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Animal and Plant
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Service

Revisions to USDA-APHIS 7 CFR part 340 Regulations Governing the Movement of Organisms Modified or Produced Through Genetic Engineering

Final Programmatic Environmental Impact Statement – May 2020

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ACRONYMS AND ABBREVIATIONS

AA	Asynchronous Authorization
AIR	Am I Regulated
ALS	Acetolactate Synthase
AMS	Agricultural Marketing Service
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
ASTA	American Seed and Trade Association
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
EIS	Environmental Impact Statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FAO	Food and Agricultural Organization of the United Nations
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
GHG	Greenhouse gas
GR	Glyphosate resistant
HR	Herbicide resistant, herbicide resistance
IP	Identity preservation
IR	Insect resistant
LLP	Low Level Presence
MOA	Mode of Action
N_2O	Nitrous oxide
NOx	Nitrogen oxides

Acronyms and Abbreviations

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
PIP	Plant incorporated protectant
PMPI-producing plants	GE plant that produces pharmaceutical or industrial compounds
PPA	Plant Protection Act
PPRA	Plant Pest Risk Assessment
RSR	Regulatory Status Review
SARE	Sustainable Agriculture Research and Education
TES	Threatened and Endangered Species
TSCA	Toxic Substances Control Act
U.S.	United States, territories, and possessions
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
WTO	World Trade Organization

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, 2015), provisions of the 2008 Farm Bill (Pub.L. 110–234, H.R. 2419, 122 Stat. 923), and to make its regulation commensurate with the potential environmental risks as described by the National Research Council (NRC 2002).

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 reviewing all transgenic plants to separate those that require additional regulatory oversight from those that do

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

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 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. 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 and that APHIS clarify its regulations regarding the use of metal shipping containers and movement of GE seeds. APHIS agreed with these recommendations (USDA-OIG 2015), and has, as part of implementing the recommendations, issued 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 3 Revisions to Regulations

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

- Codify, in the regulations, the Secretary of Agriculture's March 28, 2018, statement[2] that provided clarification on the USDA's oversight of plants produced through plant breeding innovations and exempt certain categories of plants from the regulations in 7 CFR part 340 because they could be produced through conventional breeding techniques[3], which APHIS does not regulate.
- Change the basis for APHIS regulatory review from one in which GE plants are regulated based on the use of plant pests in their development, to one in which APHIS reviews the GE plants themselves for plant pest risks. Regulated status will be based on regulatory status reviews (RSR, see section 2.2) rather than a petition process.
- Refine the regulatory framework so that APHIS oversight is focused on those GE organisms that are found to have plausible pathways to increased plant pest risk, as

[2] The statement and the further details are available at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018_brs_news/plant_breeding.

[3] The term "conventional breeding" may be used interchangeably with "traditional breeding." In the June 2019 proposed rule, APHIS used both terms, with "traditional breeding" appearing more frequently in the text. Based in part on dialogue with other agencies involved in regulating biotechnology, we have elected to use the term "conventional breeding" throughout this document, except when the need to quote directly indicates otherwise. For purposes of this document, "conventional breeding" has the meaning it is understood to have within the context of part 340, based on the examples provided in the final rule. Other Federal or State regulations may use the term "conventional breeding" in the context of their regulations and attribute slightly different meanings.

determined by science-based risk assessments, and thereby reducing unnecessary regulatory burdens.

- Eliminate the notification procedure and authorize the interstate movement, importation, or environmental release only under permit of GE organisms that APHIS found had a plausible pathway to greater plant pest risk or did not review for plant pest risk.

The revisions are expected to promote process efficiency by allowing APHIS to focus its resources on oversight of GE organisms that have a plausible pathway to greater plant pest risk, and reducing oversight of GE organisms that are unlikely to pose such risks. By focusing on those GE organisms that pose plausible pathways to greater plant pest risk, inefficient regulatory burdens will be eliminated without compromising safety. This revision will allow for a level of oversight consistent with the degree of risk associated with GE organisms regulated by APHIS.

ES 3.1 Scoping and Public Involvement

Public scoping for an environmental impact statement (EIS) is required under NEPA regulations (40 CFR §1501.7 - Scoping). Subject matter considered in this programmatic environmental impact statement (PEIS) was in part identified in a scoping process during which government agencies, the public, and other stakeholders were invited to submit comments.

Scoping for this PEIS began on June 29, 2018, when APHIS published its notice of intent (NOI) to prepare a PEIS in the *Federal Register*.[4] The NOI solicited public comment to help define the issues to be considered in the PEIS and scope of Alternatives to consider in revision of the 7 CFR part 340 regulations.

The comment period on the NOI lasted until July 30, 2018. At the close of this comment period APHIS had received 35 submissions from the public. The submissions were from individuals from academic organizations (2), professional organizations (2), trade groups (2), commodity groups (4), industry (4), Non-Governmental Organizations (NGOs)s (4), federally recognized Tribes (2), and unspecified individuals (15). Full text of the comments are available online at: https://www.regulations.gov/document?D=APHIS-2018-0034-0001. Many commenters requested that APHIS analyze certain topics in the PEIS, summarized in Appendix 2.

On June 6, 2019, APHIS published a notice in the *Federal Register* (84 FR 26514-26541, Docket No. APHIS-2018-0034) announcing the availability of the proposed rule, draft PEIS, and supporting documents for a 60-day public review and comment period. The comment period closed on August 6, 2019. APHIS received a total of 6,151 public submissions. The comments specific to the PEIS are summarized in Appendix 3, along with the APHIS responses.

ES 3.2 Alternatives Considered and Evaluated in this PEIS

Based in part on scoping, APHIS developed two Alternatives for consideration in revision of 7 CFR part 340, which are evaluated in this PEIS. A summary of the Alternatives evaluated is provided below and further details discussed in Chapter 2:

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[4] 83 *Federal Register*, No. 126 (June 29, 2018), pp.30688-30689: Available at https://www.gpo.gov/fdsys/pkg/FR-2018-06-29/pdf/2018-14019.pdf

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 include exemptions for certain types of plants created through plant breeding innovation that could otherwise have been created by conventional breeding; to refine the scope of organisms considered under the regulations by instituting a risk-based regulatory system so regulation is commensurate with risk; to institute a more efficient risk analysis process where redundant reviews due to "event by event" regulation are eliminated; to institute regulatory status reviews in place of a petition process where developers can choose to have their GE plants reviewed for plant pest risks prior to movement (import, interstate movement, environmental release) such that GE plants that have no plausible pathway to increased plant pest risk need not be subject to permitting requirements; and to eliminate the notification process and authorize the interstate movement, importation, and environmental release of regulated GE organism only under permit.

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 PEIS, but are discussed briefly below along with the specific reasons for dismissing them from further consideration.

ES 3.3.1 Regulation to Facilitate Coexistence

In the PEIS for the proposed rule change published January 19, 2017 (Docket No. APHIS-2015-0057-0006), APHIS analyzed a third Alternative where GE organisms that cause no physical damage to plants would have been regulated if they could have resulted in economic harm to non-GE producers from the mere presence of the GE trait as a result of cross pollination or commingling.

Under this Alternative, APHIS' proposed regulatory framework would have incorporated the noxious weed authority under the PPA as inclusive of GE plants that could have caused economic harms due to the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurred 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 would have been 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 have been interpreted to include any adverse impacts that could have resulted from the mere presence of GE plant material where it was not wanted. In its review of a GE plant, APHIS would have assessed not only the likelihood that the modifications made to the genome of the plant altered its ability to cause physical harm or injury but in addition, APHIS would have considered the economic harms that may have resulted from commingling or cross pollination of the GE plant with a non-GE crop plant or its products.

Under this regulatory framework, APHIS would likely have found many of the GE plants under regulation would have been unlikely to pose a physical risk to plants, but may have posed a risk of potential economic impacts resulting from the mere presence of GE materials in crops produced for non-GE markets. If implemented, APHIS would have served as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and those that would be grown. In effect, the only GE organisms that would not require permits for interstate movement, importation, and environmental release would be those that did not cause physical harm to plants and did not cause economic harms due to mere presence. A distinction would have been made in the permitting requirements for GE plants that cause physical harm from those that cause only economic harm due to mere presence where in the latter case the conditions would have been aimed at promoting coexistence and minimizing incidents of unauthorized and unintended presence.

Under this Alternative, developers and growers of GE crops that only cause economic harm due to mere presence would have been 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 and non-GE crops. In this case, the permit conditions would have been 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 have addressed and mitigated potential economic impacts that could result from cultivation of GE crops.

Further, the only regulated GE crop plants that would have been permitted for commercial-scale cultivation in the United States would be those crop plants that had received regulatory approval in the major export markets. This requirement would have been instituted to reduce the potential for low level presence (LLP)[5] occurring in countries importing U.S. agricultural commodities.

APHIS has never regulated based on economic impacts alone in the absence of any actual biological, chemical, or physical damage. This regulatory role would have been inconsistent with the Agency mission and with current APHIS programs, which are aimed at protecting plants from biological, chemical, and physical damage. As this Alternative was expected to increase regulatory costs to the agency and industry out of proportion to benefits (USDA-APHIS 2020f), to increase cost to consumers for food production, to decrease competitiveness of the U.S. biotechnology industry, and to stifle innovation resulting in a loss of environmental benefits expected to result from plant breeding innovation, APHIS dismissed this Alternative from further consideration.

ES 3.3.2 Withdraw 7 CFR part 340 and Regulate Plant Pests under part 330, and Noxious Weeds under part 360

[5] 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 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 7 CFR part 360 (Noxious Weed Regulations) if they posed a plant pest or noxious weed risk, respectively. APHIS previously proposed to examine this Alternative, based on the assumption that most GE crop plants are unlikely to pose a noxious weed or plant pest risk.

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, respectively. 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. 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.

Although the merit of this regulatory framework, in principle, was recognized, stakeholder concerns, APHIS' review of these concerns, and APHIS' initial examination of this Alternative prompted APHIS to dismiss this alternative as a plausible path forward. 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 further.

ES 3.3.3 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 a risk assessment to determine whether an organism is regulated prior to field testing. In the event field testing was needed or the developer requested to field test in lieu of a regulatory status review, the agency would retain the option of authorizing field testing these GE organisms under the notification procedure.

The term "notification" can be misleading to the public, as sending a notification does not mean automatic authorization by APHIS. In many ways, APHIS' review 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 clarity, 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.

ES 3.3.4 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 conventional 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.

ES 4 Summary of Potential Impacts on the Human Environment

APHIS evaluated the potential impacts that could derive from APHIS decisions and actions under the two regulatory Alternatives described; namely decisions and actions in the oversight of the importation, interstate movement, and field testing of GE organisms subject to the regulations. Under both Alternatives, the geographic range of potential impacts encompasses all 50 states and U.S. territories, with the areas impacted by 7 CFR part 340 primarily those used for cropland, rangeland, and forestland. Those aspects of the human environment addressed in the PEIS 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 two Alternatives considered. Based on the PEIS and Regulatory Impact Analysis conducted by APHIS (USDA-APHIS 2020f), 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.

ES 4.1 Socioeconomic Impacts

The 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.

ES 4.1.1 APHIS Cost Changes

Annual APHIS personnel costs of conducting GE activities under current regulations that would be affected by the final rule total about $3.5 million. These include compliance activities, inspection activities, AIR process activities, notification activities, permit activities, and petition activities. Under the final rule, APHIS' overall annual personnel costs of regulating GE organisms are not expected to change. While the volume of specific activities will change, the overall volume of regulatory activities, the general nature of those activities and the level of skills necessary to perform those activities will not change. There would be costs to APHIS of implementing the final rule and 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 $77,000. Requests for regulatory status and response letters under the final rule could be handled in a manner similar to the current 'Am I Regulated' process outside the electronic permitting system without incurring new costs.

ES 4.1.2 Agricultural Biotechnology Sector

Direct regulatory costs to biotechnology developers would be reduced under the Preferred Alternative. The process for achieving non-regulated status would change. Petitions would no longer be required and costs for achieving non regulated status would be reduced. Under the Preferred Alternative, permitting would only be required for those GE organisms that APHIS found had a plausible pathway to greater plant pest risk. No APHIS regulatory oversight would be needed once APHIS has concluded, via a regulatory status review, that a GE plant does not pose a plausible pathway to greater plant pest risk.

In terms of net reductions in costs to developers, APHIS estimates that biotechnology developers could save from $551,000 to $937,000 per GE trait when the EPA and/or FDA also have regulatory oversight, and from about $1.6 million to $5.6 million per GE trait when APHIS is the only regulatory agency with oversight. 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 plants from 5 (the current annual average of processed petitions) to 10 (twice this average). APHIS assumes that about 20% of those new GE plants would have required only APHIS oversight, and the remaining would still be covered under FDA and/or EPA oversight. If 5 new

GE plants are developed annually without APHIS permits (all with no APHIS permit, but 4 still with EPA and/or FDA evaluation), the annual savings would be $6.5 million. If 10 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 8 still with EPA and/or FDA evaluation), the annual savings would be $13.0 million.

Because the regulatory cost savings for GE crops that require only APHIS approval are expected to be much larger, the final 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.

Indirect benefits are also expected to result from a more expedient review and regulatory 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 procedural changes codified in the final rule.

ES 4.1.3 Producers of GE Crops

Potential beneficial impacts to producers of GE organisms are similar under both Alternatives. 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 2015a). 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 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. These types of trait development are also expected under the No Action Alternative. In comparison to the No Action Alternative, the revisions to APHIS' regulation of GE organisms in the Preferred Alternative may more readily help sustain or even improve farm-level profitability.

ES 4.1.4 Consumers

Potential beneficial impacts to consumers of commodities derived from GE crops would be expected to continue under both Alternatives. 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 (Fernandez-Cornejo et al. 2014b; Klümper and Qaim 2014; Brookes and Barfoot 2015a; Brookes and Barfoot 2017b).

The final 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. In that case, it may spur innovation by public sector researchers. Such innovation may ultimately benefit biotech companies, farmers, and consumers.

ES 4.1.5 Producers of Non-GE Crops

One of the challenges in organic and non-GE crop production systems is preventing the accidental commingling 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.

The risk to organic and non-GE growers from cross-pollination or commingling may increase under the Preferred Alternative but would depend on the extent to which 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 GE fields 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%) reported total losses of $506,552. In 2014, the total value of sales of certified and exempt organic field crops was $5.5 billion (USDA-NASS 2015). The total value of sales from certified and exempt organic crops in 2014 was $3.3 billion.[6] 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 reported 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 reported 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.

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. 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 be due to the possibility that there would be more GE crop varieties in production and therefore more non-GE crop types that could potentially have commingling issues with the corresponding GE crops. An increase in development and adoption of new varieties of GE crops would entail maintaining segregation of GE crop products from a wider variety of "non-GMO" and identity-preserved cropping systems along supply chains.

[6] This includes nursery and greenhouse crops, which skews the total sales data when evaluating food crops.

The economic impact to growers of organic and non-GMO commodities from such unintended presence would depend on the price premium impacted. For instance, 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 impacted 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 varieties on the market. These are crops where the seed is the valued part of the plant and are therefore the crops most likely to be impacted by commingling or cross pollination with GE crops, in the event such GE crops are commercialized.

ES 4.1.6 Unauthorized Releases

In contrast to commingling of nonregulated GE plant material in non-GE crops or crop products, which can impact the price premium of certain commodities as described above, commingling of GE plant material subject to the regulations at 7 CFR part 340 in agricultural commodities can render a product unmarketable and, consequently, can have significant economic impacts. The Preferred Alternative is expected to reduce the number of unauthorized releases of these GE plants by limiting unnecessary regulation of GE organisms and focusing regulatory oversight on those GE organisms that have a plausible pathway to greater plant pest risk. As fewer GE organisms will likely be subject to the 7 CFR part 340 regulations, 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 impacts of such 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 such incidents could occur again, albeit rarely. Financial losses resulting from unauthorized releases are difficult to quantify due to a variety of factors governing the market price of agricultural commodities. However, several examples are provided in Section 4.6.2.

While it is possible that 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 subject to regulatory oversight by APHIS would likely be less than that regulated under the No Action Alternative.

ES 4.1.7 Low level Presence (LLP)

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 food/feed in some countries, but not others, the low level presence (LLP)[7] of GE crop material in internationally traded crop commodities has become a focus of discussion (FAO 2014b). LLP situations occur in the importing country when there is asynchrony between the authorization of the exporting country and that of the importing country; this is an issue described as an “asynchronous authorization” (AA). These occurrences can result from natural processes such as the movement of seeds or pollen, or human-mediated processes associated with field testing, plant breeding, or seed production or post-harvest handling. The issue of asynchronous authorization, and resulting LLP situations, can lead to trade delays, shipment rejection, and costs to traders (FAO 2014b).

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 2020a). 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 an import is deterred or directed to another trading partner (Atici 2014). In addition to situations arising from asynchronous authorizations 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 bans. 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. In the United States, a GE crop plant for human or animal food generally is not released for commerce until (1) APHIS determines it is not subject to regulation, (2) the developer has successfully completed a voluntary consultation with the FDA on the human or animal food derived from the plant, and (3) if the plant contains a plant incorporated protectant (PIP), EPA has registered/licensed/approved the PIP.

LLP instances can be very costly. As an example, China refused entry of corn with trace amounts of a GE corn variety (MIR-162) that it had not approved. The embargo, from November 2013 until China ultimately approved the use of MIR-162 on December 16, 2014, affected corn sales and prompted extensive litigation, including class action lawsuits, where U.S. corn producers and U.S. grain merchants sued Syngenta (now owned by ChemChina) (Chaney et al. 2015). In 2017, a $1.51 billion settlement was reached with Syngenta to resolve the complaints of more than 100,000 U.S. farmers. The settlement does not include Canadian lawsuits (Smethie and Heilshorn 2019). Archer Daniels Midland Co. reached a confidential settlement with Syngenta in 2018 (Begemann, 2018). A grain and feed industry study of the MIR 162-induced trade disruptions on the U.S. corn, distillers dried grains with solubles, and soybean sectors of the U.S. grain industry, claimed estimated losses of up to $3 billion during the 2013/14 marketing year (Fisher 2014). Disruptions in international trade can be minimized, albeit at substantial cost (as noted below), by delaying commercialization of new GE traits until regulatory approval has been secured in all major markets. Some biotechnology firms have self-regulated toward that end by

[7] Low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline) in one or more countries that may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined (Codex 2003).

not releasing new GE traits until they have been approved for use in major import markets (CLI 2020b).

Though innovation may increase, that does not necessarily mean that the rate of LLP incidents would change under the Preferred 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 would not significantly change under the Preferred Alternative relative to the No Action Alternative unless the review and approval process for the EPA also substantially changes, and/or the FDA's recommended consultation process also substantially changes. Because FDA reviews different endpoints than we do (e.g., food safety versus creation or enhancement of plant pest properties), we do not expect that our adoption of the Preferred Alternative would, in and of itself, cause FDA to change its procedures for plants with these kinds of modifications. One unknown factor is whether the approval process in other countries will change if USDA codifies the Preferred Alternative.

If the regulatory process is more efficient under the Preferred Alternative, the number of GE crop plants in commerce could increase. There would then need to be authorizations of such GE crop plants in foreign countries prior to export, to preclude instances of LLP. If more regulatory authorizations and commercial production of new GE crop plants in the United States occurs and these new GE crop plants have not been reviewed and authorized by foreign countries, then there is potential increased risk of LLP for certain commodities, such as corn and soybean.

ES 4.2 Summary of Other Potential Impacts to the Environment

As of July 2018, APHIS has issued more than 19,500 authorizations for the environmental release of GE organisms, primarily for research and development of improved crop varieties for agriculture. Additionally, APHIS has issued nearly 14,000 authorizations for the importation of GE organisms, and more than 12,000 authorizations for the interstate movement of GE organisms. APHIS has denied slightly more than 1,600 requests for authorizations, 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 subject to APHIS regulations 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 have had any identifiable impacts on the environment.

As of April 2020, APHIS has determined nonregulated status in response to 128 petitions and extension requests (not including one petition for Roundup Ready® Alfalfa and two petitions for Roundup Ready® Sugarbeet submitted after court ordered injunctions), out of 162 petitions received, where 32 petitions were withdrawn. All of these determinations have been for GE plants, and the vast majority for crop plants. 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 those resulting from conventional crops and cropping systems (e.g., (Sanvido et al. 2007; Brookes and Barfoot 2013b; Klümper and Qaim 2014; NAS 2016b) and others). APHIS maintains a publicly available list of petitions and determinations of nonregulated status on its website.[8]

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 2017a) . EPA now also addresses management of herbicide resistant weeds (US-EPA 2017c) through reporting and labeling requirements and education and stewardship guidance. Pest resistance is not unique to GE crops; it is a concern in any cropping system, GE and non-GE alike, for which pesticides are used. Development of feral populations of GE crop plant-wild type hybrids, and introgression of traits conferring fitness advantages into wild populations, will also remain a concern for a limited number of crops with well-established wild relative species in the United States.

Currently, insect resistance (IR) and herbicide resistance (HR) are the most widely used GE traits in commercial agriculture. These traits are used largely in corn, soybean, cotton, canola, alfalfa, and sugarbeet. These types of GE plant-trait combinations currently in commercial production have been found to have no more or fewer adverse impacts on the environment than non-GE crops produced conventionally (NRC 2010; NAS 2016b). A few other GE traits, such as resistance to specific viruses (e.g., in papaya and plum) and reduction of browning in the flesh of apples and potatoes, have also been utilized, although these types of GE crops are currently produced 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 2010). For example, a 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. This change has been primarily attributed to the use of GE IR crops, which reduced the application of insecticides, and less use of environmentally harmful 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). 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) and herbicide use appears to be increasing in GE HR corn, soybean, and cotton, as glyphosate resistant weeds have become more prevalent (USDA-NASS 2019c). Major factors affecting overall herbicide use trends (as measured in lbs a.i./year and lbs a.i./acre) have been: (1) changes in crop acreage, which is influenced by economic and policy factors, (2) the replacement or discontinuance of older pesticides (MOAs) with newer ones (changes in per-acre application rates) contributing to changes in overall pesticide quantities, (3) the introduction and adoption of GE crops from 1996 onward, and (4) the emergence of weed populations resistant to various herbicide MOAs over the last several decades.

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[8] USDA-APHIS-BRS: Petitions for Determination of Nonregulated Status; https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions

Advances in biotechnologies are expected to refine the precision with which crop varieties will be developed, and lead to 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; resistance to fungal, bacterial, and viral diseases; and new types of herbicide resistance (NAS 2016b). Such GE crop plants could facilitate more sustainable agricultural practices, reduce the adverse environmental impacts 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.

