alternative 3: Most trade groups, some organic groups, environmentalists, biotech industry, academics

1. Pathway to commercialization not apparent
2. Doesn't go far enough:
    a. Need to prohibit the commercialization of GE organisms that cannot be completely contained through mitigation measures.
    b. Needs a post-market monitoring system

   c. Needs enforcement of mandatory contamination prevention measures
   d. Needs improvement to experimental field trial transparency and oversight
   e. Needs to require the collection of independent experimental data to enable regulators to assess plant pest and noxious weed risks.
   f. GE product developers should bear liability for costs and risks associated with their products.
   g. Needs to include measures to ensure biocontainment incorporated into each GE crop to prevent Horizontal Gene Transfer.
3. Some risky organisms could entirely escape APHIS regulation.
4. Creates great barriers to innovation without protecting plant health or the natural environment.
5. Costly and difficult to administer.
6. Would increase environmental risks by inhibiting innovation
7. Not science or risk based
8. It is not justifiable either from a regulatory or a scientific perspective to hold GE plants to a different standard than non-GE plants for risks regulated under the same statutory authority by the very same agency

Alternative 4 - Withdraw 7 CFR part 340 and Regulate Plant Pests under part 330, and Noxious Weeds under part 360

For Alternative 4: Some academics, some industry, some trade groups

1. Voluntary program would work because in general products of biotechnology do not pose a plant pests or noxious weed risk, product developers would engage in a voluntary process because its demanded of their investors and customers, and FDA program is voluntary and there is high industry compliance.
2. It is the responsibility of the developer to assure the safety and efficacy of their product(s) and that process based regulations will only serve to stifle innovation and increase cost throughout the value chain with no discernable increase in product safety.
3. Epitomizes the premise that regulations should be commensurate with risk.
4. Consistent with the principles underlying the coordinated framework
5. Developers currently have stringent and robust testing programs that seek to fully characterize and evaluate new plant varieties, including those developed utilizing biotechnology, prior to their commercial introduction. This alternative recognizes that developers of all new plant varieties have processes in place to meet the standards under these statutes. It eliminates the current double standard under which biotechnology products are subject to a different level of oversight.
6. A visionary goal that might require intermediate steps, and significant outreach and advocacy, to ensure its successful implementation.

Against Alternative 4: Environmental Groups, organic, some industry

1. Would allow the biotechnology industry to regulate itself amounting to an impermissible abdication of APHIS' statutory duties under PPA.
2. Won't protect non GE farmer, environment, or public health
3. Concern that would have a negative impact on international trade and coexistence.
4. Concern that would create a regulatory vacuum that another state or federal agency would feel compelled to fill
5. Public acceptance not expected to be high
6. a radical departure from the current approach, and in consideration of current global regulatory schemes, it may not be practical to move to such a model quickly
7. Current system works, no need to reinvent the wheel.
8. 7 CFR parts 330 and 360 may need revision to be applicable to field testing products of biotechnology
9. GM crops require careful assessment and regulation because they have caused demonstrable economic losses and environmental problems.

Appendix 3: Public Comments – dPEIS

Public Comment Sought: This dPEIS is a comprehensive document designed for more environmentally informed decision-making for future regulation of GE organisms under the Agency's purview. As described in Appendix 2, APHIS published its NOI for this dPEIS on February 5, 2016, soliciting public comment. APHIS considered comments received in response to the NOI, and now seeks public comments on the dPEIS. Following consideration of the comments APHIS receives on this dPEIS, APHIS will issue a final PEIS in accordance with NEPA. Supplements to the final PEIS may be necessary as new or improved processes are developed, changes occur in the program or its administration, or coverage of the document is expanded.

Appendix 4: USDA and USFWS MOU

Memorandum of understanding (MOU) to define and clarify policies and procedures for interaction between the United States Department of the Interior, Fish and Wildlife Service (FWS) and the United States Department of Agriculture [07-2000-0039-MU], 2007. A copy of the MOU is provided on the following pages.

07-2000-0039-MU

MEMORANDUM OF UNDERSTANDING
BETWEEN
UNITED STATES DEPARTMENT OF INTERIOR
UNITED STATES FISH AND WILDLIFE SERVICE
AND THE
UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

ARTICLE 1 - PURPOSE

The objective of this Memorandum of Understanding is to define and clarify policies and procedures for interaction between the United States Department of the Interior, Fish and Wildlife Service (FWS) and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (BRS), in support of common objectives, interests, and statutory requirements of the Endangered Species Act. Further, it will identify when BRS actions and decisions taken during the process of regulating the release of genetically engineered (GE) plants require an effects analysis in accordance with the Act.