ES 4.3 Federal, Tribal, and State Governance

ES 4.3.1 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 revisions to 7 CFR part 340 under the Preferred Alternative to be entirely consistent with this principle: APHIS will no longer consider GE plants to be regulated articles solely because a plant pest was used as a donor, vector, or vector agent in its development. Instead, APHIS will consider whether GE plants will be subject to regulatory oversight based on whether the GE plant has a plausible pathway to greater plant pest risk. 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.

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 safety 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 multiple 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 procedures 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, under the Preferred Alternative while research, development, and innovation in the agricultural biotechnology sector is expected to increase, the pace of commercialization of GE crop plants would not necessarily 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. We do not anticipate that our adoption of the Preferred Alternative in and of itself would lead developers to alter their use of the FDA voluntary consultation process. 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.

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 that APHIS considers to be unlikely to pose a plant pest risk under the Preferred Alternative, other agencies may continue to exercise oversight within their authority. However, APHIS acknowledges that the revisions to 7 CFR part 340 could have direct or indirect impacts on the manner in which the FDA and EPA exercise their roles within the Coordinated Framework.

Plant-Made Pharmaceutical and Industrial Compounds (PMPIs)

Certain plants are genetically engineered to produce pharmaceutical and industrial compounds, also known as plant-made pharmaceuticals and industrials (PMPIs). When plants are genetically engineered in such a manner, the plants and the pharmaceutical and/or industrial products they produce may fall within the purview of multiple regulatory agencies: APHIS, EPA, and/or FDA.

Under the current regulations in 7 CFR part 340, APHIS requires permits, as opposed to notifications, for the environmental release of all GE plants that meet the definition of a regulated article and produce PMPIs. APHIS exercises oversight of all outdoor plantings of these regulated PMPI-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring. Products obtained from PMPI-producing plants may be regulated by FDA (authority over food and drugs) or EPA (chemical substances as defined by the Toxic Substances Control Act (TSCA)), depending on their use or intended use. To date, producers of PMPI-producing plants, or products derived from such plants, have not intended for such plants or plant products to be used for human or animal food. However, if such a plant or plant product were potentially to be used for human or animal food, food additive approval might be required under the Federal Food, Drug, and Cosmetic Act.

We stated in the June 2019 proposed rule that the likelihood existed that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined to be not regulated if a regulatory status review (RSR) found them to be unlikely to pose a plant pest risk. We also noted that our proposed rule envisioned that were this to occur, such plants could be grown outdoors without the need for APHIS permits and without APHIS oversight. Federal oversight of outdoor plantings of PMPI-producing plants, however, could be necessary to maintain the status quo. 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 the FDA or EPA when the company plants PMPI-producing plants. For example, for PMPI-producing plants whose products are subject to FDA oversight, the FDA has no regulations governing planting of such crops. For crops genetically engineered to produce human drugs, companies generally engage with the FDA only 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 the company first started growing the pharmaceutical-producing plant in the field.

Under TSCA, the EPA has requirements for new chemical substances, including industrial compounds produced in genetically engineered plants. However, given existing APHIS oversight, the EPA does not currently have an oversight program nor regulations for genetically engineered plants producing industrial compounds.

After further deliberation, including review of the numerous comments APHIS received expressing concern about the possible lack of oversight over PMPI-producing plants, APHIS has revised 340.2(e) to state that a permit is required for the movement of a plant that encodes a product intended for pharmaceutical or industrial use. Accordingly, under the final rule, PMPI producing plants will not be eligible for the RSR process.

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 without regard to acreage. As the regulatory authorities overlap, to date, the EPA has largely relied on USDA oversight and inspections of field trials under 10 acres. APHIS oversight of PIPs includes a notification or permitting system to set appropriate environmental release conditions and inspections to ensure compliance.

Under the Preferred Alternative (final 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 subject to permitting requirements. Rather, the GE plant would be subject to the regulations if it had a plant-trait-MOA combination that APHIS found had a plausible pathway to greater plant pest risk, or has not yet been reviewed for plant pest risk. Because most plants are unlikely to present a plausible pathway to greater plant pest risk, particularly domesticated plants, and traits introduced for the production of PIPs may not always confer plant pest risk to a domesticated plant, it is expected that some of the GE PIP producing plants, if subjected to a regulatory status review, would be found unlikely to pose a plant pest risk and therefore, could be grown outdoors without the need for permits and without APHIS oversight. Because EPA generally requires Experimental Use Permits for field tests only on 10 acres or more of land, only APHIS has historically exercised regulatory oversight of plantings of PIP-producing plants on 10 acres or less of land. Under the Preferred Alternative, there would be a likelihood that many PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not to be covered by the regulations after RSRs, because such plants are unlikely to pose greater plant pest risks by comparison with their comparators. Such plants could therefore be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight. Thus, Federal oversight over small-scale (10 acres or less) outdoor field test plantings of some PIP-producing plants would rest solely with 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.

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, 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 fall within the scope of the final regulations. Under the Preferred Alternative, APHIS expects that many of the GE HR plant-trait combinations it evaluates, if subjected to a regulatory status review, would be found unlikely to pose plant pest 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 the EPA regarding the timing of determination of nonregulated status of HR crops and the registration of herbicides. APHIS recognizes that the asynchronous timing of the deregulation of HR plants and the associated herbicide registration may lead to situations where a developer could sell the GE HR 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 the EPA, APHIS will work with the EPA to explore solutions to better coordinate the commercial availability of seed for HR 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 HR crop basis (e.g., glyphosate resistant cotton) so that the EPA and APHIS are making decisions on the same specific HR crop/herbicide combinations.

This coordination presents challenges because once APHIS determines a GE organism does not represent a risk as a plant pest, APHIS would not regulate the GE organism or delay announcing the status. Under the Preferred Alternative, there could be several years between the time when APHIS makes a finding of no plausible pathway of increased plant pest risk and the time when a developer is ready to undergo registration review at the EPA. If APHIS determines that the HR plant is unlikely to pose a plant pest risk, APHIS does not have the authority in the PPA to require permits with regulatory controls for the movement and outdoor planting of that HR plant during those subsequent years. Nor is it within APHIS authority for APHIS to withhold making a finding of unlikely to pose a plant pest risk for several years and to require permits for field testing during that time. The primary issue of concern with asynchronous authorizations between the USDA and EPA has not been the illegal use of pesticides during the field testing of HR crops by developers but instead has been the illegal use of pesticides 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.

ES 4.3.2 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 both of the Alternatives, APHIS would continue to consult with tribal representatives, and share applications for permits with tribal representatives, when appropriate.

ES 4.3.3 State Governments

The revision of 7 CFR part 340 would not affect APHIS partnerships with states in the oversight of GE organisms. Under both 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 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.

ES 5 Potential Cumulative Impacts

A cumulative impact is defined by 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." If there are no direct or indirect impacts associated with those aspects of the human environment discussed in Chapter 4, there can be no cumulative impacts.

In general, APHIS sees little differences in the cumulative impacts expected under the No Action and Preferred Alternatives. Some of the cumulative impacts of agriculture and how they are influenced by the No Action and Preferred Alternatives are summarized below.

ES 5.1 Cumulative Impacts: Physical Environment

ES 5.1.1 Soils

Most cumulative impacts on soils involve tillage, cover crop selection, crop rotation, irrigation practices, and pesticide and fertilizers inputs used in conjunction with the particular type of crop and cropping system. Conventional tillage has an adverse cumulative impact resulting in soil erosion which adversely impacts soil and water quality. Conservation tillage is a practice that reduces the degree of this cumulative impact. Conservation tillage has been widely adopted because of the availability of effective herbicides for weed control. 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 cropping systems in the Southeast), conventional tillage has increased to help control HR weed populations, and conservation tillage has diminished. 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 impacts from practicing conservation tillage are also expected to continue.

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). As described in Section 4.2.1, there is a major effort underway to engineer cover crops to be more valuable to growers. It is likely that under either the No Action Alternative or the Preferred Alternative, cover crops will continue to be modified to add value for growers. As a result, it can be expected that the use of cover cropping will increase and this in turn may have the beneficial cumulative impact of reducing herbicide use and improving soil quality.

ES 5.1.2 Water Resources and Quality

Agriculture is one of the leading causes of impairment in U.S. waterways (US-EPA 2019b). The impacts of agriculture on water quality and water resources are inherently cumulative in nature. The biggest cause of impairment is pathogens followed by sediment and then nutrients. Pesticides are 16th on the list (US-EPA 2019b). The adverse impacts from agriculture on water quality are a function of agriculture in general and are not attributable to GE cropping systems per se, as described in more detail in Chapter 5.

ES 5.1.3 Air Quality

As summarized in Chapter 3, crop production practices can generate air pollutants that can potentially impact the environment and human health and can challenge regional National Ambient Air Quality Standards (NAAQS). These emission sources include: smoke from crop 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 et al. 2009; US-EPA 2013b). One of the most significant sources of emissions from cropping systems is soil based N_2O. For example, 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% of emitted N_2O (US-EPA 2018c). CO_2, and CO, would also be released during use of farm equipment and transport of products, growers, scientists, and APHIS officials to and from field sites. Crop residue is also burned on some farms, and burning is a source of CH_4, N_2O, CO, and NOx.

Conservation tillage practices reduce emissions by reducing the use of internal combustion engines and soil disturbance (e.g., PM). GE crops with pest resistant traits require fewer pesticide applications thereby reducing fossil fuel consumption and associated emissions. Newly developed GE crop plants with improved nitrogen or phosphorous use efficiencies could facilitate reduction in fertilizer needs. Under both the No Action and Preferred Alternative, there may be varieties of GE crop plants with such traits developed and available for commercial production. These types of crops could potentially contribute to reduction in the cumulative emissions from U.S. agriculture.

ES 5.2 Cumulative Impacts: Biological Environment

ES 5.2.1 Soil Biota

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 et al. 2006; Gupta et al. 2007) and tillage (Gupta et al. 2007; Roger-Estrade et al. 2010). Soil biota are typically tolerant of pesticides when they are applied at recommended rates, with only minor, transient impacts on soil populations (Locke and Zablotowicz 2004). Cover cropping, especially if used for weed control, could reduce pesticide applications and tillage.

APHIS determinations of nonregulated status or findings of unlikely to pose a plant pest risk under either Alternative would have little effect on how GE or non-GE crop production may impact soil biota. If more sustainable practices are adopted under either the No Action Alternative or Preferred Alternative, such that there is less tillage, more cover cropping, and less use of certain pesticides, potential adverse cumulative impacts on soil biota would be expected to be reduced. If not, the cumulative impacts on soil biota would not be expected to change.

ES 5.2.2 Invertebrates

Adverse impacts on non-target invertebrate communities can result from applications of insecticides, which occurs in both GE and non-GE cropping systems. GE IR crops have reduced insecticide use resulting in a reduction in adverse cumulative impacts on invertebrate communities. That trend is expected to continue under both the No Action and Preferred Alternatives.

However, as discussed in Chapter 3, there will be a continued contribution of crop production, particularly GE IR crops, to cumulative impacts on the emergence of insecticide-resistant populations. The contribution or impact of GE IR crops on the emergence of insecticide-resistant populations, and the management of this issue, would not differ under either Alternative. The development of insect pest populations resistant to PIPs represent a cumulative impact likely to occur under both of the Alternatives. The intensity and significance of the impact is not likely to differ under either Alternative because the EPA-required resistance-management practices will remain in place regardless of which Alternative is selected.

By making weed control more effective, GE HR crops may have indirectly impacted monarch populations. Milkweed plants, which are the sole food source for monarch caterpillars are estimated to have declined in Iowa by 58% from 1999 to 2010 (Pleasants and Oberhauser 2013). Over a similar time period, monarch populations overwintering in Mexico have also declined (Brower et al. 2012b). The cause–effect relationship between lower abundance of milkweed in the United States and decreasing overwintering populations is uncertain and summarized more fully in chapter 5. As yet, there is no consensus among researchers that increased glyphosate use is associated with decreased monarch populations. Given the uncertainty of the impact of milkweed decline on monarch populations, APHIS cannot draw conclusions on cumulative impacts of glyphosate use on monarch population.

ES 5.2.3 Wildlife

Pesticides are used on both commercial GE and non-GE 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. Improper use of herbicides on HR crops, especially the over-reliance on a single herbicide MOA can facilitate the selection of HR weeds that can ultimately lead to higher use of herbicides and tillage, thereby resulting in adverse cumulative impacts on air and water quality, affecting wildlife habitat. As mentioned in Section 4.2.2, some biotech crops that can lead to lower reliance on the herbicides commonly used today are under development.

As discussed in Chapters 3 and 4, runoff of sediment and agricultural inputs such as pesticides and nutrients can have cumulative impacts on wildlife. The Gulf of Mexico dead zone and its impacts on marine wildlife are a well-recognized cumulative impact that can result from U.S. crop production.

Atrazine, the herbicide noted by the EPA as causing the greatest impairment to rivers and streams, has been linked to amphibian declines. Surfactants in glyphosate formulations can also harm amphibians. However, whether amphibians are exposed to glyphosate formulations in crop fields and runoff that are at harmful levels is still controversial.

The adverse cumulative impacts on wildlife are caused by agricultural practices and inputs common to both GE and non-GE cropping systems. Certain GE crop traits, such as insect and disease resistance, and nitrogen and phosphorous use efficiency are expected to reduce the cumulative impacts of crop production on wildlife, relative to current crop varieties and associated practices and inputs. Varieties of GE plants incorporating these traits are expected to be developed under both the No Action and Preferred Alternatives, and if widely adopted may help mitigate adverse cumulative impacts.

ES 5.2.4 Pest and Disease Management

GE IR and disease resistant crops can and do reduce reliance on pesticides used to suppress plant pests and pathogens. The beneficial impacts are both direct within the GE crop, and indirect on crops nearby due to an overall area-wide reduction of the pest or pathogen 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 can promote eradication of plant pests–a beneficial cumulative impact. Under both the No Action and the Preferred Alternatives, increased options are expected in the variety of GE crops available to growers in managing plant pests and disease, with a reduction in adverse cumulative impacts on pest and pathogen resistance management.

In terms of adverse cumulative impacts associated with these varieties, as GE IR and disease resistant crops become more widely used, there is an increased potential for selection of resistance to the introduced traits and emergence of insect and pathogen resistant populations. This applies 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 for individuals in the population resistant to that agent. Thus, it is not unique to the GE IR or pathogen resistant crop itself (there are in fact conventionally bred disease resistant varieties of canola and wheat, for instance, that likewise face the problem of emergence of resistance).

These factors considered, when PIP-based strategies for pest and disease management are not utilized, APHIS expects that more synthetic chemical use will ensue for control of pests and diseases, which can also result in selection of resistant pests. 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.

ES 5.2.5 Agricultural Weeds and Herbicide Resistant Weeds

Development of HR weed populations is a notable example of a cumulative impact that can derive from crop production. This 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.

Crops with glyphosate resistance traits have been widely adopted, and those conveying resistance to other herbicides such as glufosinate, 2,4-D, dicamba, and potentially other herbicides, are expected to increase in use under both the No Action and Preferred Alternatives.

Many of the newer GE HR crop plants are stacked-trait varieties resistant to two or more herbicides. These are intended to allay development of HR 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 HR weeds from pre-plant to post-emergent treatment, offering growers flexibility in the control of weeds. In this respect, stacking HR traits helps manage HR weed populations. However, where these crops are adopted by growers for commercial use, a greater variety of herbicides will be applied, and in some instances an increase in the amount. Depending on the herbicide rotation and use practices applied, this could potentially increase the selection pressure for herbicide resistance in weeds.

Some argue that stacked traits will make the management of HR weeds more difficult. If growers fail to use a diversity of approaches, the value of HR traits are likely to diminish quickly (NAS 2016b). Fundamentally, sustainable weed management will be achieved only if there is diversity in both the agroecosystem and in the herbicide and non-herbicide tools employed for weed control (IWM) (Shaner and Beckie 2014; Harker and O'Donovan 2013).

While there have not been herbicides released with new MOAs in at least 30 years,[9] there are still opportunities to find resistance traits to existing herbicide chemistries that can be inserted into new GE HR crop varieties. For example, GE plants are being developed to use phosphite as both an herbicide and a nutrient, as the phosphite is expected to be toxic to plants lacking the enzymes to metabolize it to phosphate. Novel herbicides and technologies are emerging, such as RNA interference (RNAi) (branded BioDirect™ by Monsanto), biologicals/natural products, application of 'omics' for resistance management, and robotics for weed scouting and removal (Shaner and Beckie 2014).

Under both the No Action and Preferred Alternatives, APHIS expects 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. This trend has been documented by recent polls (Prince et al. 2012). Under both the No Action and Preferred Alternatives, effective weed resistance management will rely on the grower's effective implementation of crop specific strategies, and support from industry, federal and state governments, and university extensions.

ES 5.2.6 Gene Flow and Weediness

The salient environmental concern is whether the flow of a GE trait gene (i.e., herbicide resistance, insect resistance) to a wild relative will result in 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.

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 crosses with wild relatives. A little over 20 such incidents have occurred since the first field release of a GE crop in 1987 (Ellstrand 2018). 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. 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,

[9] 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

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 potential environmental and economic consequences of gene flow that are of concern.

ES 5.3 Cumulative Impacts: Socioeconomics

ES 5.3.1 Domestic Economic Environment

Both the organic and "non-GMO" verified sectors are increasing in value, 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, a lower regulatory burden on developers would be expected, so there would be a possible increase in research, development, and innovation in the agricultural biotechnology sector, and consequently, more options available to growers to meet 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 socioeconomic benefits to growers, consumers, and the environment (by reducing externalities).

Notwithstanding the benefits of GE crops, USDA acknowledges that stakeholders in the non-GE sector can be adversely affected by the presence of a GE trait in a non-GE crop or crop commodity. When an unauthorized release occurs, APHIS and industry may undertake actions to remove the unauthorized material from the commercial supply, which may be costly. Under the No Action Alternative, APHIS would continue these actions even in cases where there are no harms other than those resulting from the mere presence of a GE trait. Under the Preferred Alternative, many fewer unauthorized releases are expected to occur because APHIS would regulate only those GE organisms that APHIS found to have a plausible pathway of increased plant pest risk. By focusing regulatory oversight on those field trials that pose risks, APHIS is expected to reduce the cumulative risks to agricultural resources from unintended releases of GE organisms that pose plant pest risks. Furthermore, it is expected that there will be fewer cases where Agency action to rectify an unauthorized release is inconsistent with its protection goals, resulting in a more efficient use of Agency resources.

Under both the No-Action and Preferred Alternatives, farmers catering to the non-GE market (growers of organic and "non-GMO" crops) who have had no neighboring GE crops could be adversely impacted if these Alternatives contribute to increasing the number and variety of GE crops grown in the United States. The growers of 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 and are thus susceptible to the introduction of GE traits during fertilization.[10] Other crops such as hops and peanuts could also be affected.[11] By reducing regulatory barriers for academics and small companies, the Preferred Alternative is expected to produce more innovation than the No Action Alternative. In this way, the Preferred Alternative may facilitate more development of new GE varieties that leads to more adoption of new varieties by growers and more incidences of unintended presence of GE plant material in non-GE crops. As a result, non-GE producers could be more negatively impacted under the Preferred Alternative.

Bearing these considerations in mind, because many of the new GE crop plants are expected to be developed through genome editing techniques, genetic engineering may not be easily detectable in the resulting modified plants unless the specific genetic changes are clearly known or distinguishable from conventionally bred crop varieties. The expected future modifications may present a new challenge in regard to what constitutes unintended presence, or even the ability to identify unintended presence if it has occurred. As a result, it is difficult to predict the extent of the harm the non-GE sector will accrue from the unintended mere presence of products of gene-editing that could practically be achieved through conventional breeding.

ES 5.3.2 International Trade

In some cases, unauthorized releases of GE crop plants occurred at a low level in much of the commercial seed and grain supply. This occurred most notably in the case of LibertyLink rice and resulted in a significant adverse economic impact to the rice industry.[12] In the case of LibertyLink rice, there was a large economic cost estimated to be between $741 million to $1.3 billion (US-GAO 2008) 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 presence at low levels (3 seeds in 10,000 seeds).[13] In regard to international trade, under the Preferred Alternative the cumulative socioeconomic impacts of such unauthorized releases are expected to diminish relative to the No Action Alternative, as APHIS would be regulating fewer GE crop plants with more oversight for those GE crop plants that APHIS did regulate.

The Preferred Alternative represents a change from the current regulatory process, and this change could have either positive or negative cumulative impacts on international trade. For example, 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 (S&P 2015). One possibility is that regulatory bodies in other countries will follow all or some of the changes being codified by APHIS. Another possibility is that regulatory bodies in other countries 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.

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[10] A variety of GE rice has been deregulated but not commercialized.

[11] 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.

[12] 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

[13] 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

Another possibility is that changes made by APHIS would not be acceptable to the international community, in which case international trade would be hindered because, prior to exporting a GE product, regulatory approval of a commercialized GE product in key export markets must occur to minimize trade disruptions. Even the trace presence of 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 3.9.3 for more details).

Hence, cumulative impacts could be seen across the international regulatory community under the Preferred Alternative. 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.

ES 6 Endangered Species Act Compliance

It is important to note that the adoption of the Preferred Alternative in and of itself would not result in direct or indirect impacts to threatened and endangered (T&E) species. However, individual decisions made during implementation 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) and/or the National Marine Fisheries Service (NMFS) as required by the ESA.

The revisions to the regulations do not change the processes APHIS would use to analyze effects on T&E species or critical habitat. APHIS will continue to use the processes it has developed over the years in consultation with the USFWS. Changes to the regulations under the Preferred Alternative 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 the ESA.

ES 7 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 PEIS describes the relationship of federal laws, regulations, and EOs to APHIS regulation under 7 CFR part 340, and APHIS' compliance with these requirements. The PEIS also describes trade agreements, and other international agreements and arrangements to which the United States is party. Under both 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[14] 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 (7 CFR part 340), implementing the PPA, address plant pest risks that may be associated with certain 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, 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, 2015), provisions of the 2008 Farm Bill (Pub.L. 110–234, H.R. 2419, 122 Stat. 923), and to make its regulation commensurate with the potential 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 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:

". . . 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

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

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 pest and noxious weed risks under different regulatory schemes. APHIS regulates non-GE plant pests under 7 CFR § 330.200 and 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. To date, APHIS has not regulated any GE plants as 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 organisms (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 and that APHIS clarify its regulations regarding the use of metal shipping containers and movement of GE seeds.

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,”[15] and where appropriate, promulgate regulations.

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

1.4 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.[16] 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 unlikely to pose a 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 it was unlikely 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 regulatory oversight of GE organisms. Under APHIS authority, pursuant to 7 CFR part 340, 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 permits for these to provide additional oversight and enforcement requirements to assure that they remain confined.

APHIS is again proposing to revise its regulations. The revisions to 7 CFR part 340 are expected to promote process efficiency by focusing APHIS' resources on oversight of GE organisms that APHIS found had a plausible pathway to increased plant pest risk, 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 30 years, and APHIS' understanding of the plant pest risks posed by 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).

[16] 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 Nonregulated 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).

- Make the regulation commensurate with the potential risks described by the National Research Council (NRC 2002).

1.5 Summary of 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:

- Codify in the regulations, the Secretary of Agriculture's March 28, 2018, statement[17] that provided clarification on the USDA's oversight of plants produced through plant breeding innovations and exempt certain categories of modified plants from the regulations in 7 CFR part 340 because they could be produced through conventional breeding techniques,[18] which we do not regulate.
- Change the current APHIS regulatory review framework so that APHIS would assess the plant pest risk posed by the GE plant, to establish whether APHIS has regulatory authority under the PPA to regulate the organism under 7 CFR part 340.
- Refine the regulatory framework so that APHIS oversight is focused on those GE organisms that APHIS found had a plausible pathway to plant pest risk, as determined by science based risks assessments, and unnecessary regulatory burdens are eliminated.
- Eliminate the notification procedure and authorize the interstate movement, importation, or environmental release of GE organisms that APHIS found had a plausible pathway of increased plant pest risk only under permit.

The revisions to the regulations will allow for more efficient use of Agency resources because permits will be required for only those GE organisms that APHIS found had a plausible pathway to increased plant pest risk. This will allow for a level of oversight consistent with the degree of risk associated with some GE organisms.

1.6 Background on the Regulation of Genetically Engineered Organisms

GE organisms have been regulated in the United States for over 30 years. During this time, genetic engineering has evolved to become a routine 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 2018, commercial GE crop production occurred in 26 countries on six continents, in both developing and industrialized countries. Collectively, GE crops were grown on more than 474 million acres worldwide. Eighteen countries had GE crop acreage exceeding 120,000 acres (ISAAA 2018a). 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 2015a). In Figure 1-1, two important trends in the global adoption of GE crops are apparent. Between 1996 and 2017 there was a continuous

[17] The statement and the further details are available at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018_brs_news/plant_breeding

[18] Conventional 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.

increase in acreage used for GE crops in every year except 2015, and between 2010 and 2011 the acreage of GE crops in developing countries began to exceed that of industrial countries.

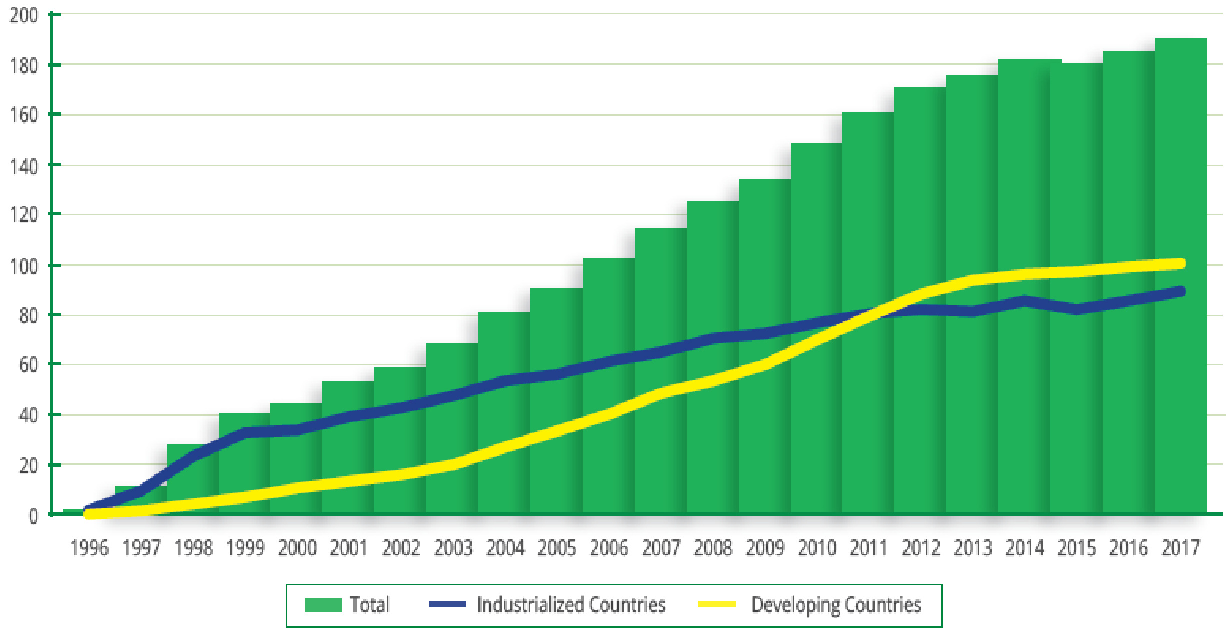

Figure 1-1. Global Adoption of GE Crops: From 1996 to 2017 Source: (ISAAA 2017)

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[19] that conferred resistance[20] 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 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

[19] 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.

[20] "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 PEIS.

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-MOA combinations are expected to provide benefits in the way pests and diseases are managed, to sustain crop product quality and yield, and to reduce agronomic inputs such as pesticides, irrigation, 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, may require a more refined attention as to their potential environmental risks. In the United States, GE organisms are reviewed under what is called the Coordinated Framework, described below.

1.6.1 Federal Oversight Under the Coordinated Framework

On June 26, 1986, the White House Office of Science and Technology Policy issued the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework),[21] which outlined the federal regulatory policy for ensuring the safety of biotechnology products. The primary federal agencies responsible for oversight of biotechnology products are the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). On January 4, 2017, the USDA, EPA, FDA released a 2017 update to the Coordinated Framework (USDA-APHIS 2018b), and accompanying National Strategy for Modernizing the Regulatory System for Biotechnology Products (ETIPCC 2017).

USDA-APHIS is responsible for protecting animal and plant health. USDA-APHIS regulates products of biotechnology that may pose a risk to agricultural plants and agriculturally important natural resources under the authorities provided by the plant pest provisions of the PPA, as amended (7 U.S. Code (U.S.C.) 7701–7772), and implementing regulations at 7 CFR part 340.

The purpose of EPA oversight is to protect human and environmental health. The EPA regulates pesticides, including pesticides that are produced by GE organisms, termed plant incorporated protectants, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). The EPA also sets tolerances (maximum limits) for pesticide residues that may remain on or in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 et seq.). The USDA and FDA enforce tolerances to ensure the safety of the nation's food supply (USDA-AMS 2020a). In addition, the EPA regulates certain GE microorganisms (e.g., those used for agricultural uses other than pesticides or in the production of chemicals) under the Toxic Substances Control Act (15 U.S.C. 53 *et seq.).*

The purpose of FDA oversight is to ensure human and animal foods are safe and drugs are safe and effective. The FDA regulates a wide variety of products, including human and animal foods, cosmetics, human and veterinary drugs, and human biological products under the authority of the FFDCA and the Public Health Service Act.

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

1.7 NEPA Analysis of Revisions to 7 CFR part 340

APHIS has prepared this programmatic environmental impact statement (PEIS) 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,[22] 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 revisions to 7 CFR part 340 regulations. Consequently, APHIS has prepared this PEIS to evaluate the potential effects of the 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 PEIS encompasses a broad geographic and temporal scale. This is necessary to clarify and sufficiently communicate the range of 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 PEIS, as appropriate.

1.7.1 Public Involvement

Public scoping for an EIS is required under NEPA regulations (40 CFR §1501.7 - Scoping). Subject matter considered in this PEIS 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 June 29, 2018, when APHIS published its notice of intent (NOI) to prepare a

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

PEIS in the *Federal Register*.[23] The NOI solicited public comment to help define the issues to be considered in the PEIS and scope of Alternatives to consider in revision of 7 CFR part 340 regulations. A summary of the Alternatives evaluated in this PEIS is provided below, and further details discussed following 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 under the current regulatory framework.

Alternative 2 – Preferred Alternative (Final Rule): Revise 7 CFR part 340 to Codify in the regulations, the Secretary of Agriculture's March 28, 2018, statement[24] that provided clarification on the USDA's oversight of plants produced through plant breeding innovations and exempt certain categories of modified plants from the regulations in 7 CFR part 340 because they could be produced through conventional breeding techniques,[25] which we do not regulate.

Change the current APHIS regulatory review framework so that APHIS would review the plant pest risk posed by the GE plant, to establish whether APHIS has regulatory authority under the PPA to regulate the plant under 7 CFR part 340.

Refine the regulatory framework so that APHIS oversight is focused on those GE organisms that APHIS found to have a plausible pathway to increased plant pest risk, as determined by science based risks assessments, and unnecessary regulatory burdens are eliminated.

Eliminate the notification procedure and authorize the interstate movement, importation, or environmental release of GE organisms APHIS found to have a plausible pathway to increased plant pest risk only under permit.

The comment period on the NOI lasted until July 30, 2018. At the close of this comment period APHIS had received 35 submissions from the public. The submissions were from individuals from academic organizations (2), professional organizations (2), trade groups (2), commodity groups (4), industry (4), NGOs (4), federally recognized Tribes (2), and unspecified individuals (15). Full text of the comments are available online at: https://www.regulations.gov/document?D=APHIS-2018-0034-0001. Many commenters requested that APHIS analyze certain topics in the dPEIS, summarized in Appendix 2.

On June 6, 2019, APHIS published a notice in the *Federal Register* (84 FR 26514-26541, Docket No. APHIS-2018-0034) announcing the availability of the proposed rule, draft PEIS, and supporting documents for a 60-day public review and comment period. The comment period

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[23] 83 *Federal Register*, No. 126 (June 29, 2018), pp.30688-30689: Available at https://www.gpo.gov/fdsys/pkg/FR-2018-06-29/pdf/2018-14019.pdf

[24] The statement and the further details are available at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018_brs_news/plant_breeding

[25] Conventional 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.

closed on August 6, 2019. APHIS received a total of 6,151 public submissions. The comments specific to the PEIS are summarized in Appendix 3 along with APHIS responses.

2 Program Alternatives

APHIS is considering two 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 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 that APHIS is evaluating. The potential impacts of these Alternatives on the human environment is discussed in Chapters 3 through 7. APHIS will use this PEIS, 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

One of the Alternatives that must be considered by APHIS is a "No Action" Alternative, pursuant to CEQ regulations at 40 CFR part 1502.14. For this PEIS, "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, 2012c). 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, 2012c), 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.

Under the existing regulations, APHIS deems GE organisms "regulated articles" based upon the use of a plant pest in the genetic engineering process. 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" (7 CFR part 340.1).

Current regulations provide for a petition process (§ 340.6), which allows individuals to request that APHIS consider nonregulated status of GE organisms that were previously determined by the Agency to be regulated articles. The petition process stems from the manner in which *regulated article* is defined. As noted above, the current regulations consider a GE organism to pose a plant pest risk and therefore be a regulated article if the donor organism, recipient organism, vector, or vector agent is a plant pest. Published APHIS decisions made under the current regulations in § 340. 6 have used different ways to express the basic standard "unlikely to pose a plant pest risk" in determining whether to grant nonregulated status to a specific GE organism. Alternative characterizations that have been used include "poses no more of a plant pest risk than its non-GE counterpart," "will not pose a plant pest risk," "no plant pest risk," and "no direct or indirect plant pest effects." Regardless of the phrases used, APHIS has applied the same basic review criteria to each determination to conclude that the GE organism is unlikely to pose a plant pest risk and therefore is not subject to the part 340 regulations. Those criteria include, conclusions on the potential of the GE organism to create pest or disease problems, the potential for non-target effects that might affect organisms beneficial to agriculture, changes in agricultural practices that might exacerbate pest or disease problems, the potential for a GE organism to become a weed or increase its weediness or that of sexually compatible species, and the potential of the GE organism to transmit the introduced trait to organisms with which it does not interbreed.

A petitioner is required to present detailed information and scientific data regarding the regulated article indicating why the article should no longer be regulated. The current requirements specify that a petition must contain field reports for all trials conducted under permit or notification procedures involving the regulated organism, including the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment. A petition is typically requested after lengthy field testing. Currently, most of the field data submitted are intended to demonstrate that there have not been unintended deleterious effects on plants, non-target organisms, or the environment. To date, APHIS has authorized more than 100,000 field trials—a single permit or notification may authorize multiple trials—and APHIS has not received any evidence of unintended deleterious effects on plants, non-target organisms, or the environment in the submitted reports.

As of April 2020, APHIS has determined nonregulated status in response to 128 petitions and extension requests (not including one petition for Roundup Ready® Alfalfa and two petitions for Roundup Ready® Sugarbeet submitted after court ordered injunctions), out of 162 petitions received for review. Thirty-two petitions were withdrawn. All of these determinations have been for GE plants, and the vast majority for crop plants. APHIS determinations of nonregulated 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 nonregulated status on its website.[26]

While the majority of GE organisms APHIS has regulated, and currently regulates, are plants, APHIS also regulates invertebrate and microbial species that are, or are believed 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 EPA under the 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 receives requests from developers who wish to ascertain, prior to conducting a potentially regulated activity, i.e., importation, interstate movement, or environmental release, whether a specific organism that they have developed meets our definition of regulated article and is therefore subject to the regulations. 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.[27]

[26] USDA-APHIS-BRS: Petitions for Determination of Nonregulated Status; https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions

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

APHIS has been responding to such inquiries from developers since the late 1990's. In 2011, APHIS implemented a formal "Am I Regulated" (AIR) process[28], providing a webpage that instructs developers on how to submit an AIR inquiry. APHIS developed the AIR process in response to an increasing number of such requests as a result of the rapid development of new plant breeding innovations. The process was intended to guide developers to provide consistent and predictable information that would enable the Agency to respond to inquiries in a timely manner so as to not inhibit innovation. This process is not codified in the existing regulations, however.

The primary analysis conducted under this process is to determine whether or not the organism described in the AIR inquiry is a regulated article as defined in 7 CFR part 340. The organisms in question have ranged from clearly regulated (e.g., GE plants with DNA inserted by the plant pest *Agrobacterium tumefaciens*) to clearly not regulated ones, such as GE organisms that are genetically engineered without the use of a plant pest. Products of new genome editing techniques, such as TALENs and CRISPR, have presented intermediate scenarios that have been evaluated over the past few years. Additional considerations by APHIS under this process include weediness potential. If the organism in question is weedy or has weedy wild relatives, these concerns are also addressed in APHIS' response.

Plants that are not engineered with plant pest sequences often do not meet the definition of a regulated article under 7 CFR part 340. In cases where the recipient organism has characteristics of a weedy species or has wild and weedy relatives and is engineered with a fitness trait, APHIS evaluates the potential noxious weed risk posed by the engineered plant. In the event the agency identifies a plausible noxious weed risk associated with the engineered plant, APHIS considers whether to regulate that plant pursuant to our statutory authority and the regulations issued under that authority. Where warranted, APHIS will request additional data and information to further evaluate potential noxious weed risks. In this way, plants that pose noxious weed risks may still be regulated by APHIS even when they are not regulated by APHIS under 7 CFR part 340 because they are unlikely to pose plant pest risks. APHIS has used this approach in the Am I Regulated process to request additional data to evaluate weediness risks for a GE plant that was constructed without plant pest sequences or the use of the plant pest, *A. tumefaciens,* and was therefore not subject to 7 CFR 340 (USDA-APHIS 2014b, a).

In two cases, APHIS was petitioned to list a GE plant as a noxious weed (USDA-APHIS-PPQ 2014). This request occurred for both creeping bentgrass and glyphosate resistant creeping bentgrass and Kentucky bluegrass and glyphosate resistant Kentucky bluegrass. APHIS completed risk assessments for each of the four plants and concluded that none of the four should be listed as noxious weeds (USDA-APHIS 2018a).

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 environmental 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

[28] 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

Agency has implemented a Biotechnology Quality Management Support (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 while certain plants may be eligible for authorization through notification, which is like a streamlined permitting process.[29] 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.

Actions taken by APHIS on permit applications and notifications are subject to NEPA. APHIS performs a variety of functions to ensure compliance with NEPA. Issuance of permits and acknowledgement of notifications are typically authorized under a categorical exclusion from the requirement to conduct an EA or EIS,[30] consistent with APHIS' NEPA implementation regulations (7 CFR part 372). This process complies with CEQ and USDA regulations for implementing NEPA.[31]

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 review 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 notifications 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 PPA (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:

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

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

[31] 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.

  - 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.

- 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 it is not inadvertently mixed with nonregulated plant materials of any species that 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 risk. Under the final 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 final regulation is to reduce regulatory burden where it is not warranted thereby freeing up resources to focus more oversight where plant pest 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 2012c). 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, university researchers frequently request courtesy permits for the importation of fruit flies (*Drosophila melanogaster*), which are commonly used in research and which may be confused with Mediterranean fruit fly, a serious agricultural pest.[32]

Under the final rule, courtesy permits would be eliminated. A key goal of the final regulation is to reduce regulatory burden where it is not warranted thereby freeing up resources to focus more oversight where plant pest risks may occur.

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

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

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 nonregulated status (§ 340.6).

2.1.3.2 Environmental Release

Field tests are standard practice in research and development of new plant varieties, including GE plants. Field releases authorized under the current APHIS permit or notification procedures have been conducted by industry, academia, and the government, and have taken place throughout the United States and its territories. As of September 2018, APHIS has issued more than 19,500 permits and notifications for field testing of GE organisms (the vast majority plants) (USDA-APHIS 2020a). 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.

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[33] 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.[34]

Current regulations describe the compliance and enforcement actions APHIS may take under the authority of the 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.

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[33] See https://usdagcc.sharepoint.com/sites/aphis-brs/340/340%20SC%20Working%20Documents/FPEIS/18-034-2%20340%20Final%20PEIS%2010-21-19.docx

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

2.1.5 Determinations of Regulatory Status

Petition for Determination of Nonregulated Status

Under the current regulations, APHIS may issue a determination of nonregulated status for a GE organism in accordance with the petition procedure described in § 340.6. Regulations at § 340.6, "Petition for determination of nonregulated status," provide that an individual can petition APHIS to evaluate submitted information and 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 nonregulated status allowing introduction of the article without regulatory oversight under 7 CFR part 340.

A petition must include information and data demonstrating that the GE organism is unlikely to pose a plant pest risk for APHIS to make a determination of nonregulated status. Required information includes a description of the biology of the organism before it was genetically engineered, a comparison of the GE organism and its non-GE counterpart, and data from field trials previously approved under permit for a GE organism. Depending on the organism and the GE trait involved, the petitioner may also voluntarily 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 nonregulated status have been for GE organisms that are plants.

A determination of nonregulated 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 the EPA, and other federal and state agency requirements, as applicable. The FDA recommends that sponsors and developers that intend to commercialize human or animal food derived from new plant varieties, including GE plants, consult with the FDA about the safety and composition of food from the GE plant prior to its introduction into the human or animal food supply. For determinations of nonregulated 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 nonregulated status for a GE organism, APHIS prepares a NEPA analysis to assess the possible impacts of its decision on the quality of the human environment.[35] This assessment includes a review 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 nonregulated 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 sugarbeet variety. The deregulation applied to sugar beets grown for the root crop while the seed crop was grown under

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

permit. The approval in part was done in response to a court decision to vacate a previous APHIS determination of nonregulated status.

Petition for Extension of Determination of Nonregulated Status

The current regulations also provide for extensions of determinations of nonregulated status. Petitioners seeking nonregulated status for a GE organism that is similar to one or more organisms for which a decision of nonregulated status has been previously made by APHIS, may request an extension of nonregulated status under 7 CFR §340.6(e). Decisions related to extension requests are made based on a review of the similarity of a regulated article to one or more antecedent organisms for which a determination of nonregulated status has been made by APHIS. If the organism is sufficiently similar to the antecedent with respect to plant pest risk, then nonregulated status is extended from the antecedent(s) to the organism that is the subject of the petition request. The extension of nonregulated status has been issued 24 times since the process was initiated (USDA-APHIS 2020e). For extensions, APHIS conducts a plant pest risk similarity assessment (PPRSA) and appropriate NEPA analyses.

As of April 2020, APHIS has made determinations of nonregulated status for 128 GE organisms all of which have been for GE plants. Approximately 40% have been plants engineered for herbicide resistance, and 25% for insect resistance (USDA-APHIS 2020e). 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 nonregulated 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 Final Rule

Revise the regulations concerning the introduction of GE organisms to codify in the regulations, the Secretary of Agriculture's March 28, 2018, statement[36] that provided clarification on the USDA's oversight of plants produced through plant breeding innovations and exempt certain categories of modified plants from the regulations in 7 CFR part 340 because they could be produced through conventional breeding techniques; to refine the scope of organisms considered under the regulations; eliminate the notification procedure and authorize the interstate movement, importation, or environmental release of GE organisms APHIS found had a plausible pathway to increased plant pest risk or did not review; change the current APHIS regulatory review framework so that APHIS would review the plant pest risk posed by the GE organism as determined by science based risks assessments rather than the process by which it was made and reduce unnecessary regulatory burdens.

[36] The statement and the further details are available at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018_brs_news/plant_breeding

2.2.1 Overview of the Revised 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 APHIS found had a plausible pathway to increased plant pest risk and may adversely affect the vitality and value of American agriculture. As discussed in Chapter 1 – Purpose and Need, the final revisions seek to update the regulations in response to advances in genetic engineering; and respond to recommendations made to APHIS by the USDA's OIG in their 2005 and 2015 audits, and the 2008 Farm Bill (Food, Conservation, and Energy Act of 2008).

The approach we are finalizing would differ from the current regulatory framework in that regulatory efforts would focus on the characteristics of the GE organism itself rather than on the method used to produce it. Based on the change in approach, the Agency is removing the petition process from the regulations. We believe that this new approach, which reflects our current knowledge of the field of biotechnology, would enable us to review GE organisms for plant pest risk with greater precision than the current approach allows. GE organisms that pose a plant pest risk would fall within the scope of the final regulations and require permits for movement. We would define plant pest risk in this final rule as "the potential for direct or indirect injury, damage, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest."

APHIS will continue to regulate GE organisms which are, in and of themselves, plant pests as well as other GE non-plant organisms that pose plant pest risks. Our approach to regulating such organisms, however, would differ from that of the existing regulations. In current § 340.2, there is a list of taxa that are considered to be plant pests. Under our final regulatory framework, however, we would not use taxonomic classification of donor organisms to determine if a GE organism is regulated. We would, therefore, remove the list from the regulations, along with the procedures described in current § 340.5 for amending this list.

Instead, when determining whether a GE non-plant organism is subject to the regulations, APHIS will assesses whether a recipient species is likely to be a plant pest based on the most up-to-date pest information maintained by APHIS. This information is more specific than the information in the list of plant pest taxa in the current regulations, and should be more useful and reliable than static lists of taxa, which become outdated. APHIS will maintain a list of taxa that contain plant pests on its website and would be available for consultation by developers to help them determine whether or not their GE non-plant organism is or is not a plant pest.