ARTICLE 2 - BACKGROUND

The Endangered Species Act was signed into law in 1973. Section 7 of the Act requires that Federal agencies, in consultation with the Fish and Wildlife Service, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. In fulfilling these requirements, agencies are to use the best available scientific and commercial data.

The Animal and Plant Health Inspection Service, through its BRS program, regulates the field release, movement, and importation of GE organisms that are known to be, or could be, plant pests. BRS issues various types of permits for each of these activities. In regulating biotechnology, BRS works in concert with the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA), which also play important roles in protecting agriculture, food safety, and the environment. An overview of the coordinated framework for regulation of genetically engineered organisms can be found on the United States Regulatory Agencies Unified Biotechnology Website at http://usbiotechreg.nbii.gov/. More detailed information explaining the regulatory and permitting systems that BRS uses can be found on the BRS website at http://www.aphis.usda.gov/brs/regulatory_activities.html.

Depending on the level of risk for a field release of a GE plant, BRS requires different levels of information, performance standards, and administrative controls. At a minimum, BRS requires all applicants to provide detailed information about the plant such as the source and identity of the genes introduced; the method of genetic engineering; and the size, duration and location of the field test. All field releases must not allow viable plant material to remain that is likely to germinate and create new plants (volunteers). The release sites must be monitored and any volunteers destroyed.

APHIS has determined that due to the nature of the regulated article, many of the releases would have no effect on federally listed threatened and endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation. If a regulated article meets the requirements below, the release would be considered to have a "no effect" determination, and would not require analysis under the Endangered Species Act.

- The GE plant is not listed as a Federal noxious weed and is not considered a weed in the area of introduction;
- The genetic material is stably integrated into the plant genome;
- The newly introduced gene's function is known and will not result in plant disease;
- The genetic material does not cause production of a plant pest; cause the plant to produce substances that are toxic to nontarget organisms; or cause the plant to produce compounds intended for pharmaceutical or industrial use;
- The newly introduced gene does not cause the creation of a new plant virus;
- The plant is not engineered to contain the following genetic material: any nucleic acid sequence derived from an animal or human virus; or coding sequences whose products are known or likely causal agents of disease in animals or humans.
- The GE plant does not have sexually compatible relatives that are federally listed or proposed as threatened or endangered plant species.
- The proposed test site and all areas that could potentially be directly or indirectly affected by the GE plant are not in designated or proposed critical habitat for a federally listed threatened or endangered species.

For field releases of GE plants that do not meet the above requirements, the applicant must provide a detailed description of protocols for the field test, a detailed description of the molecular biology of the system, and a description of the anticipated or actual expression of the altered genetic material in the regulated article. During the field trial, the applicant must follow protocols that include precautions to be taken to prevent the escape of the regulated article from the field trial site, including destruction of remaining plant material and monitoring the site to ensure no volunteer plants survive. The field trials are subject to inspection and the frequency of inspection varies depending on the type of product being tested. Plants engineered for pharmaceutical, industrial, or phytoremediation purposes receive up to seven inspections, and have additional requirements compared to those GE crops being developed for use as food or feed.

ARTICLE 3 – AUTHORITIES

Section 7 (a) (1) of the Endangered Species Act requires all Federal agencies, in consultation with and with the assistance of the Secretary (Interior or Commerce), to utilize their authorities in furtherance of the purposes of the Act by carrying out programs for the conservation of threatened and endangered species.

Section 7 (a) (2) of the Endangered Species Act requires that each Federal agency, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of a listed threatened or endangered species, or result in the destruction or adverse modification of designated critical habitat. Implementing regulations are found in 50 CFR Part 402, Interagency Cooperation Regulations.

APHIS is authorized by the Plant Protection Act, Sec. 431(a), Public Law 106-224, to cooperate with other Federal agencies, the governments of foreign countries, international organizations or associations, states and their political subdivisions, farmer's associations and similar organizations, and other persons to detect, eradicate, suppress, control, and prevent or retard the spread of plant pests and diseases.