Under § 340.2(c), we would also regulate GE organisms that are not plants but have received DNA from a plant pest, but only if the DNA from the donor organism is sufficient to produce an infectious entity or encodes a pathogenesis-related compound that is expected to cause plant disease symptoms. DNA from a donor organism that is a plant pest could, when inserted into an organism which is not a plant pest, result in a GE organism that is a plant pest if: (1) The DNA sequence that is encoded in the organism is able to be expressed as a functioning infectious entity capable of causing plant disease; or (2) if the inserted DNA enables the organism to produce pathogenesis-related compounds, that is, compounds that are typically produced by pathogens and involved in producing disease symptoms. Examples of such compounds would include plant degrading enzymes, plant growth regulators, phytotoxins, or compounds that can clog plant vascular systems. Such organisms would require permits for movement.

APHIS intends this criterion to be specific to GE organisms other than plants, such as nonpathogenic soil bacteria that through genetic engineering may become capable of producing plant disease symptoms in plants. This contrasts with the current regulations, under which we regulate GE organisms based merely on the presence of DNA from a plant pest. Other GE non-plants organisms that do not pose a plant pest risk would not fall under the scope of the regulations and therefore would not require permits for movement.

In addition, under § 340.2(d), we would regulate GE organisms that are microbial pathogens used to control plant pests, microbial parasites used to control plant pathogens, or invertebrate predators or parasites (parasitoids) used to control plant pests if they are likely to pose a plant pest risk. The PPA provides the authority to regulate such biological control organisms used to control plant pests if they pose a plant pest risk, and we already regulate non-GE biological control organisms under 7 CFR part 330 insofar as they may pose a plant pest risk. As with non-GE biological control organisms, the types of GE biological control organisms APHIS would regulate, could pose a plant pest risk by lacking sufficient specificity for the target pest and thereby harming beneficial non-target organisms, such as other invertebrate predators or parasites (parasitoids), pollinators, or microbes that promote plant health. Because biological control organisms are almost always intended for eventual release into the environment, it is not sufficient for us only to consider their use in controlling their target plant pest. We must also take into consideration the indirect plant pest risks that the organism may pose due to harmful impacts on beneficial non-target organisms. If the GE organism is known to have harmful impacts on beneficial non-target organisms, it is consistent with APHIS's mission to prohibit or restrict its release. To the extent that we do not know whether a GE biological control organism is sufficiently specific to avoid harming beneficial non-target organisms, it is also prudent for us to place regulatory controls on the movement and release of the GE biological control organism until the non-target impacts and effects are better understood.

While APHIS has found that most plants reviewed to date do not pose plant pest risks, it is conceivable that some of those produced in the future may. For example, certain modifications may change the relationship of the plant to plant pests. In most cases, this would not be of concern, as APHIS understands that resistance to disease and insects varies widely among varieties. Still, if as a result of the modification, the plant became a reservoir for pests or diseases in such a way that plant pest issues were exacerbated not just for those who used the new variety, but for others in the surrounding area, APHIS might find it appropriate to take regulatory action. For instance, plants and their wild relatives could have increased importance as reservoirs for plant pests if the introduced trait resulted in an increase in their weediness, increasing their prevalence and/or causing a change in their distribution. For these reasons, APHIS believes it is appropriate to examine novel plant-trait-MOA combinations for plausible pathways to increased plant pest risk. Regulatory oversight is needed for such plants until the level of plant pest risk associated with their movement is known.

For the purposes of the scientific community, this final rule would define trait as an "An observable (able to be seen or otherwise identified) characteristic of an organism." We would define mechanism of action as the "biochemical process(es) through which genetic material determines a trait." For example, a plant may be modified to confer the trait of male sterility by either of two MOAs in pollen: Expression of a protein that is toxic to the pollen grain (barnase system) or expression of a dysfunctional protein that interferes with pollen development (DNA adenine methylase system).

As noted in Section 2.1.2, a petition process is initiated by the developer to seek nonregulated status for a GE plant and this process is typically requested after lengthy field testing. Based on the risk assessments we have performed in accordance with the petition process over 30 years, we have determined that, in many cases, we would have been able to review the plant pest risks associated with a GE organism without field-test data. Rather, the Agency has discovered that the introduced trait of the GE organism provides the most reliable indicator of the organism's potential for deleterious effects on plants and plant products. These observations are expected and are consistent with findings of several reports of the National Research Council (NRC 1989; Ellstrand et al. 2010).

Accordingly, APHIS considers information from field tests to be unnecessary, in most cases, for a determination of regulatory status under the final regulations and, therefore, would not require the submission of such data. The approach APHIS is finalizing focuses primarily on reviewing the genetics and characteristics of the GE plant-trait-MOA combination and the likelihood that, based on these genetics and characteristics, the plant will pose a plant pest risk if it is released into the environment for the uses intended by the developer.

This change would not preclude a developer from providing such information, if he or she considered it to be pertinent to our analysis. For example, if a developer wished for APHIS to reevaluate the status of a GE plant that the Agency had previously considered to be subject to the regulations, field-test information demonstrating a lack of adverse effects on plants and plant products could be provided in support of that request. Nor would the provisions preclude APHIS from asking for field-test information if APHIS considers it necessary in order to conclude a review of a particular request. However, field-test information would not be a generally applicable requirement for the initial review stage of a regulatory status reviews and would only be requested on an as-needed basis when further analysis is needed.

APHIS is providing developers of novel GE plants that have not been previously reviewed by APHIS the option of either requesting a regulatory status review by the Agency to determine regulatory status or applying for a permit for movement under the regulations. Developers choosing to apply for a permit would, upon approval of the permit application, be able to immediately import, move interstate, or field test their plant under APHIS-imposed conditions and oversight. If they choose to request a regulatory status review, and the agency finds that the plant-trait-MOA combination is unlikely to pose a plant pest risk and therefore is not subject to the regulations, the developer could proceed with product development and marketing activities free from regulation under this part.

The current petition process contained in the current regulations is only applicable to GE plants; likewise, the regulatory status review described in § 340.4 would apply only to plants and not to GE plant pests or other GE non-plant organisms. The latter two categories would fall within the scope of the final regulations in § 340.2 and therefore require permits for movement. Unlike most plants, other organisms described in § 340.2(b), (c), and (d) are either known to be plant pests, engineered in such a way that they are likely to be plant pests, or will be used to control plant pests and therefore need to be regulated for direct or indirect plant pest risks.

Decisions on regulatory status would be based on our review of plant pest risk. When reviewing the plant pest risk posed by a newly developed GE plant, it is necessary to consider three fundamental elements in combination and individually: (1) The basic characteristics of the plant that has been genetically modified; (2) the trait that resulted from the genetic modification; and (3) the biochemical basis for the new trait, referred to in the accompanying rule with the scientific term mechanism of action (MOA). Since any one or any combination of these three elements may affect plant pest risk, APHIS would determine the need for regulatory oversight by appraising the risk posed by the plant's unique combination of the three elements. APHIS would further consider the effect of the trait and mechanism-of-action on:

- The distribution, density, or development of the plant and its sexually compatible relatives;
- The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;
- Harm to non-target organisms beneficial to agriculture; and
- The weedy impacts of the plant and its sexually compatible relatives.

APHIS uses knowledge and information on the biology of the progenitor plant and its sexually compatible relatives, including its spatial and temporal distribution in the absence of intentional human assistance and its interactions with or impacts on other plants and the environment, as the foundation for considering whether alterations in the GE plant will result in a plausible pathway to increased plant pest risk.

As in plant pest risk assessments prepared in response to petitions for nonregulated status under the current regulations, APHIS would evaluate whether planting or release of the GE plant could result in direct or indirect harm to non-target organisms that are beneficial to agriculture, such as pollinators and predators of plant pests. APHIS would also evaluate the potential of the plant to displace native/established organisms or otherwise alter community composition or structure in a manner that harms beneficial non-target organisms.

APHIS recognizes that genetic engineering may be used to introduce a trait that increases the distribution, density, or development of a plant or the weedy impacts of the plant, factors that are considered aspects of a plant's weediness. Accordingly, we would continue the current practice of considering the weediness of the unmodified plant and whether the new trait could in any way change the weediness. We would also consider potential effects on the weediness of other plants with which the engineered plant can interbreed. This analysis of weediness is important for two reasons. First, it is relevant to the review of the plant's plant pest risk. Plants and their sexually compatible relatives could have increased importance as reservoirs for plant pests if they are distributed differently, are more prevalent, or are altered in the timing during which they serve as a host for plant pests due to the introduced trait. As part of the regulatory status review, APHIS would continue to consider whether the trait might change plant pest interactions, establishment, and persistence for both the plant engineered, and any other plants with which it can interbreed.

Second, if the plant had the potential to be a truly troublesome and impactful weed, we would need to consider whether the plant with the specific trait being reviewed should be considered for regulation pursuant to our statutory authority and the regulations issued under that authority. The final regulation does not change this analysis.

Because the initial review is objective, rapid, and based on transparent predetermined criteria, it has functional similarity to the current Am-I-Regulated process. In both processes, the outcome is merely a finding of whether a GE organism is subject to the regulations at 7 CFR part 340. APHIS will maintain on our website a list of all GE plant-trait-MOA combinations, without confidential business information, which have been reviewed. The list will include the inquiry, and the Agency finding. In cases where no plausible pathway to increased plant pest risk is identified, APHIS will conclude that the plant-trait-MOA combination is unlikely to pose a plant pest risk and therefore the agency will have no discretion to regulate. If APHIS does not identify a plausible pathway to plant pest risk in the initial review, the GE plant would not be subject to the regulations in this part, and APHIS would post the finding on its website.

Under § 340.4(b)(3), in cases where the Agency finds a plausible pathway to increased plant pest risks, APHIS would conduct a plant pest risk assessment, a more robust analysis than the initial review, to evaluate the factor(s) of concern and to determine the likelihood and consequences of the potential plant pest risks identified in the initial review. In some cases, the Agency may be able to reach a finding that the plant-trait-MOA combination is not subject to the regulations based on the outcome of the plant pest risk assessment. In other cases, the Agency may determine that additional information is needed to evaluate the potential plant pest risks and field trials or greenhouse studies may be necessary to collect additional information to inform the risk assessment. In either case, under § 340.4(b)(3), APHIS would make CBI-deleted versions of both the initial review and the subsequent plant pest risk assessment conducted pursuant to this paragraph in a notice in the *Federal Register,* prepare NEPA documents as appropriate for an unconfined release, and take public comments. After reviewing the comments, APHIS would make a final determination of regulatory status and notify the public via a second *Federal Register* notice. In addition, if the GE plant were found not to require regulation under this part, APHIS would post the finding on its website. If it did require regulation, its movement would be allowed only under permit. NEPA documents prepared in this case would be for confined release.

The final revisions under the Preferred Alternative would eliminate the notification procedure and require instead that all movements of GE organisms subject to the regulations be conducted under APHIS permit, a change responsive to the OIG and Farm Bill recommendations. The final revisions would update the regulations by revising terms and definitions and would more appropriately regulate under 7 CFR part 340 those GE organisms that APHIS found had a plausible pathway to increased plant pest risk. The revisions would focus and limit ultimate regulatory oversight to the subset of GE organisms that APHIS found to have a plausible pathway to increased plant pest risk. 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 plant pest risk would not be subject to the regulation. Developers will have the option of requesting a regulatory status review at the “front end” of research and development activities before any permits are issued for the import, interstate movement, or environmental release of GE plant. The outcome of a regulatory status review would be that either the plant is found to be unlikely to pose a plant pest risk and would not fall within the authority of the regulations and could be moved without restriction or that it falls under the authority of 7 CFR part 340 and does require permits for movement. The decision to regulate an organism would be based on finding a plausible pathway to increased plant pest risk and no longer would be based on whether the organism was created using a plant pest or plant pest sequences. In effect, APHIS will be providing oversight over a broader variety of GE organisms, but requiring fewer permits, or rather, predominantly permitting GE organisms that APHIS found to have a plausible pathway to increased plant pest risk based on risk assessment. Alternatively, a developer may request permits for movement in lieu of a regulatory status review.

Until anyone wishes to import a GE organism, move it interstate, or release it into the environment, no action would be required of that person. Under the final rule, certain categories of modified plants would be exempted from the regulations in 7 CFR part 340 because they could be produced through conventional breeding techniques, which we do not regulate. Certain additional categories of GE plants, such as those having plant-trait-Mechanism of Action (MOA) combinations that we have already assessed and found to be unlikely to pose a plant pest risk, would be exempt from further review in this part as well. Under the current system, when making decisions regarding regulatory oversight of GE plants, APHIS assesses each transformation event (also sometimes referred to as the individual transformed line, transgenic line, or GE line) separately, even though the inserted genetic material may be identical or very similar to transformation events already assessed. This approach has sometimes been referred to as “event-by-event” regulation. APHIS believes this approach is redundant and unnecessary. The final revision aims to end event by event regulation. The exempted categories are discussed in detail in the preamble to the new rule (USDA-APHIS 2020d).

Under our final new regulatory framework, a developer would have the option to make a self-determination as to whether his or her GE plant belongs to one of the categories listed under 340.1(b) or (c) and is therefore exempt from the regulations.

A developer who makes a self-determination that his or her GE plant belongs to one of the categories listed under 340.1(b) or (c) and is therefore exempt from the regulations would have the option to request written confirmation from APHIS that the self-determination is valid under 340.1(d). These confirmation letters, which would provide a clear and succinct statement about the regulatory applicability of the GE plant and the nexus to plant health, may be useful to developers wishing to market their products domestically or overseas by allowing them to provide verification to an importing country or other party that APHIS concurs with their self-determinations. APHIS anticipates a 60-120 day turnaround time in developing and providing these confirmation letters to developers. Allowing for self-determinations would provide developers with substantial regulatory relief and open more efficient and predictable pathways for innovators to get new modified plants that are unlikely to pose a plant pest risk to market, in turn supporting further innovation. APHIS anticipates that benefits will accrue to developers of all sizes, including small and mid-sized ones, as well as academic institutions. At the same time, APHIS would be able to allocate its resources more efficiently than under the current regulations. Because we would no longer have to perform the redundant task of assessing GE plants with plant-trait-MOA combinations that we have already determined are not subject to these regulations, we would be able to devote more attention to assessing and regulating those GE organisms that are likely to be associated with potential plant pest risks.

We would note here that a developer making a self-determination that APHIS determines not to be valid may be subject to remedial measures of penalties in accordance with the compliance and enforcement provisions, which are discussed in § 340.6(c), if the organism is moved without proper authorization under this part. In addition, penalties and remedial measures (including but not limited to, quarantine, seizure and/or destruction) under the authority of the PPA may be exercised.

Information pertaining to the results of all completed regulatory status reviews, without confidential business information, would be publicly accessible in a separate document on the Regulations.gov website and on the APHIS website. Developers could use the list to aid them in making their self-determinations. For example, if a developer were to find that his or her newly developed GE plant had the same plant-trait-MOA combination as a GE plant previously found by APHIS to be outside the Agency's jurisdiction, the developer would know immediately that the newly developed plant would not be subject to APHIS regulation. We anticipate that should this rule be implemented, this list would grow as new regulatory status reviews are completed.

Though the regulatory status review would represent a change in our regulatory approach, GE plants for which determinations of nonregulated status have been made under the current system have been evaluated for the same plant pest risk factors which will be used under the final rule. Specifically, both reviews analyze the biology of the GE plant and its non-GE progenitor, potential changes in plant pest impacts, impacts on non-target organisms, and the propensity for increased weediness of the GE plant and any sexually compatible relatives.

Plants produced using biotechnology which were reviewed in response to an "Am I Regulated?" (AIR) inquiry under our current regulations were not reviewed using all the plant pest risk factors listed above, but rather were reviewed for regulatory status based on whether the modified plant conformed to the definition of a "regulated article" in the current regulations and in a some instances on one or more of the factors, but not all. We know of no plant pest issues raised during the review of the AIR inquiry and that none have arisen from use of any of these plants. We propose to retain these decisions made under the current rule to prevent potential market disruptions and provide regulatory certainty for developers, while the new rule will apply to all future cases. These plants will be listed separately than those evaluated at the MOA level, and will not be used for determining regulatory status based on MOA.

If the GE plant does not qualify for an exemption and has not been reviewed by APHIS, the person may request a permit (as described in § 340.5) or they may request a regulatory status review to ascertain whether APHIS has authority over the organism. The process for submitting such a request, as well as the possibilities for how APHIS would act on that request, are described in § 340.4.

If APHIS found that a plant had a plausible pathway to increased plant pest risk, permits from APHIS will be required to import, move interstate, or release it into the environment. APHIS' permitting process would be set forth in § 340.5.

If APHIS issues a permit for the importation, interstate movement, or release into the environment of an 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 those organisms. These requirements would also be set forth in § 340.5.

To respond to the recommendations of the 2015 OIG audit, APHIS would add a requirement as a general permitting condition that the responsible person must notify the Agency in writing or electronically if any activity associated with environmental release under permit will not be conducted. OIG recommended that APHIS implement improvements to track the status of all authorized test field locations. Thus, APHIS is requiring the submission of reports so APHIS knows the status and location authorized field trials. Specifically, APHIS is requiring the submission of report of no release to account for all approved test fields under an authorization. For example, APHIS may approve 50 test fields within various locations in the United States. However, test field releases only occur in 30 of the 50 approved locations. Thus, a report of no release would allow APHIS to account for the 20 other test fields. This will lead to efficient compliance oversight of the 30 test fields that have permitted releases. This general condition would work in tandem with the reporting requirement mentioned above, and help APHIS resolve what could otherwise be considered inconsistencies between the permit conditions and the regular reports.

The individual would have to retain certain records regarding any permitted activities, which would be set forth in § 340.6. 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 § 340.6.

Finally, based on the terms and definitions that APHIS has added or removed from 7 CFR part 340, as well as the refined scope of the regulations, the Agency has revised the title of 7 CFR part 340 to "Movement of organisms modified or produced through genetic engineering."

For a detailed description of the changes anticipated under the final rule as well as the final rule language please refer to the final rule document "Movement of Certain Genetically Engineered Organisms" found at Docket No. APHIS-2018-0034 ((retrieved from https://www.regulations.gov/docket?D=APHIS-2018-0034).

2.3 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 PEIS, but are discussed briefly below along with the specific reasons for dismissing the Alternative from further consideration.

2.3.1 Regulation to Facilitate Coexistence

In the PEIS for the draft 340 rule published January 19, 2017 (Docket No. APHIS-2015-0057-0006), APHIS analyzed a third Alternative where GE organisms that cause no physical damage to plants would have been regulated if they could have resulted in economic harm to non-GE producers from the mere presence of the GE trait as a result of cross pollination or commingling.

Under this Alternative, APHIS' proposed regulatory framework would have incorporated the noxious weed authority under the PPA as inclusive of GE plants that could have caused economic harms due to the mere presence of GE plant material in non-GE crops or crop products, regardless of whether this occurred 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 would have been 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 have been interpreted to include any adverse impacts that could have resulted from the mere presence of GE plant material where it was not wanted. In its reviews of a GE plant, APHIS would have assessed not only the likelihood that the modifications made to the genome of the plant altered its ability to cause physical harm or injury but in addition, APHIS would have considered the economic harms that may have resulted from commingling or cross pollination of the GE plant with a non-GE crop plant or its products.

Under this regulatory framework, APHIS would likely have found many of the GE plants under regulation would have been unlikely to pose a physical risk to plants, but may have posed a risk of potential economic impacts resulting from the mere presence of GE materials in non-GE agriculture, marketing, or shipping. If implemented, APHIS would have served as a wide-scale permitting authority overseeing the production of many of the commercial GE crops currently grown, and those that would be grown. In effect, the only GE organisms that would not require permits for interstate movement, importation, and environmental release would be those that did not cause physical harm to plants and did not cause economic harms due to mere presence. A distinction would have been made in the permitting requirements for GE plants that cause physical harm from those that cause only economic harm due to mere presence where in the latter case the conditions would have been aimed at promoting coexistence and minimizing incidents of unauthorized and unintended presence.

Under this Alternative, developers and growers of GE crops that only cause economic harm due to mere presence would have been 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 and non-GE crops. In this case, the permit conditions would have been 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 have addressed and mitigated potential economic impacts that could result from cultivation of GE crops.

Further, the only regulated GE crop plants that would have been permitted for commercial-scale cultivation in the United States would be those crop plants that had received regulatory approval in the major export markets. This requirement would have been instituted to reduce the potential for low level presence (LLP)[37] occurring in countries importing U.S. agricultural commodities.

Registration: Under this Alternative, all non-GE crop producers (conventional and organic) that wished to receive protections from economic harm from GE crops provided under the regulations would have needed to be registered with APHIS to confirm that they are legitimate business entities. A voluntary registration system for non-GE crop producers would have needed to be developed, and non-GE crop producers would have needed to register their production systems with APHIS to establish authenticity and qualify for protections from APHIS's regulatory program. This requirement would have prevented non-legitimate interests from unfairly imposing heavy requirements on neighboring GE producers by spuriously claiming non-GE crop status.

Pinning Map: In addition, a voluntary national web-based pinning map would have needed to 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 would have need to 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 have been allowed to participate.

Tracking and reporting: GE plant developers would have been 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 have been 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 have needed to track, record, and report the location and acreage of their crops on a national pinning map in order to have received protections under 7 CFR part 340.

Isolation distances: Biotechnology developers and producers would have needed to verify that all regulated GE crops maintained the isolation distances from non-GE crops specified in the permit. Permits would have specified 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 have needed to contribute equally to the isolation distances required for maintenance of registration and permit requirements, respectively. Biotechnology developers would have had the responsibility for obtaining permits and ensuring isolation distances and volunteer plant management requirements were met. Similarly, non-GE crop producers would have been required to maintain their registration with APHIS and adhere to registration requirements.

[37] 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.

Volunteer plant management: Permits would have required 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.

Biotech developers and growers of regulated GE crops would have been held accountable for harm to non-GE producers if isolation distances and other permit conditions were not followed. 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.

Stakeholder concerns expressed in comments on the 2017 dPEIS, APHIS review of these concerns, and APHIS' examination of this alternative in the dPEIS and regulatory impact analysis (USDA-APHIS 2020f) prompted APHIS to dismiss this alternative as a plausible path forward as described in more detail below.

Costs and Benefits of the Alternative: This alternative would have assigned liability on strictly economic terms for products that did not demonstrate physical harm to plants. It would have provided some protection to organic and other non-GE plant growers against losses from the unintended presence of GE traits. It would have also provided producers with protection against export market disruptions and associated losses that may have occurred when adoption of a GE trait occurs in the United States prior to its approval in an export market.

However these types of benefits would have come at a very high cost. Crops produced on approximately one-half of the arable land in the United States, 170 million acres, would have been subject to costly regulation. Biotech developers would have had increased tracking and monitoring responsibilities, and the collection and monitoring of planting data could have been intrusive for affected GE plant producers. Biotech developers would also have had greatly increased liability exposure.

GE growers would have been responsible for removing farmland from production or at least growing non-GE plants on a portion of the isolation buffer areas. This would have decreased the profitability of those acres for GE adopters, and potentially decreased the adoption and planting of GE crops overall and increased consumer prices. To the extent that this alternative would have increased buffer areas, the cost of providing those areas is a net loss to society regardless of who pays for them. Grass buffers are often not harvested, so farmers lose all of the value that could have been gained from growing crops on that land. Organic farmers who grow conventional crops as buffers are able to sell the harvested buffer to the conventional market, but they lose the value of the organic premium for those acres. Farmers of GE crops who grow conventional crops as buffers are also able to sell the harvested buffer to the conventional market, but they similarly lose the benefits of the adoption of GE crops on those acres. All of the above factors may also reduce GE innovation and the associated benefits to biotech developers, GE crop growers, and consumers.

Organic and non-GE crop growers would also have been impacted by this alternative. They would have received some protection against losses from the unintended presence of GE traits. However, in order to receive protection, organic and non-GE crop growers would have needed to record their crop locations, and take part in a certification program to establish authenticity. Certification of non-GE crop producers would have been necessary to prevent non-legitimate interests from spuriously claiming non-GE status in order to impose requirements on neighboring GE producers. Some costs for non-GE crop producers may have declined because GE adopters would have absorbed some of the cost of reducing the risk of unintended cross-pollination. USDA would have needed to develop a national system to identify the location of non-GE plants, and a system to certify non-GE plant producers. USDA would also have needed to provide a large number of additional inspectors and devote increased resources for the testing of GE plants that may grow within the isolation buffer areas. APHIS would also have needed 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 were expected to be significant considering APHIS inspections currently administer around 400,000 acres and this alternative would have increased the scope of potentially permitted area to about 170 million acres.

In addition, this alternative would have delayed the launch of GE plants until approvals had been granted in major export markets. Such delays in commercialization of a GE trait could substantially impact the returns to the biotech developer and the growers who adopt that trait (Phillips 2014). Furthermore, this alternative would have reduced U.S. competitiveness because it would allow foreign governments to control when biotech products could be deployed in the United States. The reduction in competitiveness together with increased regulatory burden for adopters, would be expected to have reduced innovation.

This Alternative was expected to lead to fewer environmental benefits. Innovations in plant breeding have provided benefits to the environment through reductions in the use of insecticides, replacement of more toxic herbicides with glyphosate, improvements in water, air, and soil quality through the development of crops that could be managed with reduced tillage and less greenhouse gas emissions. The reduced plant breeding innovation expected under this Alternative would undermine the technology that could lead to more sustainable agriculture solutions such as plants that need fewer pesticide, fertilizer, and water inputs.

APHIS has never regulated based on economic impacts alone in the absence of any actual biological, chemical, or physical damage. This regulatory role would have been inconsistent with the Agency mission and with current APHIS programs which are aimed at protecting plants from biological, chemical, and physical damage. Together with the expected increased regulatory costs to the agency and industry (USDA-APHIS 2020f), the increased cost to consumers for food production, the decreased competitiveness of the U.S. biotech industry, and the loss of environmental benefits from plant breeding innovation, APHIS has rejected this Alternative from further consideration.

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

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. APHIS previously proposed to examine this Alternative, based on the assumption that most GE crop plants are unlikely to pose a noxious weed or plant pest risk.

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. 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 Weed Risk Assessments 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 that intend to commercialize human or animal food derived from GE plant varieties 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, stakeholder concerns, APHIS review of these concerns, and APHIS' initial examination of this alternative prompted APHIS to dismiss this alternative as a plausible path forward. Commenter concerns, shared by APHIS, were that by 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. The latter could result in a patchwork of biotech regulation. 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 nonregulated 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.

The current 7 CFR part 330 and 7 CFR part 360 are based on listing harmful species but do not have a process for reviewing new crop trait combinations for plant pest or noxious weed risks as practiced under 7 CFR part 340. Withdrawing 7 CFR part 340 would therefore necessitate substantial changes in both 7 CFR parts 330 and 360 in order to maintain a satisfactory regulatory framework for GE organisms. Based on APHIS' reevaluation, it was determined that this Alternative is not operationally feasible without substantial changes to the regulations in 7 CFR parts 330 and 360. For this reason, and those stated above, APHIS decided not to evaluate this Alternative further.

2.3.3 Revise the Regulatory Framework in 7 CFR part 340 that Describes APHIS's Ability to Determine a GE Organism poses a Plant Pest Risk, 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 a plant pest risk assessment to determine whether it had regulatory authority prior to field testing. In the event field testing was needed or the developer requested to field test in lieu of a regulatory status review, the agency would retain the option of field testing these GE organisms under the notification procedure.

The term "notification" can be misleading to the public, as sending a notification does not mean automatic authorization by APHIS. In many ways, APHIS' review 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.

2.3.4 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 conventional 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.

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

340 PEIS Alternatives Summary		
	ALT 1: No Action	**ALT 2: Preferred Alternative**
Statutory Authority	PPA	PPA
Implementing Regulations	7 CFR part 340	7 CFR part 340
Risk Reviewed	PP	PP
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. [(a)]	Except under a permit issued by the Administrator in accordance with § 340.5, no person shall move any GE organism that: (a) Is a plant that has a plant-trait-mechanism of action combination that has not been evaluated by APHIS in accordance with § 340.4 or that, as a result of such evaluation, is subject to the regulations; or (b) Meets the definition of a *plant pest* in § 340.3 [(b)]; or (c) Is not a plant but has received deoxyribonucleic acid (DNA) from a plant pest, as defined in § 340.3, and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or (d) Is a microorganism used to control plant pests or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests and could pose a plant pest risk; or (e) Is a plant that encodes a product intended for pharmaceutical or industrial use.
Risk Assessment	PPRA [(c)]	PPRA [(d)]
Regulatory Review	Via Petition for nonregulated status [(e)]	Via (1) APHIS initiated regulatory status review and (2) individual requests for a regulatory status review [(f)]

340 PEIS Alternatives Summary		
	ALT 1: No Action	**ALT 2: Preferred Alternative**
Authorization Requirements	Notification or Permit	Permit only [(g)]
Compliance	Inspections, reporting, enforcement per current part 340	Augments current record retention, compliance, and enforcement requirements relative to No Action Alternative. Clarified enforcement actions.
Basis of Determination	PPRA under definition of regulated article, NEPA as appropriate	Regulatory status review, NEPA as appropriate
Summary of Changes		Refines regulatory review, inquiry, and determination process for greater efficiency. Focuses regulation on GE organism that pose a plant pest risk.

* PP – GE Plant Pest; PPRA – Plant Pest Risk Assessment.

Notes:

(a) 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.

(b) Plant pest (ALT 2): 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.

(c) PPRA: Plant Pest Risk Assessment. The Risk Assessment APHIS uses to evaluate plant pest and weed risks, currently

(d) The PPRA for the final rule is similar but not identical to the risk assessment used currently.

(e) 7 CFR part 340.6 - Petition for determination of nonregulated status.

(f) § 340.4 Regulatory status review: (1) Any person may submit a request to APHIS for an Agency regulatory status review, pursuant to § 340.4(b)(3) of this section. (2) Any person may request re-review of a GE plant previously found to be subject to this part, provided that the request is supported by new, scientifically valid evidence bearing on the plant pest risk associated with movement of the plant. (3) APHIS may also initiate a regulatory status review or re-review of a GE plant to identify whether it is subject to regulation under this part. (4 Information submitted in support of a request for a regulatory status review or re-review must meet the requirements listed in paragraphs (a)(4)(i) through (a)(4)(iii).

(i) A description of the comparator plant, to include genus, species, and any relevant subspecies information;

(ii) The genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant; and

(iii) A detailed description of the new trait(s) of the modified plant.

Additional guidance on how to meet these requirements will be available on the APHIS website

When APHIS receives a request for a regulatory status review of a GE plant, the Agency will conduct an initial review to determine whether there is any plausible pathway by which the GE plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, could pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator(s), based on the following factors:

(1) The biology of the comparator plant and its sexually compatible relatives;

(2) The trait and mechanism-of-action of the modification(s);

(3) The effect of the trait and mechanism-of-action on:

(A) The distribution, density, or development of the plant and its sexually compatible relatives;

(B) The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

(C) Harm to non-target organisms beneficial to agriculture; and

(D) The weedy impacts of the plant and its sexually compatible relatives.

APHIS will complete the initial review within 180 days of receiving a request that meets the requirements specified in this section. If the Agency does not identify a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s) in the initial review, the GE plant will not be subject to the regulations in this part, and APHIS will post the finding on its website for reference in determining whether a GE plant is exempt from the regulations under this part pursuant to § 340.1(c). If the Agency does identify a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor may apply for a permit and/or request that APHIS complete the regulatory status review by conducting an evaluation of the factor(s) of concern to determine the likelihood and consequence of the plant pest risk posed by the GE plant or its sexually compatible relatives. APHIS will make available information on the results of both the initial review and the complete review in a notice in the *Federal Register* and will take comments on its findings from the public. APHIS will review the comments and make the final determination within 15 months of receiving a request that meets the requirements specified in this section.

If APHIS finds that the GE plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the GE plant does not require regulation under this part and APHIS will announce the final determination in a subsequent *Federal Register* notice, and post the finding on its website for reference in determining whether a GE plant is exempt from the regulations pursuant to § 340.1(c).

All other GE plants will remain regulated under this part and their and movement will be allowed only under permit in accordance with § 340.5.

APHIS will maintain on its website information on all requests for and results of regulatory status reviews.

(g) Permit (ALT 2) APHIS would issue core permit conditions in § 340.5 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.

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 1 & 2. APHIS is evaluating two regulatory options, or Alternatives, in revision of 7 CFR part 340. This chapter describes those aspects of the human environment[38] 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 subject to 7 CFR part 340 regulations developed for uses other than food or fiber, such as ornamental plants, microbial pesticides, and those developed for pharmaceutical and industrial purposes.

3.1 Estimates of Major Land Uses in the United States

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 nonregulated GE food and fiber crops have been and may be grown, or animal food derived from GE plants is 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 2020b) can occur in the general areas where GE crops are produced. While the focus is on GE crop production, U.S. agricultural production of both GE and non-GE crops, as well as forestry activities, are addressed.

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. If APHIS determines that a GE organism is not subject to 7 CFR part 340, that organism may be grown anywhere in the United States or its territories without APHIS authorization, although, it may be

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

subject to EPA regulations, or an FDA recommendation for a voluntary consultation, as well state and local requirements.

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 2015b).

This PEIS primarily uses ERS and USFS data in the 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 et al. 2011) (Figure 3-1). As the primary source of the Nation's food and fiber, as well as a source of biofuel feedstocks, 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 et al. 2011; USDA-NASS 2014g).

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.[39]

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 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

[39] 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 non-forested) that are not included in the NASS definition of a farm.

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 et al. 2011).

Historic and projected land-use trends are shown in Figure 3-1. Though areas of cropland, forest, and rangeland are expected to marginally decline over the next several decades, these three uses are projected to continue as the dominant land uses in the United States. The most significant change is projected to be urban land use, which is projected to substantially increase in line with increases in the 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 et al. 2010).

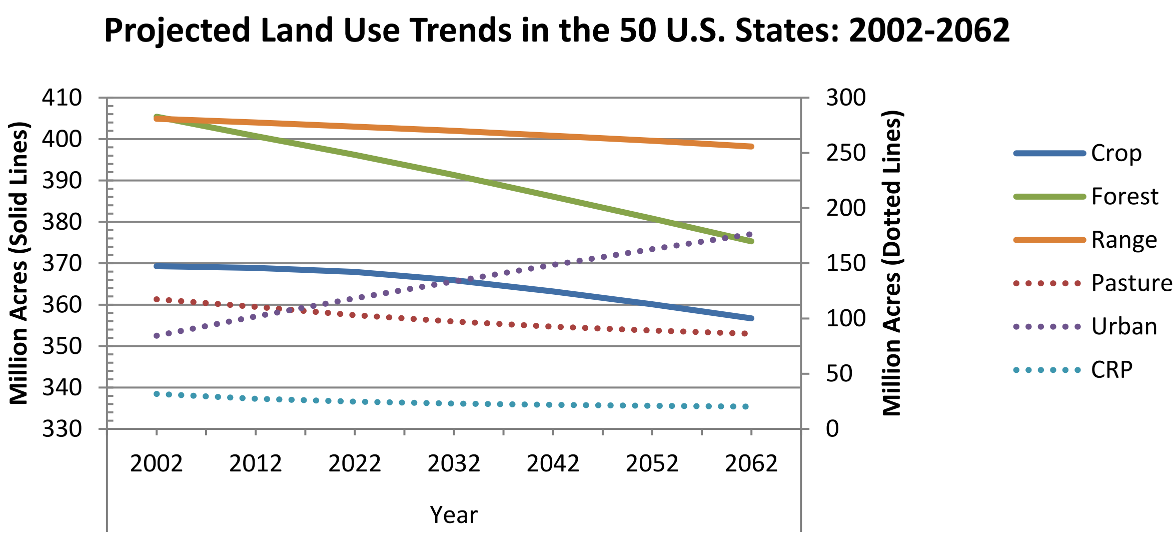


Figure 3-1. Historic and Projected Land Use Trends in the United States
Source: (Alig et al. 2010)

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 3-2) (USDA-NASS 2014b).[40] 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 (Wang et al. 2015). Consequently, the

[40] 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.

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.

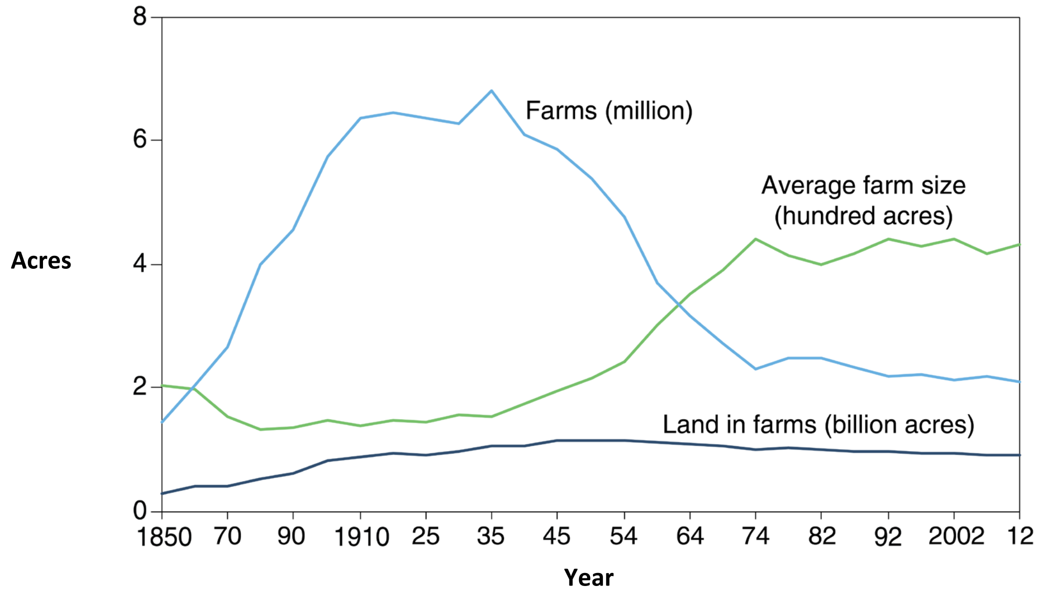


Figure 3-2. Land Use Trends: Farms, Land in Farms, and Average Acres per Farm, 1850-2012
Source: (USDA-ERS 2013)

Since the 1970s, trends in the decline of farm number and increase in the size of farms has stabilized. Despite slight declines in the number of farms and total farmland acreage in recent years, with acreage dropping from 914.5 million acres in 2012 to 900.2 million acres in 2017 (Table 3-1) 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 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 3-3).

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

	2017	2012	% Change
Number of Farms	2,042,220	2,109,303	-3.18
Farmland (acres)	900,217,576	914,527,657	-1.56
Average Farm Size (acres)	441	434	-1.61

* 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.

Source: (USDA-NASS 2019a)

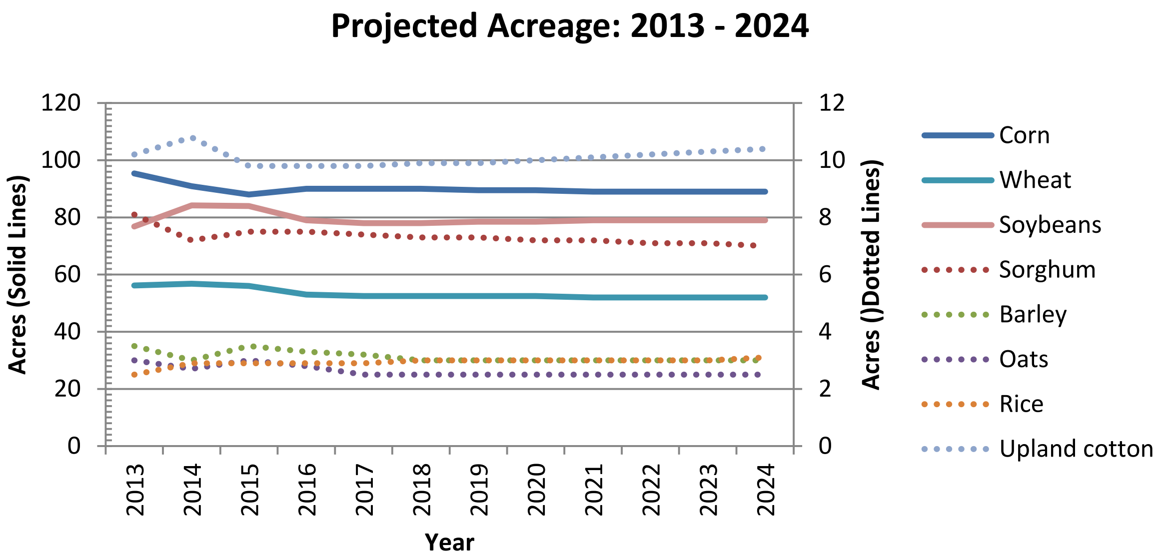


Figure 3-3. Projected Acreage for the Eight Major Crops: Continental United States and Hawaii
Source: (Westcott and Hansen 2015)

Farmland comprises around 40% of all land in the contiguous 48 states. Production of various crops occurs in all states to some degree, although is most heavily concentrated in the central United States (Figure 3-4).

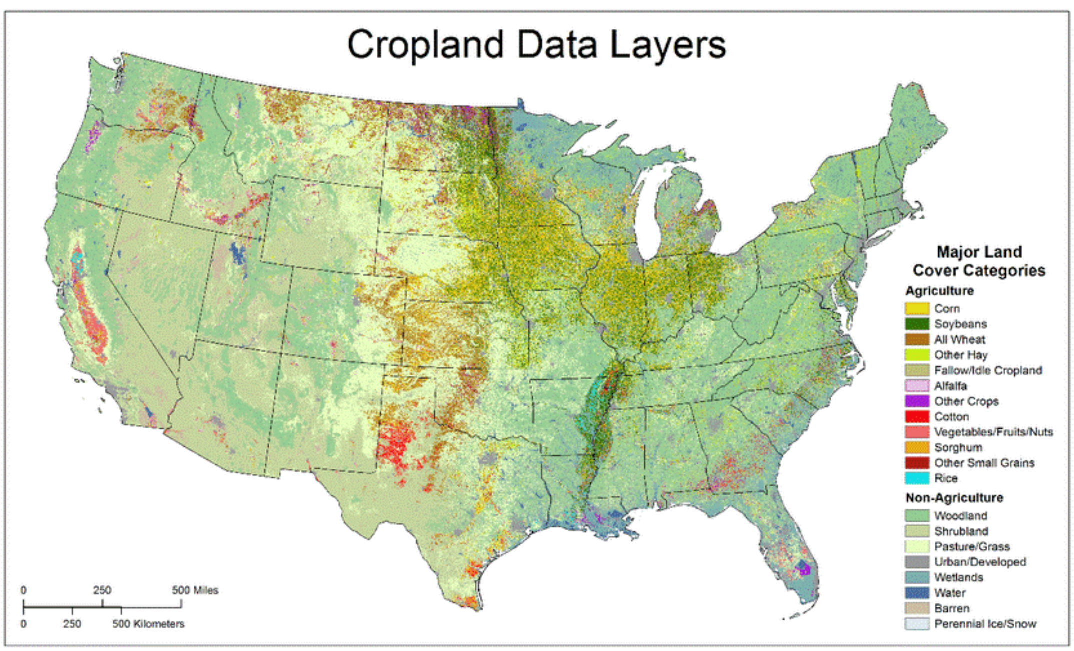


Figure 3-4. Farmland as Percent of Land Area in the Continental United States and Hawaii: By County, 2012
Source: (USDA-NASS 2014b)

3.2.2 Agricultural Land Uses

Table 3-2 summarizes the primary uses of farmland in the United States for 2012 and 2017. The total area of cropland is about 396 million acres (2017 census data). As with total farmland, variance in these uses is not expected to significantly change through 2024. Minor annual fluctuations in the types of farmland uses will occur in response to market demand for specific agricultural products, although substantial changes in cropland, pasture and rangeland, and woodland are not anticipated through 2024 (Westcott and Hansen 2015).

Table 3-2. Farmland Uses in the Continental United States and Hawaii, 2012-2017

	2012	2017	% Change
	Million Acres		
Total	914.5	900.2	-1.56
Permanent Pasture	415.3	400.7	-3.52
Total Cropland	389.7	396.4	1.72
Harvested Cropland	314.9	320.0	1.62
Woodland	77	73.1	-5.06
Other Land*	32.5	29.9	-8.00

* Other land: Remaining 3.6% was land in farmsteads, buildings, ponds, livestock facilities, etc.
Source: (USDA-NASS 2019a)

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).

Table 3-3. Farmland Uses in Caribbean Territories, 2012 - 2015

Year	Cropland	Pastureland	Rangeland	Forest Land	Other Rural Land
			Thousands of Acres		
2012	256.7	360.0	118.6	810.4	49.1
2015	252.3	349.7	118.5	824.9	47.7
% Change	-1.71%	-2.86%	-0.08%	1.79%	-2.85%

Source: (USDA-NASS 2019a)

In Puerto Rico (2.2 million total acres of land), farmland comprises approximately 26% of total land; around 585 thousand acres (USDA-NASS 2014c). 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 2014d). The most recent data available for farmland uses in the U.S. Virgin Islands is summarized in Table 3-5.