ARTICLE 4 – APHIS RESPONSIBILITIES

APHIS will evaluate all applications for releases that do not meet the exclusionary qualifications listed in Article 2 of this MOU for their potential effect on federally listed threatened and endangered species and species proposed for listing, and the effect on designated critical habitat and habitat proposed for designation, in accordance with requirements of the Endangered Species Act. The process will be as follows:

Step 1: Define the action area. The action area includes all areas that could be affected directly or indirectly by the release. The action area is dependent on factors such as the size of the field trial and the nature of the regulated article.

Step 2: Determine which federally listed threatened and endangered species, and species proposed for listing are in the action area. Resources available for this are:
http://ecos.fws.gov/tess_public/StartTESS.do - to search by State and county
http://www.fws.gov/Endangered/wildlife.html - to find proposed species.
Additional data can be found at:
http://www.natureserve.org/explorer/servlet/NatureServe?init=Species

Step 3: Determine if designated critical habitat and proposed designated critical habitat is within the action area. The FWS website (http://crithab.fws.gov) can be used for this to obtain information at the county level.

Step 4: The following decision tree will then be used to determine if further analysis under the ESA is required, and also the parameters of the analysis.

1. Are federally listed threatened or endangered species or species proposed for listing found in the action area? Is there designated critical habitat or habitat proposed for designation in the action area? If both answers are no - if there are no federally listed threatened or endangered species or species proposed for listing, and no designated critical habitat or habitat proposed for designation in the action area, no further analysis is required. Document the permit file. If either of the answers is yes, proceed to step 1a.

   a. If there is designated critical habitat or habitat proposed for designation within the action area, perform an effects analysis of the action on the critical habitat. If it is determined that the action "may affect, not likely to adversely affect" designated critical habitat, it will be necessary to consult with FWS before proceeding with the proposed action. If it is determined that the action "may affect, likely to adversely affect" designated critical habitat, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to adversely modify proposed critical habitat, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is "no effect," document the file. Then proceed to 1.b.

   b. If there are federally listed threatened or endangered species or species proposed for listing found in the action area, go to 2.

2. Will disturbance of the field site for the release (e.g. plowing, removing vegetation, burning etc.) directly or indirectly affect a federally listed threatened or endangered species or species proposed for listing?
   - If no, go to 3.
   - If yes, analyze the effect on the species (unless the site would be disturbed even if the action were not to occur, resulting in no change to the baseline). If it is determined that the action "may affect, not likely to adversely affect" listed threatened or endangered species, it will be necessary to informally consult with FWS before proceeding with the proposed action. If it is determined that the action "may affect, likely to adversely affect" listed threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to jeopardize the continued existence of a proposed species, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is "no effect", document the file. Then proceed to 3.

3. Is the engineered plant sexually compatible with a federally listed threatened or endangered plant species or plant species proposed for listing that could be found in the area?

   - If no, go to 5.
   - If yes, go to 4.

4. Are there measures that can be taken to prevent escape of the genetic material to sexually compatible federally listed or proposed listed threatened or endangered species?
   - If no, analyze the effect to those species that are sexually compatible. If it is determined that the action "may affect, not likely to adversely affect" listed federally listed threatened or endangered species, it will be necessary to consult with FWS before proceeding with the proposed action.. If it is determined that the action "may affect, likely to adversely affect" listed threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to jeopardize the continued existence of a proposed species, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is "no effect", document the file. Go to 5.
   - If yes, include the measures in the supplemental permit conditions and that the field site is inspected to ensure compliance. Go to 5.

5. Is the transgenic modification intended to result in the production, or increase the production, of a toxin, natural toxicant, allelochemical, pheromone, hormone, etc. that could directly or indirectly result in killing or interfering with the normal growth, development, or behavior of a federally listed threatened or endangered species or species proposed for listing?
   - If no, no further analysis is required. Document the permit file.
   - If yes, analyze the effect on those species that are likely to be susceptible to the mode of action with consideration of the route of exposure. If it is determined that the action "may affect, not likely to adversely affect" listed threatened or endangered species, it will be necessary to consult with FWS before proceeding with the proposed action. If it is determined that the action "may affect, likely to adversely affect" listed threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to jeopardize the continued existence of a proposed species, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is "no effect", document the file.

End of Decision Tree

If for any reason, APHIS believes there could possibly be an effect on federally listed threatened or endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation, by a release of a regulated article that meets the exclusionary criteria listed in Article 2 of this MOU, APHIS will complete an effects analysis as described in the decision tree. Similarly, if it comes to APHIS' attention that the action may have an effect that was not determined by the decision tree, APHIS will also perform the necessary effects analysis.