Table 3-4. Puerto Rico Farms and Farmland, 2007 and 2012

	2007	2012	% Change
Number of farms	15,745	13,159	-16.4
	Cuerdas		
Land in farms	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 2014d)

*Note: Figures are in cuerdas, 1 cuerda = 0.97 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		
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 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 2014e).

In Puerto Rico, important 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 (USDA-NASS 2014c). 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 (USDA-NASS 2009).

Table 3-6. Principal U.S. Crops Harvested, 2012 and 2017			
	2012	2017	% Change
	Millions of Acres		
Corn for Grain	87.4	84.7	-3.09
Soybeans	76.1	90.1	18.40
Forage	55.8	56.9	1.97
Winter Wheat	34.7	26.2	-24.50
Spring Wheat	12.2	10.4	-14.75
Cotton	9.4	11.4	21.28
Corn for Silage	7.2	6.2	-13.89
Orchard Crops	5.2	5.7	9.62
Sorghum for Grain	5.1	5.1	0.00
Vegetables	4.5	4.4	-2.22
Barley	3.3	2.2	-33.33
Rice	2.7	2.4	-11.11
Durum Wheat	2.1	2.2	4.76
Sunflower Seed	1.9	1.3	-31.58

Source: (USDA-NASS 2019a)

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 (e.g., 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.[41]

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, lumber, paper, and paperboard (FAO 2014c). These comprise the

[41] 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.

primary wood products derived from U.S. timberlands,[42] accounting for around 94% of all timberland removals in 2010 (USDA-FS 2015).

The United States has approximately 751 million acres of forest land, 623 million of which are in the contiguous United States (Nickerson et al. 2011). Timberlands, including natural stands and planted forests, comprise the largest category of forest at 514 million acres (or around two-thirds of total forested land, nationally) (US-DOI 2013). The greatest proportion of timberland is in the Southeast, Appalachian, Northeast, Pacific, and Mountain regions (Figure 3-5). 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 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 et al. 2010; Nickerson et al. 2011).

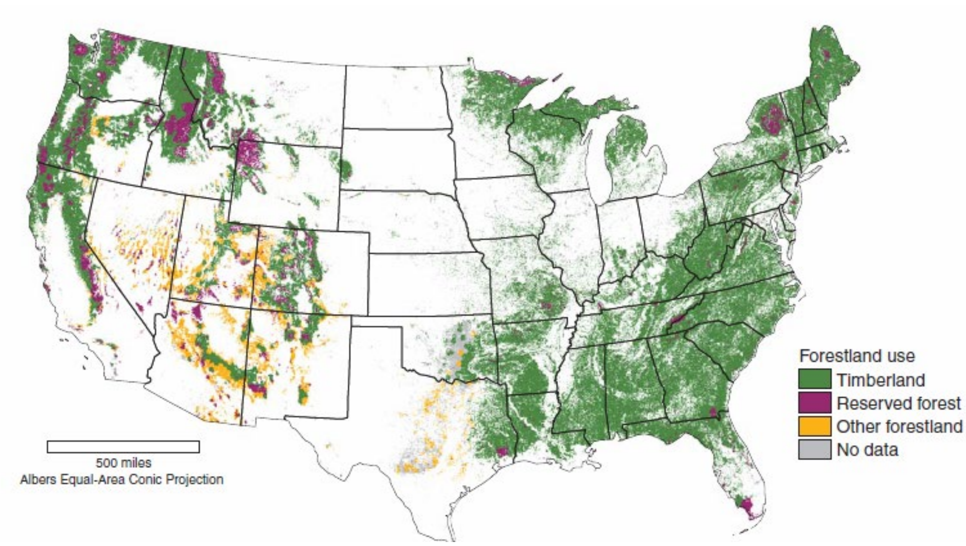


Figure 3-5. Timberland, Reserved Forests, and other Forest Lands in the 48 States, 2007
Source: (Nickerson et al. 2011)

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 et al. 2010). Timber harvesting over the past 50 years has remained well 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

[42] Forest is classified as timberland if the forest is capable of growing 20 cubic feet of commercial wood per acre 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.

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 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 Puerto Rico and the U.S. Virgin Islands. 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. Timberland in the U.S. Virgin Islands is owned by non-industrial private entities and local government (Brandeis and Turner 2009). The inventory of forest covers about 45,163 acres, or about 45% of the islands, and a very small percentage of that 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/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 3-6. Nearly half of the Nation's cropland is concentrated in 2 of the 10 Farm Production Regions, the Corn Belt and the Northern Plains.

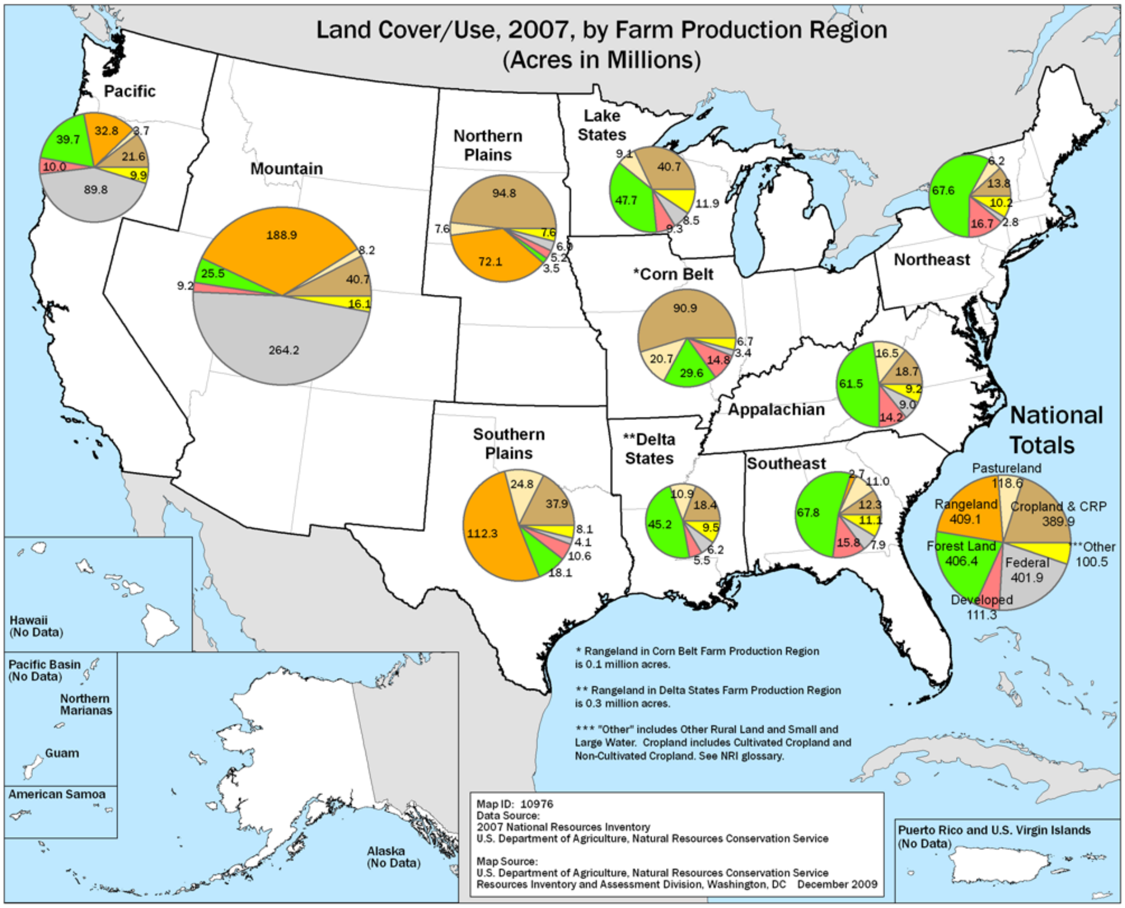


Figure 3-6. Regional Agricultural and Forestry Land Use Types in the United States, 2007

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 3-7). The agricultural activities occurring in LRRs and associated environmental concerns are summarized in Table 3-8.

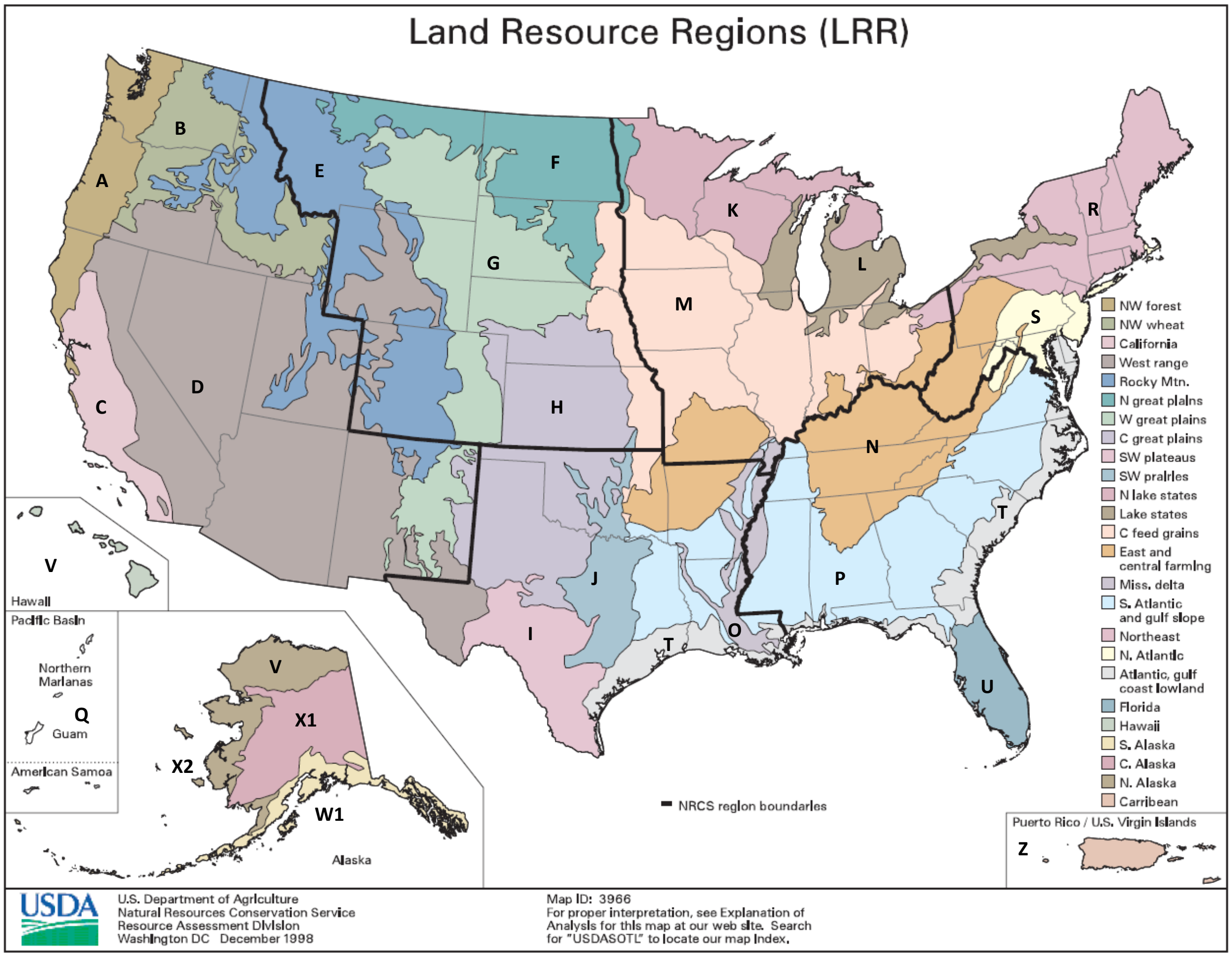


Figure 3-7. Major Agricultural Activities by Land Resource Region in the United States, Caribbean, and Pacific Basin

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 • sugarbeets • 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.

C	**California Subtropical Fruit, Truck, and Specialty Crop**	• citrus fruits and other subtropical and tropical fruits • nuts (major crop) • vegetables • rice • sugarbeets	• 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 • sugarbeets • 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 • sugarbeets • 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 • sugarbeets • 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 • sugarbeets	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 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 • 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 • sugarbeets • 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-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.
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.
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 et al. 2014a). For example, GE soybeans expanded from 17% of U.S. soybean acreage in 1997 to 94% in 2018; GE cotton from about 10% of U.S. acreage in 1997 to 94% in 2018; and GE corn from about 6% of U.S. acreage in 1997 to around 92% of U.S. corn acreage in 2018 (USDA-NASS 2019c). 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 et al. 2014b). Other GE crops commercially grown in the United States are HR canola, HR sugarbeets, HR alfalfa, virus-resistant papaya, virus-resistant squash, non-browning apples, and non-browning, low acrylamide, blight resistant potatoes.

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 et al. 2014b; Brookes and Barfoot 2016), 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, as well for ecological restoration purposes.

APHIS currently takes two major types of actions in the regulation of GE plants and other organisms: (1) authorizing the importation, interstate movement, or environmental release of certain regulated GE organisms and (2) determination of a GE organism's regulatory status (see Chapter 2 for detailed discussion). 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 certain regulated GE organisms through a permit or notification process (USDA-APHIS 2011, 2012c), as described in Section 2.1.3. 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 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, 2012c), as described in Section 2.1.3. As of July 2018, APHIS has issued nearly 14,000 authorizations for the importation of GE organisms, and more than 12,000 authorizations for the interstate movement of GE organisms. The purpose of the permit and notification procedures is to prevent the unintended release of a GE organism into the environment during importation or interstate movement. For these activities, applicants must disclose the origin and destination, the means of movement, and procedures to safeguard against the unintended release of the GE organism. The introduction into the United States of such regulated articles may also be subject to other regulations promulgated under the PPA (7 U.S.C. 7701–7772; PPA)[43] and found in 7 CFR parts 319, 330, and 360.

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

[43] 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 plants
- 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 and identification that apply to shipments of regulated GE organisms (USDA-APHIS 2011, 2012c).

Among the GE organisms APHIS regulates, some microorganisms meeting certain conditions are exempt from permit and notification for interstate movement.[44] These include research organisms such as *Escherichia coli* genotype 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 permit and notification requirements (USDA-APHIS 2011, 2012c). To date, APHIS has received only a small number of requests to import GE organisms for non-propagative uses (e.g., human or animal food or food processing), and these have been addressed on a case-by-case basis based on familiarity, 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 to authorize the import, or it must work through a domestic agent to obtain a determination of nonregulated status pursuant to the petition process described in 7 CFR part 340.6. In the latter option, the GE

[44] For a description of exemptions see 7 CRF 340.1 (b) and (c)

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.

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

Environmental releases authorized via APHIS permits or notifications, which have been conducted by industry, academia, and government, have taken place throughout the United States and its territories. As of July 2018, APHIS has issued more than 19,500 authorizations for the environmental release of GE organisms at multiple sites, primarily for research and development of improved crop varieties (USDA-APHIS 2020a). APHIS has, to date, denied slightly more than 1,600 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.[45] Less than 1% of the total number of authorized field releases involved non-plant species such as insects, mites, nematodes, fungi, bacteria, and viruses. 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

Crop and Pasture Plants	**Grasses**	**Orchard Trees & Vines**	**Insects/Invertebrates**
Alfalfa	Bahiagrass	Apple	Diamondback moth
Arabidopsis thaliana	Bermudagrass	Avocado	*Heterorhabditis bacteriophora*
Barley	Creeping bentgrass	Banana	pink bollworm
Barrel clover	Dwarf Bahiagrass	Blueberry	Western orchard predatory
Black nightshade	Tall fescue (*Festuca arundinacea*)	*Carrizo citrange* (sweet orange)	
Brassica juncea	Italian ryegrass	*Citrus sinensis* x *poncirus*	**Microorganisms**
Brassica oleracea	Kentucky bluegrass	Coffee	*Agrobacterium tumefaciens*
Brassica rapa	*Miscanthus*	Cranberry	*Agrobacterium vitis*
Camelina / false flax	Perennial ryegrass	European plum	*Aspergillus flavus*
Canola	*Poa* hybrid	Grape	*Cephalosporium gramineum*
Carrot	Russian wildrye	Grapefruit	*Citrus tristeza virus*
Cassava	St. Augustine grass	lemon	*Clavibacter*
Chicory	switchgrass	Mexican lime	*Cryphonectria parasitica*
Chickpea	Velvet bentgrass	Papaya	*Erwinia amylovora*
Corn		Pear	*Erwinia carotovora*
Cotton	**Ornamental Plants**	Persimmon	*Fusarium graminearum*
Cow pea/black eyed pea	*Anthurium*	Plum	*Fusarium moniliforme*
crambe	*Begonia semperflorens*	Raspberry	*Fusarium verticilloides*
Cucumber	bunchberry	*trifoliata* (orange)	*Neotyphodium*
Eggplant	*Chrysanthemum*	Walnut	*Pectobacterium carotovorum*
Ethiopian mustard	Clary (*Salvia sclarea*)		*Pseudomonas syringae*
Field pea	Cypress Vine	**Trees**	*Rhizobium etli*
Lettuce	*Dendrobium* (Orchid)	Allegheny serviceberry	*Rhizobium leguminosarum*

[45] 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			
Melon	Easter Lily	American chestnut	*Rhizobium meliloti*
Oat	Geranium	American elm	*Tobacco etch virus*
Onion	Gladiolus	Aspen	*Tobacco mosaic virus*
Pea	Iris	Black cottonwood	*Xanthomonas campestris*
Peanut	Marigold	Eastern cottonwood	*Xanthomonas perforans*
Pepper	*Nicotiana attenuate*	*Eucalyptus camaldulensi*	
Peppermint	*Nicotiana glauca*	*Eucalyptus grandis*	**Pharmaceutical and Industrial**
Pineapple	*Nicotiana hybrid*	Eucalyptus hybrid	Alfalfa
Pinto bean	*Nicotiana sylvestris*	*Eucalyptus urophylla*	Barley
Potato	Petunia	Grey poplar	Corn
Rapeseed	Rhododendron	Hybrid aspen	Guayule
Rice	Rose (*Rosa hybrida*)	Hybrid black poplar	Pea
Safflower	Serviceberry	hybrid pine	Rapeseed
Sorghum		Hybrid poplar	Rice
Soybean		Loblolly pine	Safflower
Squash		Poplar	Sugar cane
Strawberry		Sweetgum	Tobacco
Sugarbeet			*Tobacco mosaic virus*
Sugarcane			Tomato
Sunflower			
Sweet potato			
Sweet sorghum			
Tobacco			
Tomato			
triticale			
Watermelon			
Wheat			
White clover			
yucca			

Source: (USDA-APHIS 2020a)

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 3-8). APHIS authorized field releases occur at discrete locations for specified periods of time, generally from 1 to 3 years. Approval of field test sites involves consideration of potential environmental effects associated with the particular GE organism being reviewed. 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.

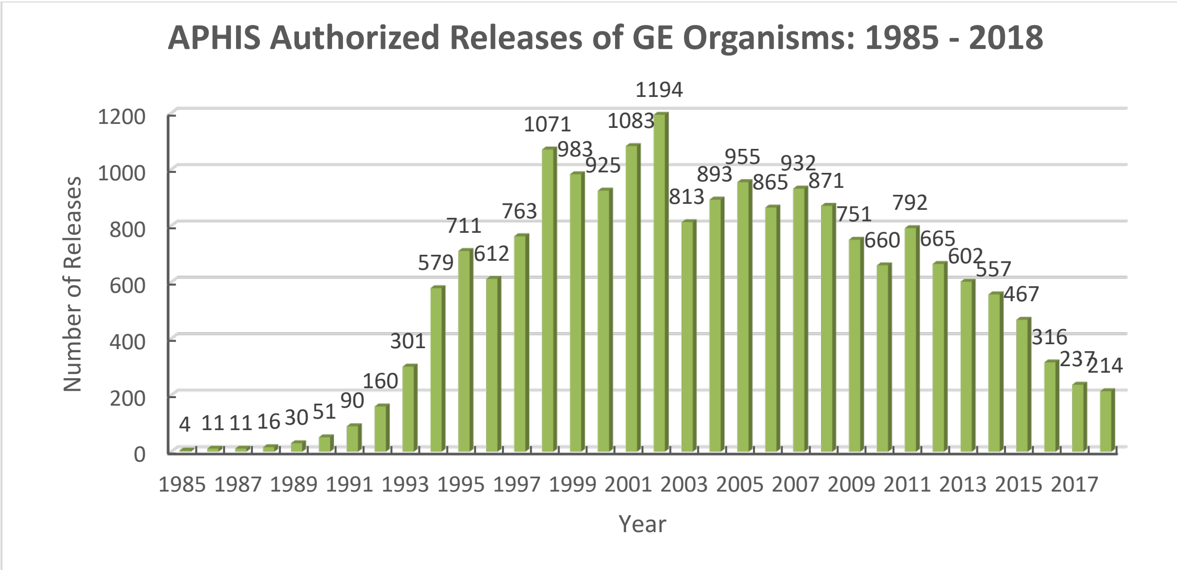


Figure 3-8. Authorized Field Releases of GE Organisms: Permits and Notifications, 1985 – 2018

Source: (USDA-APHIS 2020a)

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 40,000 acres were authorized for environmental releases in 2000, around 447,631 acres were authorized for environmental release in 2015 (Figure 3-9). 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. Typically only a fraction of these authorized acres are actually planted.