If the APHIS determination is "no effect", consultation will not be required. BRS will file the analysis and decision in the permit file.

If APHIS determines that the action "may affect, but is not likely to adversely affect" federally listed threatened or endangered species, or designated critical habitat, APHIS will initiate consultation before proceeding with the proposed action. The effects analysis along with a copy of the applicant's permit application from which confidential business information has been deleted will be submitted to FWS for review, comment, and concurrence. In addition, if an Environmental Assessment is being prepared as a requirement of the National Environmental Policy Act, a copy will be provided to FWS reviewers.

If APHIS determines that the action "is likely to adversely affect" federally listed threatened or endangered species, or designated critical habitat, APHIS will initiate a formal consultation. BRS will develop a Biological Evaluation (BE) that will be sent for review to the FWS Field Supervisor of Ecological Services and/or others within FWS as requested.

If it is determined that the action is likely to jeopardize the continued existence of a species proposed for listing, or adversely modify proposed designated habitat, BRS will confer with the FWS before proceeding with the proposed action.

If FWS timely requests more information from BRS, BRS will provide all information requested to the best of its ability. If FWS recommends modification to the proposed action, BRS will effectuate those FWS requested modifications to the extent appropriate and permitted pursuant to BRS' statutory authorities.

BRS agrees not to make any binding or irreversible decisions regarding a particular proposed action that requires an ESA determination until FWS has completed its review and has concurred with the BRS analysis or has provided the Biological Opinion, as applicable. BRS will have the option of appropriately elevating its concerns through accepted agency procedures regarding any undue delays in receiving FWS' review and/or Biological Opinion.

ARTICLE 5 – USFWS RESPONSIBILITIES

If APHIS has determined that a release "may affect", but is "not likely to adversely affect" listed species or designated critical habitat, BRS will enter into consultation with FWS. FWS will receive the effects analysis along with a confidential business information deleted copy of the applicant's permit application, and a copy of the Environmental Assessment, if one has been prepared or completed as a requirement of the National Environmental Policy Act. Upon receipt of the effects analysis and any other supporting documents, FWS will reply by letter to the BRS Document Control Officer and/or other BRS regulatory official within 30 days and either:

1. Request additional information,

2. Offer concurrence on the "may affect, not likely to adversely affect" determination,
3. Recommend modification to the proposed action, or
4. Recommend that BRS initiate a formal consultation if there is a "may affect, likely to adversely affect" determination by FWS. In its recommendation, FWS will explain why the effects are not insignificant, discountable, or beneficial.

If a formal consultation is recommended, FWS will work with BRS to identify options to avoid adverse effects to listed species and/or critical habitat. If no solutions are available, BRS will initiate a formal consultation and submit a Biological Evaluation (BE). Within 30 working days of receipt of the BE, FWS will provide written acknowledgement of the consultation request, and request any information it needs that has not been submitted. BRS will modify the BE and provide all information requested by FWS. Within 90 days of receipt of the completed initiation package (the agreed upon BE), FWS will complete its evaluation. Within 45 days of completing their evaluation (not more than 135 days after receipt of the agreed upon BE), FWS will provide a written biological opinion. Both the 90 day review time and the 45 day period to develop the written biological opinion may be extended if both parties agree.

If it is determined that the action is likely to jeopardize the continued existence of a proposed species, or adversely modify proposed designated critical habitat, BRS will confer with FWS. FWS will provide recommendations to avoid or minimize the adverse effects of the action in a conference report or conference opinion. If the action also results in a formal consultation with FWS, the conference may be combined with the consultation.

ARTICLE 6 – MUTUAL RESPONSIBILITIES

APHIS and the United States Fish and Wildlife Service mutually agree to cooperate fully and perform their required roles as specified in the act and in accordance with regulations found in 50 CFR Part 402, Interagency Cooperation Regulations.

ARTICLE 7 - STATEMENT OF NO FINANCIAL OBLIGATION

Signature of this MOU does not constitute a financial obligation on the part of APHIS. Each signatory party is to use and manage its own funds in carrying out the purpose of this MOU. Transfers of funds or items of value is not authorized under this MOU.