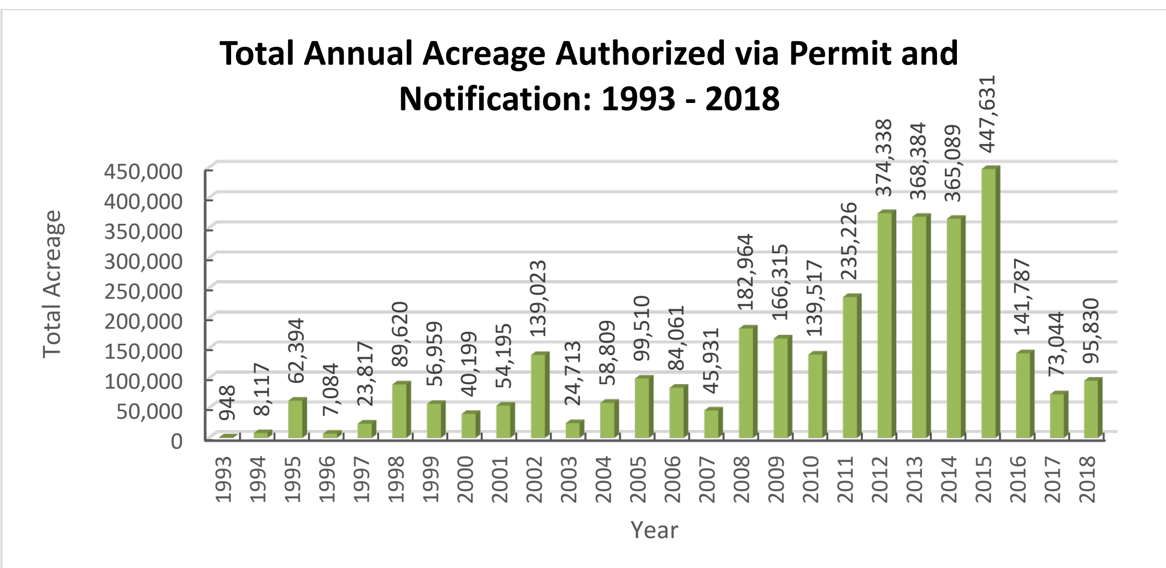


Figure 3-9. Total Acreage for Authorized Environmental Releases: 1993 – 2018

Source: (USDA-APHIS 2020a)

*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

An authorized permit or notification can comprise multiple release sites. Authorization can also include testing of more than one GE variety with various gene combinations and representing different phenotypic categories,[46] at the authorized sites. 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-MOA 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 3-10 and Figure 3-11. 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 website (USDA-APHIS 2020a).[47]

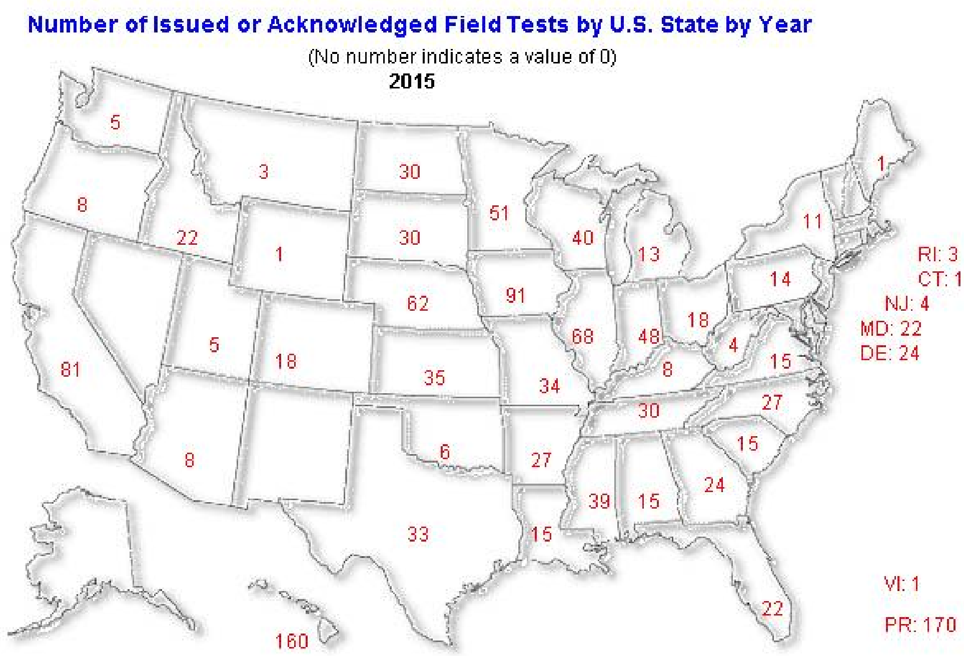


Figure 3-10. Total Number of Field Tests Authorized by APHIS in 2015
Source: (USDA-APHIS 2020a)

[46] Phenotype is the set of observable characteristics of an individual resulting from the interaction of its genotype (DNA) with the environment. APHIS currently categorizes the traits that are expressed in GE organisms into 10 phenotypic categories.
[47] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/sa_permits/ct_status

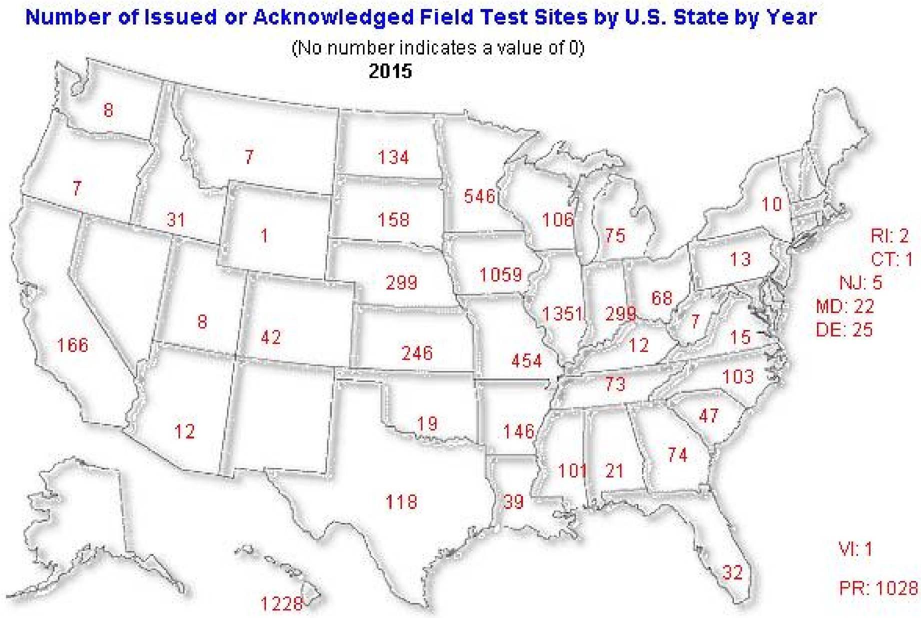


Figure 3-11. Total Number of Field Sites Authorized by APHIS in 2015

Source: (USDA-APHIS 2020a)

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, and California (used for year round breeding operations), in addition to Illinois, Iowa, Indiana, and Nebraska, which are the major production areas for GE corn and soybean. Figure 3-12 summarizes the distribution of field trials authorized throughout the United States and its territories.

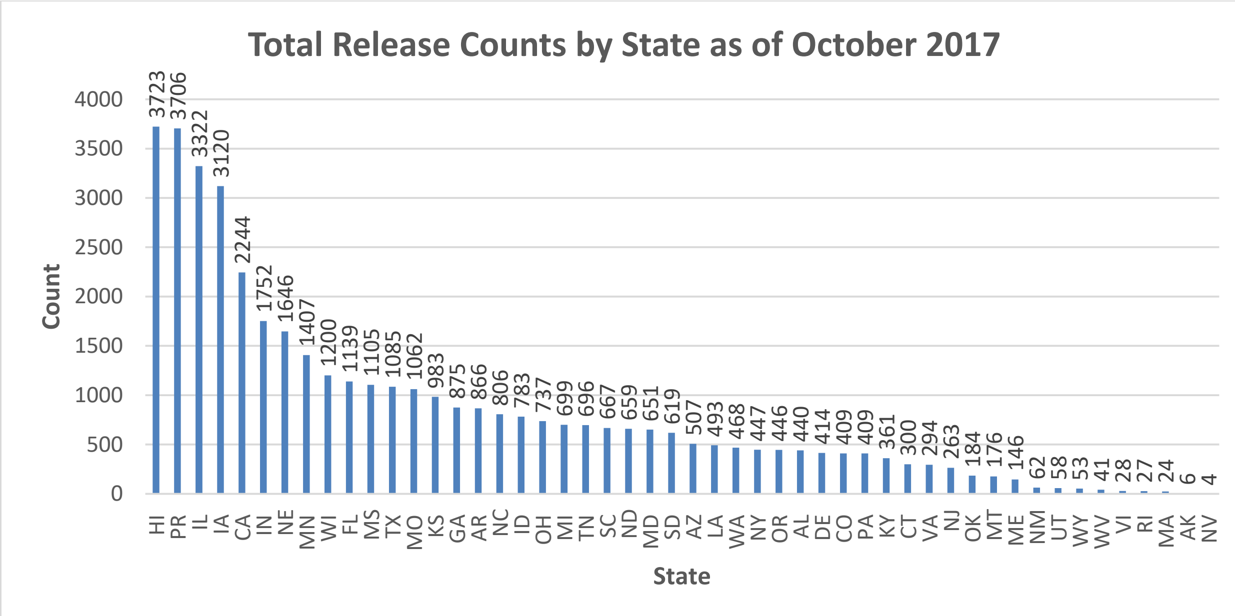
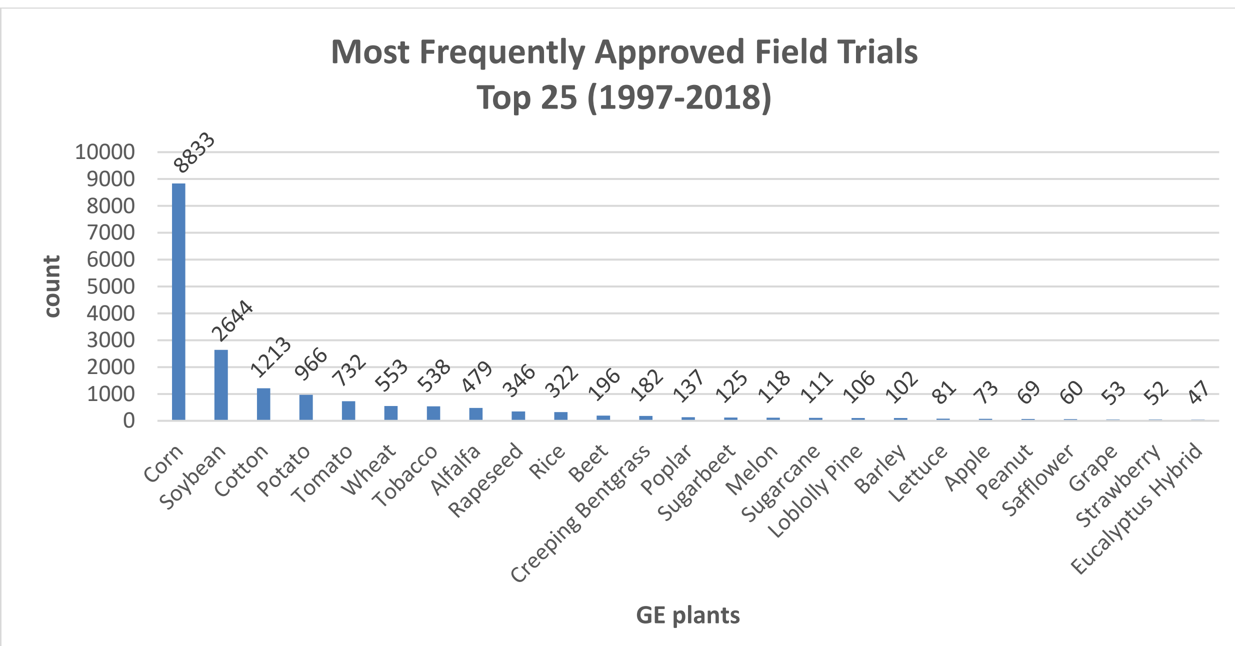


Figure 3-12. GE Organism Field Trials by State

Source: (USDA-APHIS 2020a)

3.3.3.1 GE Plants

Most authorized field trials have involved major crop plants. For example, between the years 1997 and 2018 GE corn has been approved for 8,833 field releases; GE soybeans for 2,644 field releases; GE cotton for 1,213 field releases; and GE potatoes for 966 releases (Figure 3-13).[48]



[48] Data current as of September 2018

Figure 3-13. GE Plant Varieties Approved for Field Trials
Source: (USDA-APHIS 2020a)

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 ~45.2% of field trials, soybean 13.5%, cotton ~6.2%, and potato ~4.9% of all field trials. Field releases for all other GE plant varieties have each comprised less than 4% of total field releases (as of September 2018).

Table 3-10. Total and Percentage of Field Trial Counts: 25 Most Frequently Approved GE Plants as of September 2018

Regulated GE Plants	Total Releases	% of Total Releases
Corn	8833	45.2%
Soybean	2644	13.5%
Cotton	1213	6.2%
Potato	966	4.9%
Tomato	732	3.7%
Wheat	553	2.8%
Tobacco	538	2.8%
Alfalfa	479	2.4%
Rapeseed	346	1.8%
Rice	322	1.6%
Beet	196	1.0%
Creeping Bentgrass	182	0.9%
Poplar	137	0.7%
Sugarbeet	125	0.6%
Melon	118	0.6%
Sugarcane	111	0.5%
Loblolly Pine	106	0.5%
Barley	102	0.4%
Lettuce	81	0.4%
Apple	73	0.4%
Peanut	69	0.3%
Safflower	60	0.3%
Grape	53	0.2%
Strawberry	52	0.3%
Eucalyptus Hybrid	47	0.2%

Source: (USDA-APHIS 2020a)

Authorizations of field trials for GE plants, via permits and notification, has included total acreage ranging from 0.001 up to 100,000 acres. An authorized field trial could include either one site or multiple sites across an authorized area. 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, 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 2012, of which 1,160 were planted (42.5%). 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 the 25 most frequently approved 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	Average Acreage per Authorized Permit and Notification
Corn	261
Soybean	480
Cotton	249
Potato	160
Tomato	3
Wheat	17
Tobacco	30
Alfalfa	66
Rapeseed	94
Rice	31
Beet	16
Creeping Bentgrass	32
Poplar	3
Melon	4
Sugarbeet	45
Sugarcane	3
Loblolly Pine	3
Barley	2
Lettuce	3
Peanut	1
Apple	3
Safflower	144
Grape	5
Strawberry	1
Eucalyptus Hybrid	22

Source: (USDA-APHIS 2020a)

3.3.3.2 GE Microorganisms

GE microorganisms are developed for a variety of purposes (Amarger 2002; Vidaver et al. 2012). Current research is investigating their use in the bioremediation of contaminated soils and water; as bio-control agents; to serve as nitrogen-fixing bacteria; and for the 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 under FIFRA and the FFDCA. The EPA also regulates certain GE microorganisms, referred to as intergeneric 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.

GE 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)
- *Aspergillus flavus,* which is an opportunistic pathogen of crops.

APHIS authorizes on average around 2 to 6 environmental release permits per year for GE microorganisms.

The few examples of GE microorganisms that are currently used in agriculture include GE *Agrobacterium 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 *Agrobacterium 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 et al. 2012). *Bacillus thuringiensis kurstaki* strain EG7841, known by the trade name Crymax, has been engineered to guard against lepidopteron larvae that defoliate and damage plant tissue (Vidaver 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). Other 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 engineered with a marker gene and 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 that is engineered with a marker gene. 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*.

3.3.3.3 GE Insects and Invertebrates

APHIS has issued permits for insects, mites, and nematodes developed to explore their use as biocontrol agents. Mites are arthropods like spiders that include species that are plant pests and species that are beneficial. APHIS has issued one permit for a beneficial species, the Western orchard predatory mite, *T. occidentalis* that feeds on the spider mites and rust mites that attack deciduous tree fruits. Naturally occurring *T. occidentalis* have been used commercially on apples since 1965 (Hoyt and Beers 1993). However, the usefulness of predatory mites on pear has been limited due to the harmful effect of chemicals needed to suppress pear psylla. Nematodes are a phylum of roundworms found in soil or water, and some species are plant pests while others are naturally parasitic in plants or animals. To date, APHIS has authorized one GE nematode, *Heterorhabditis bacteriophora*, for field release. This species was genetically engineered for enhanced thermotolerance (Hashmi et al. 1998).[49] 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. Pink bollworm, *Pectinophora gossypiella*, and diamond back moth, *Plutella xylostella,* are both significant plant pests of cotton and crucifers, respectively. The male of the species has been engineered with a trait that is lethal to the offspring. The GE males compete with wild males to mate with the females. Females that mate with a GE male produce no offspring, thus reducing the next generation's population. In this way, the GE versions of these species are designed to suppress pest populations. A similar strategy using radiation treated males had been employed with the sterile insect program, that successfully eradicated, screwworm and fruit fly outbreaks and has nearly eliminated pink bollworm in the United States (Dyck et al. 2005). APHIS issued 15 permits for pink bollworm release and one permit for diamond back moth release. It is expected there will be further requests for permits for plant pests that are engineered to be biocontrol agents used to enhance pest control.

3.3.3.4 GE Organisms Developed for Pharmaceutical and Industrial Purposes

Development of GE plants and microorganisms to produce pharmaceutical or industrial products has been of 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

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

GE organisms given their purpose is not for the production of food or fiber products. To date, it is largely GE plants that are utilized for production of pharmaceutical or industrial products that APHIS has regulated (referred to in this document as PMPI-producing plants), and emphasis will be given to these. While GE microorganisms are also used as a platform for production of pharmaceutical or industrial products, they have not fallen under APHIS oversight because those used are typically not plant pests and they are grown in containment facilities that do not fall under APHIS authority.

A variety of plants such as corn, rice, tobacco, safflower, 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, tobacco, and potato to produce pharmaceutical proteins. Due to the concerns about the inadvertent mixing of PMPI-producing plants with plants that are also cultivated for human or animal food (such as corn, rice, or potato), in 2003 (USDA-APHIS 2003) APHIS added additional measures for permits for PMPI-producing plants to include (USDA-APHIS 2012c):

- a larger perimeter fallow zone (50 ft.)
- cleaning of field equipment and storage facilities using APHIS-approved procedures
- dedicated planting and harvesting equipment and storage facilities
- planting restrictions in the subsequent growing season
- authorizing releases only in areas of low agricultural production for the crop at issue
- APHIS-approved training
- additional compliance and inspection oversight by APHIS.

Field trials of PMPI-producing plants are only occasionally conducted. For example, in 2017 APHIS issued only 2 permits for the field testing of PMPI-producing plants; in 2016, 4 permits were issued; and in 2015, 4 permits were issued.[50] 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.

3.3.4 Compliance and Enforcement Actions

Currently, 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 certain GE organisms by issuing permits and acknowledging notifications, APHIS requires compliance with 7 CFR part 340, including those

[50] 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

conditional requirements that may be prescribed in the permit or notification (USDA-APHIS 2011, 2012c). 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 permit or notification.

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 or notifiers 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 (DOJ), 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). Permit and notification holders have largely had a successful history of compliance with current APHIS regulations. For example, between 1995 and 2015, there were 23 instances of noncompliance with APHIS regulatory requirements resulting in civil penalties (USDA-APHIS 2016). When the responsible person has not adhered to 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 2016). 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 nonregulated organisms; and failure to monitor for volunteer GE plants in the year following a field test. In all instances, APHIS required remediation actions, and in many instances, issued civil penalties.

3.3.5 Petition and Determination of Nonregulated 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 nonregulated 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, USFWS, and FDA.

3.3.6 Determination of Nonregulated Status and Adoption of GE Crops

As of April 2020, APHIS has made determinations of nonregulated status in response to 128 petitions (USDA-APHIS 2020e). 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 conventional 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 nonregulated status have either never been commercialized or have not been widely adopted in the market (i.e., rice, rose).

Table 3-13. APHIS Determinations of Nonregulated Status as of March 2020

GE Organism	Petitions
Alfalfa (HR, PQ)*	2
Apple (PQ)*	2
Beet/ Sugarbeet (HR)*	3
Canola (HR, AP, PQ)*	12
Chicory (AP)	1
Corn (HR, IR, AP, PQ)*	38
Cotton (HR, IR, PQ)*	18
Creeping bentgrass (HR)	1
Flax (HR)	1
Papaya (VR)*	2
Plum (VR)	1
Potato (IR, VR, PQ, FR)*	9
Rice (HR)	2
Rose (PQ)	1
Soybean (HR, IR, PQ, AP)*	21
Squash (VR)*	2
Tobacco (PQ)	1
Tomato (PQ)	11

Source: (USDA-APHIS 2020e)

*Produced in the United States. Items with no asterisk were not commercially produced in the United States as of 2020. 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 3-14). Adoption of stacked varieties in particular has accelerated in recent years. Stacked-trait cotton reached 89% of cotton plantings in 2019, and plantings of stacked-trait corn made up 80% of corn acres in 2019. All GE cotton, taking into account the acreage with either or both HR and Bt traits, reached 98% of cotton acreage in 2019. Adoption of all GE corn accounted for 92% of corn acreage, and GE soybean adoption rates reached 94%. GE HR canola and HR sugarbeets are also above 90% adoption (Fernandez-Cornejo et al. 2016). 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%-98% of planted acres. Other GE crops adopted and commercially grown in the United States are HR canola, HR sugarbeets, HR alfalfa, virus-resistant papaya, virus-resistant squash, non-browning apples, and non-browning, low acrylamide, blight resistant potatoes.

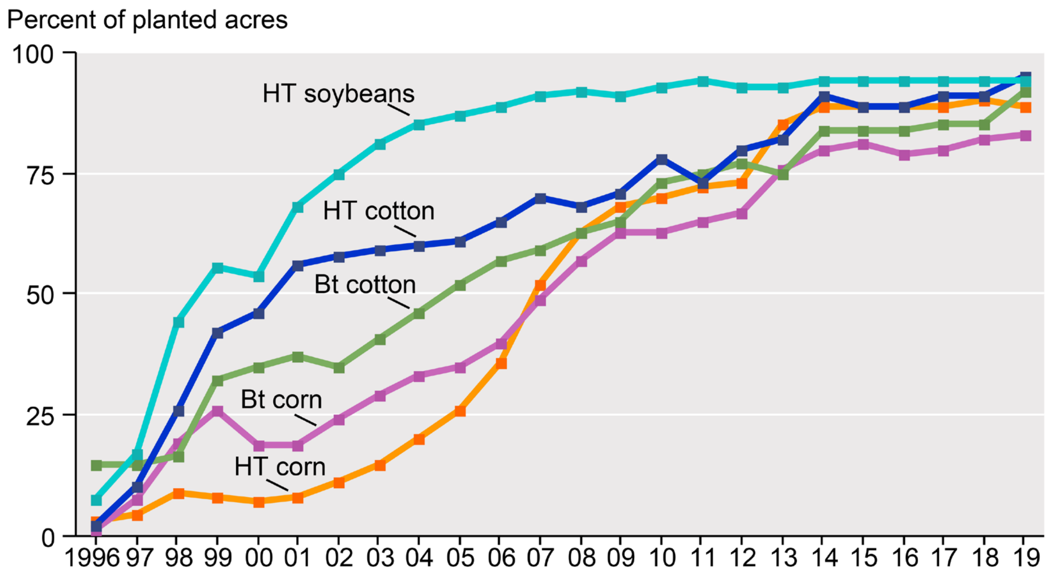


Figure 3-14. Adoption of GE Crops in the United States, 1996 through 2019
Source: (USDA-ERS 2019)

Farmers generally adopt a GE crop based on 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 et al. 2014b; Livingston 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 et al. 2014b; Livingston 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 (USDA-NRCS 2013). The market for organic crop commodities in particular has seen significant growth over the last decade, but still remains at less than 1% of total U.S. crop acreage (Table 3-14). Hence, modern agriculture is comprised of GE, conventional, and organic cropping systems, which collectively provide domestic and global needs and represent 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, canola meal, and refined sugar.