ARTICLE 8 - LIMITATIONS OF COMMITMENT

This MOU and any continuation thereof shall be contingent upon the availability of funds appropriated by the Congress of the United States. It is understood and agreed that any monies allocated for purposes covered by this MOU shall be expended in accordance

with its terms and the manner prescribed by the fiscal regulations and/or administrative policies of the party making the funds available. If fiscal resources are to transfer, a separate agreement must be developed by the parties.

This MOU is limited solely to the release of regulated GE plants. It does not include the release or regulation of other GE organisms, or a decision to deregulate a regulated article.

ARTICLE 9 - CONGRESSIONAL RESTRICTION

Under 41 USC 22, no member of, or delegate to, Congress shall be admitted to any share or part of the MOU or to any benefit to arise therefrom.

ARTICLE 10 - AMENDMENTS

This MOU may be amended at any time by mutual agreement of the parties in writing.

ARTICLE 11 - TERMINATION

This MOU may be terminated by either party upon sixty (60) days written notice to the other party.

ARTICLE 12 - EFFECTIVE DATE AND DURATION

This MOU will be in effect upon date of final signature and will continue in effect for ten years.

UNITED STATES DEPARTMENT OF INTERIOR
UNITED STATES FISH AND WILDLIFE SERVICE

Bryan Arroyo 5/17/07
Acting Assistant Director for Endangered Species Date

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

5/07/07
Deputy Administrator Date

Appendix 5: ESA Section 7 Consultation Decision Tree

DECISION TREE ON WHETHER SECTION 7 CONSULTATION WITH FWS IS TRIGGERED FOR PETITIONS OF TRANSGENIC PLANTS

This decision tree document is based on the phenotypes (traits) that have been field tested under APHIS oversight (for a list of approved field tests, visit Information Systems for Biotechnology.) APHIS will re-evaluate and update this decision document as it receives new applications for field testing of new traits that are genetically engineered into plants.

BACKGROUND

For each transgene(s)/transgenic plant the following information, data, and questions will be addressed by APHIS, and the EAs on each petition will be publicly available. APHIS review will encompass:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant),
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

FDA published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (http://vm.cfsan.fda.gov/~lrd/fr92529b.html and http://vm.cfsan.fda.gov/~lrd/consulpr.html). The FDA's policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already consumed by human and thus do not require pre-market approval. Consistent with its 1992 policy, FDA expects developers to consult with the agency on safety and regulatory questions. A list of consultations is available at http://vm.cfsan.fda.gov/~lrd/biocon.htmlhttp://vm.cfsan.fda.gov/~lrd/biocon.html. APHIS considers the status and conclusion of the FDA consultations in its EAs.

Below is a description of our review process to whether a consultation with U.S. Fish and Wildlife Service is necessary.

If the answer to any of the questions 1-4 below is yes, APHIS will contact FWS to determine if a consultation is required:

1) Is the transgenic plant sexually compatible with a TE plant[223] without human intervention?
2) Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?
3) Does the transgene product or its metabolites have any significant similarities to known toxins[224])?
4) Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside agro-ecosystem)[225]?
5) Does the pest resistance[226] gene act by one of the mechanisms listed below? If the answer is **YES** then a consultation with U.S. Fish and Wildlife Service is **NOT** necessary.

   A. The transgene acts only in one or more of the following ways:

      i. As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);
      ii. In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;
      iii. By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);
      iv. By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant;
      v. In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

   B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

[223] APHIS will provide FWS a draft EA that will address the impacts, if any, of gene movement to the TES plant.

[224] Via a comparison of the amino acid sequence of the transgene's protein with those found in the protein databases like PIR, Swiss-Prot and HIV amino acid data bases.

[225] Such phenotypes might include tolerance to environmental stresses such as drought, salt, frost, aluminum or heavy metals.

[226] Pest resistance would include any toxin or allelochemical that prevents, destroys, repels or mitigates a pest or effects any vertebrate or invertebrate animal, plant, or microorganism.

For the biotechnologist:
Depending on the outcome of the decision tree, initial the appropriate decision below and incorporate its language into the EA. Retain a hard copy of this decision document in the petition's file.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that the release following a determination of non-regulated status would have no effects on listed threatened or endangered species and consequently, a written concurrence or formal consultation with the Fish and Wildlife Service is not required for this EA.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is not likely to adversely affect any listed threatened or endangered species and consequently obtained written concurrence from the Fish and Wildlife Service.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is likely to affect adversely one or more listed threatened or endangered species and has initiated a formal consultation with the Fish and Wildlife Service.