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)
Sugarbeets	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 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. As of 2018, GE crops were planted in 26 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 474 million acres in 2018 (Table 3-15) (ISAAA 2018a). Net global economic benefits from GE crops at the farm level have been estimated to amount to approximately $15.4 billion in 2015 and $167.8 billion for the 20 year period between 1996 and 2015 (Brookes and Barfoot 2017a).

Table 3-15. Global Area of Biotech Crops in 2018: by Country

Rank	Country	**Area** (million acres)	Biotech Crops
1	**USA**	185.3	Corn, soybean, cotton, canola, sugarbeet, alfalfa, papaya, squash, potatoes, apples
2	**Brazil**	126.8	Soybean, corn, cotton, sugarcane
3	**Argentina**	59.1	Soybean, corn, cotton
4	**Canada**	31.4	Canola, corn, soybean, sugarbeet, alfalfa, potatoes
5	**India**	28.7	Cotton
6	**Paraguay**	9.4	Soybean, corn, cotton
7	**China**	7.2	Cotton, papaya
8	**China**	6.9	Cotton
9	**South Africa**	6.7	Corn, soybean, cotton
10	**Bolivia**	3.2	Soybean

Table 3-15. Global Area of Biotech Crops in 2018: by Country

Rank	Country	**Area** (million acres)	Biotech Crops
11	**Uruguay**	3.2	Soybean, corn
12	**Australia**	2.0	Cotton, canola
13	**Philippines**	1.5	Corn
14	**Myanmar**	0.7	Cotton
15	**Sudan**	.5	Cotton
16	**Mexico**	0.5	Cotton
17	**Spain**	0.3	Corn
18	**Colombia**	0.3	Cotton, corn
19	**Vietnam**	<0.1	Corn
20	**Honduras**	<0.1	Corn
21	**Chile**	<0.1	Corn, soybean, canola
22	**Portugal**	<0.1	Corn
23	**Bangladesh**	<0.1	Brinjal/Eggplant
24	**Costa Rica**	<0.1	Cotton, soybean
25	**Indonesia**	<0.1	Sugarcane
26	**eSwatini**	<0.1	Cotton
	Total	474	

Source: (ISAAA 2018a)

3.3.7 GE Traits, and Current and Future 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. The vast majority of GE organisms that APHIS regulates are plants developed for food, fiber, pharmaceutical, industrial, and forestry purposes. Examples of such traits include insect resistance, viral/fungal resistance, thermo-tolerance, drought tolerance, modified fiber properties, modified gluten content, added nutrients, and production of pharmaceutical or industrial products. APHIS currently categorizes the traits that are expressed in GE organisms into 10 phenotypic 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, Resistant
Fungal Resistance (FR)	Stalk Rot Resistance, Powdery Mildew Resistant, Fusarium Resistance
Herbicide Resistance (HR)	Phosphinothricin, Glyphosate, and Dicamba Resistant
Insect Resistance (IR)	Lepidopteron Resistant, Coleopteran Resistant, Aphid Resistant
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

The most common plant-trait combinations reviewed by APHIS have been herbicide and insect resistant crop plants (Figure 3-15)). Commercially available HR crops include soybeans, corn, cotton, canola, sugarbeets, and alfalfa. Commercially available IR crops in the United States include corn and cotton. More recently, herbicide and insect resistance traits are being combined into what are termed "stacked-trait" GE plant varieties (e.g., see (Fernandez-Cornejo et al. 2014b)).

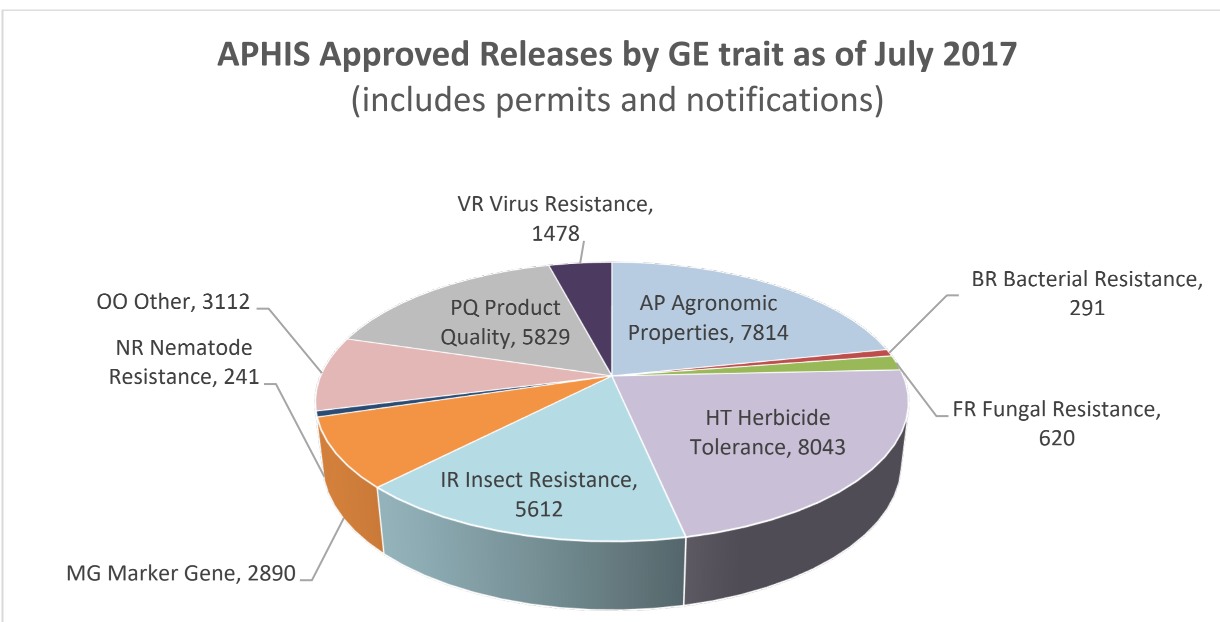


Figure 3-15. Distribution of GE Traits in Field Testing

Source: (USDA-APHIS 2020a)

APHIS expects to see continued development of HR crop varieties; more stacked-trait varieties; more traits conferring resistance to plant diseases caused by bacteria, fungi, nematodes, and viruses; and traits for enhanced product quality. As an example of the latter, in 2017, APHIS received a petition for nonregulated status for a canola that produces omega-3 fatty acids, nutrients that are beneficial to human and animal diets, in the seed.

Transgenic crops with resistance to auxinic herbicides, as well as to herbicides that inhibit acetolactate synthase, acetyl-CoA carboxylase and hydroxyphenylpyruvate dioxygenase, stacked with glyphosate and/or glufosinate resistance, could become available in the next few years (Duke 2015). In the more distant future, other herbicide-resistant crops (including non-GE), herbicides with new modes of action and technologies that are currently in their infancy (e.g., bio-herbicides, sprayable herbicidal RNAi and/or robotic weeding) may affect the role of GE herbicide-resistant crops in weed management (Duke 2015).

Rice and wheat are the only two major agronomic crops for which there are no GE varieties in commercial production. For both crops, non-GE herbicide-resistant varieties (imidazolinone resistant) have been commercialized and another non-GE rice (ACCase inhibitor resistant) is in development (Duke 2015). The use of biotechnology for development of crops that are directly consumed (fresh fruits and vegetables) is currently an area laced with uncertainty due to questions regarding consumer acceptance, and economic returns on investment in development of such (Duke 2015).

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, as well for ecological restoration purposes.

Ornamental plants are also an area that is likely to see increased research and development, namely in development of desired traits such as abiotic stress resistance, pest and disease resistance, flower color, and modified blossom characteristics. 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*). Recently, unauthorized GE petunias with altered flower color were discovered within the United States horticultural market and were systematically removed from the marketplace (USDA-APHIS 2017c, d).

GE microorganisms developed for agricultural purposes have primarily been those used for disease control and regulated by the EPA (Wozniak et al. 2012). GE microorganisms are also used for antibiotic and vaccine production, such as through processes of microbial fermentation (Nascimento and Leite 2012).

Without question, the scope, scale, complexity, and tempo of plants modified using biotechnology is increasing (NAS 2017). Many future biotechnology products may be created through new processes such as genome editing and will be virtually indistinguishable from crops created through conventional breeding. These new breeding technologies will likely allow product developers to design, build, test, and learn from experiments more quickly in the next 10 years than has been the case in the last two decades (NAS 2017).

Genome edited crops under development include drought tolerant corn, and disease resistant wheat, non-browning mushroom, grasses for phytoremediation, and crops with increased photosynthetic efficiency. Sterile insects for control of plant pest populations will continue to see development and use (e.g., diamond back moth). Also under development are RNAi-based herbicide- and insect-resistant crops.

It is anticipated that disease resistant crops and disease preventing/mitigating GE microorganisms will be a significant area of activity. There are very serious plant diseases currently affecting crops in the United States and abroad that can potentially wipe out an entire crop/industry. One example is Huanglongbing (HLB, or citrus greening), which threatens the U.S. citrus industry. Economically, citrus greening puts at risk America's entire citrus crop, worth $3.15 billion in the 2012-2013 growing season. In addition to Florida, HLB has been detected in Georgia, Louisiana, California, Texas, and South Carolina, as well as Puerto Rico and the U.S. Virgin Islands (USDA 2020a). The disease has been found in 14 states in Mexico and is a constant threat to citrus in Texas, California, and Arizona. Biotechnology approaches have shown promise in fighting the threat of HLB (Hokanson et al. 2014).

Wheat stem rust devastates wheat crops in Africa and is a threat to U.S. crops, as commercial wheat varieties have no resistance to emerging virulent strains of wheat stem rust, such as Ug99.[51] Similarly, Asian soybean rust (ASR, fungal pathogen), which currently impacts soybean production in Brazil, likewise threatens U.S. crops. The broad host range of ASR increases the likelihood of rapid spread once introduced into the United States. All commercial soybean varieties currently available are highly susceptible to the pathogen. A screen of the USDA soybean germplasm (16,595 accessions) identified no plants with immunity to ASR. Current research includes screening germplasm for resistance and evaluating fungicide efficacy. Early detection is required for the most effective management of soybean rust. Monitoring soybean fields and adjacent areas is recommended throughout the growing season. Fungicide applications may reduce yield loss, depending on the plant developmental stage, time when soybean rust is detected, and fungicide application method. Laboratory studies using genetic engineering have demonstrated proof of concept in mitigating the disease (Meyer et al. 2009; Kawashima et al. 2016; Langenbach et al. 2016). A final example, *Xanthomonas* wilt disease has devastated banana farms in Africa. Recent work using genes from sweet pepper have conferred complete resistance to a GE banana variety (Nimusiima et al. 2015).

Resistance to late blight has already been conferred to potato using genetic engineering and received a determination of nonregulated status from APHIS in the United States. This trait could presumably confer late blight resistance to pepper and tomato. Chestnut blight has devastated the American forest and GE traits have shown promise in providing resistance, and restoration of American chestnut populations (Zhang et al. 2013; Newhouse et al. 2014). GE papaya, resistant to ringspot virus, has enabled papaya to be grown again in HI after the disease decimated the industry there (Gonsalves et al. 2004).

[51] Losses are often severe (50 to 70%) over a large area and individual fields can be totally destroyed.

Given the seriousness of these and similar diseases, and their potential economic and public health impacts, it is expected that resistant varieties will be sought and developed, using both conventional breeding and methods of modern biotechnology.

Fundamentally, the increased capabilities to transform genomes afforded by advances in genomic engineering allow product developers to expand the number and kinds of modifications in future biotechnology products.

Engineered microbial consortia is a potential area of rapid growth for a broad range of markets including agriculture, mining, bioremediation, and nutrition. Researchers have worked to establish stable synthetic consortia of microorganisms – and the biological principles behind their establishment and maintenance – that could be used as the bases of a wide variety of future applications (NAS 2017). Such communities may be designed for release in open environments to enhance nitrogen fixation by plants or for bioremediation use at contaminated sites (NAS 2017). A recent report by the National Academy of Sciences anticipates growth in the genetic transformation of microbes such as yeast, algae, and bacteria to produce products such as chemicals and biofuels (NAS 2017). A much broader array of host organisms targeted for genetic transformation is also likely. APHIS would only regulate these organisms if the microbes are plant pests.

3.4 Genetically Engineered Organisms and the Environment

The potential environmental interactions that may derive from the importation, interstate movement, and environmental release of certain GE organisms subject to 7 CFR part 340 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 nonregulated status. APHIS expects that GE crop plants will continue to comprise a larger proportion of GE organisms developed for commercial purposes and 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 potential effects of the trait gene and/or gene product on other plant species, the impacts of the trait gene on beneficial non-target organisms, the potential weediness of a GE plant and its corresponding potential for disseminating pest organisms, 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.

3.4.1.1 Gene Flow and Weediness of GE Crop Plants

Gene flow among GE, conventional, and organic cropping systems is a topic of great interest to commercial farmers and international, federal, and state regulators because gene flow can adversely impact 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, 2012c).

Once APHIS has determined that a GE crop plant is not subject to 7 CFR part 340, it may be grown without APHIS oversight within the United States and its territories, though it may still be subject to EPA review and approval and per customary business practice, go through a voluntary consultation with the FDA. APHIS has not interpreted its authority to extend to market harms caused by the presence of a GE trait in a sexually compatible crop.

3.4.1.1.1 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"[52] and the terms are used here interchangeably. Neither term implies the long-term persistence or introgression[53] 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 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 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 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 crosses among species can occur (see review by (Seehausen 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

[52] 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.

[53] Introgression is the permanent incorporation of a gene(s) from one species into the genome of another. Introgression typically follows crossing 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.

trials and cultivation of GE food and fiber crops, as well as those crop plants developed to produce PMPI products.

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 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 accidental cross-pollination 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 et al. 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 gene 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 the soil incorporation of seed produced by volunteer 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. Volunteer GE plant populations can serve as reservoirs from which a transgene could be passed into the genome of a wild relative or sexually compatible crops by pollen mediated gene flow.

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 such as water streams or through the movement of equipment across or between fields (Mallory-Smith and Zapiola 2008). Vegetative propagation of field crops is also common in crops such as potato, yams, pineapple, banana, and cassava. Some of the biofuel crops, such as miscanthus (*Miscanthus x giganteus*) and giant reed (*Arundo donax* L.) commonly spread by vegetative propagation.

3.4.1.1.2 Gene Flow to Wild Relative Species

Crosses 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 crosses 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). Experience with conventionally improved plants reveals that most cases of such gene escape have been of little consequence, but on occasion they have led to the evolution of problematic plants or have resulted in an increased extinction risk for wild taxa (Ellstrand 2003; Ellstrand 2012; Ellstrand 2018). Consequently, given that GE crops differ little from their conventional counterparts other than the introduced trait, GE crops would pose no less risk of crosses with wild relatives, as well as introgression of the trait into wild populations (Ellstrand 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. Among the GE crops that are grown commercially, corn and soybean have no wild relatives in the United States. Cotton has wild relatives and feral populations in Hawaii, Florida, Puerto Rico, and the U.S. Virgin Islands (Mendelsohn et al. 2003). Consequently, the EPA restricts the sale or distribution of Bt cotton in these areas (US-EPA 2020a). Outside the United States, GE cotton-wild type hybrids (*Gossypium hirsutum*) have been reported in Mexico (Wegier et al. 2011).

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. In some cases, feral[54] populations of crop plants can establish along roadsides and in natural and semi-natural habitats, and gene flow can occur between the GE crop and feral populations. Feral populations could harbor GE traits and transmit the trait back to non-GE crop plants. 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. Though GE rice has been deregulated, it is not yet grown commercially in the U.S. Similarly, cultivated squash (*Cucurbita pepo*) is another species that will hybridize with its wild relative, *C. pepo*. The issue of bolting of and possible gene flow from GE sugarbeets to wild compatible species is primarily a concern in California where two weedy beet species (*Beta macrocarpa and Beta maritima*) can be found. While of some concern, sugarbeet (*Beta vulgaris*) rarely bolts and is not freely compatible with

[54] Cultivated alfalfa occurring outside of cultivated lands.

B. macrocarpa, while *B. maritima* is not thought to grow in proximity to the sugarbeet production area. Free living populations of transgenic sugarbeet have not been reported and we are unaware of any cases of gene flow from transgenic sugarbeet to its relatives at this writing (Ellstrand 2018).

Other important crops with weedy relatives in the United States include wheat, sorghum, and sunflower. GE varieties of these crops have not been commercialized yet, but all are field tested.

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 (e.g., physical and spatial barriers, weather).

To date, there have been no documented cases of introgression of GE traits into wild populations (Ellstrand 2012), although there have been instances of GE plants occurring outside areas of cultivation, and in some cases, crosses with wild relatives has occurred. (Ellstrand 2012; Ellstrand 2014). 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 et al. 2011; Ellstrand 2018), with some GE canola populations showing evidence of crosses with other GE canola plants. GE HR canola (*Brassica napus* L.) often volunteers outside cultivated fields where it can be a management problem (Knispel and McLachlan 2010). Multiple herbicide resistant traits have stacked in such volunteers (Knispel et al. 2008). Feral GE plants have been identified growing along railway lines and in port areas at four sites in Switzerland (Schulze et al. 2014) and along roadsides leading from Japanese ports that unload canola (Katsuta et al. 2015). While such populations of GE *Brassica napus* have been identified in the wild, evidence of adverse environmental impacts have not yet been associated with wild populations of GE *Brassica napus* (e.g., see (Warwick et al. 2009; Devos et al. 2012; Luijten et al. 2015)).

In 2003 field trials conducted in a control district in central Oregon, a strong wind dispersed GE glyphosate-resistant creeping bentgrass seed (GRCB; *Agrostis stolonifera* L.) that had recently been harvested into windrows. Despite intensive eradication efforts by Scotts, this species has persisted on the banks of irrigation ditches since that time. Furthermore, pollen from GRCB plants growing in the original field trials appears to have hybridized with wild *Agrostis* spp. relatives (Zapiola et al. 2008). Watrud et al. (2004) determined that pollen originating from this field trial was able to hybridize to sentinel plants situated over 10 miles away from the field trial.

The fact that gene flow between GE crops and wild species has occurred is not a concern per se. The salient environmental concern is whether the flow of a GE trait such as herbicide or 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 necessarily lead to the increased fitness of a hybrid. The GE trait in a wild relative or other crop plant may prove detrimental to the hybrid or have no effect (Ellstrand et al. 2007; Ellstrand 2014; Goldstein 2014). The ecological consequences of a GE trait 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 et al. 2007; Ellstrand 2014).

It is generally assumed traits that are neutral or 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 population 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 (Ellstrand 2018). This could be the case for a number of introduced traits. Whether a GE trait may confer a competitive advantage to a wild population through gene flow is assessed on a case-by-case basis through risk assessment. In general, 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) introgressed transgenes confer a selective disadvantage in small wild relative populations that exist in close proximity to the transgenic crop (Kwit 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.

To date, data providing instances where GE plant-wild relative hybrids had an increase in fitness is limited (Reichman et al. 2006; Warwick et al. 2009; Zapiola and Mallory-Smith 2012; Ellstrand 2018). 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 review on this topic concluded that new populations of invasive GE plants that originate from transgene introgression have not been observed (Kwit 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 et al. 2009; Kwit et al. 2011; Mallory-Smith and Sanchez Olguin 2011; Schafer et al. 2011; Van Deynze 2011; Ellstrand 2012; Yang et al. 2012; Ellstrand 2014; Ryffel 2014). These observations may in part be due to the fact that the vast majority of field releases have been in highly domesticated crop plants (corn, soybean, cotton) that for the most part lack weedy relatives in the United States.

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.

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 (or the potential economic harm that can derive from the unintended presence of a GE trait or its gene product in a non-GE crop or crop commodity – discussed in Section 3.9). Generally, field testing presents a very low risk of environmental harm as APHIS takes precautions to limit the likelihood of gene flow outside the field trial via notification and permitting requirements.[55] Monitoring and/or mitigation measures are routinely employed in the field testing of GE organisms to minimize risk by limiting exposure.

In summary, ecosystem level impacts, to date, have not been identified as a result of gene flow from regulated GE plants, or nonregulated 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.

3.4.1.1.3 Gene Flow to Non-GE Crops

Gene flow from regulated and nonregulated GE plants to non-GE cropping systems could potentially occur as a result of cross-pollination and/or 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 (Ellstrand 2018). This is particularly important for the identity-preserved and organic markets, which are expected 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, or processing. Therefore, 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 is it unique to GE crops. Accordingly, coexistence and gene flow

[55] Such as required by APHIS-BRS notification and permitting procedures, and APHIS-BRS compliance and inspection activities.

among conventional, organic, and GE cropping systems are addressed in further detail in the section on socioeconomics.

3.4.1.2 Volunteer and Feral 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 be characterized as native or non-native, invasive or non-invasive, 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 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 it are not feasible.

Control of agricultural weeds is a key concern and weed management practices may be based on non-selective weed control afforded by GE HR crops. GE crop plants can also be considered a "weed" if they occur where they are not wanted.

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, serve as weeds in a subsequent crop because they compete with the planted crop for light and nutrients and may impede mechanical harvesting if not removed by suitable measures. Volunteer GE plants 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.[56] For example, GE canola (*Brassica napus*) is a common volunteer plant and an increasing management problem in cultivated fields in Canada (Canola Council 2018). Volunteer GE corn, as well, can be problematic in corn-to-corn, and corn-to-soybean rotational cropping systems (Marquardt et al. 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 conventional non-HR volunteer plants because the HR resistance traits in the GE volunteers diminish herbicide options available for managing the volunteers.

Volunteer plants that persist in the environment, known as feral populations, could spread to wild unmanaged areas. If they were to dominate these areas, such weeds could disrupt ecosystem integrity. The relative weediness of a crop volunteer depends a great deal on the weedy characteristics of that particular crop plant species. 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. In general, these domestication traits make it less likely that a crop can survive without human intervention and therefore be less likely to spread and or become invasive (Warwick and Stewart 2005). However, crops vary in their degree of domestication, or the proportion of domestication traits relative to wild traits. As examples, the

[56]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.

current crop cultivars of corn and bread wheat did not naturally occur prior to human intervention. Additionally, 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).

While highly domesticated crop species, such as corn and soybean are unable to persist outside managed land and are not invasive weeds, this is not always the case. For 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, has been a serious agricultural weed problem in the Western United States (Burger et al. 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 et al. 2010). Subsequently, weedy feral rye (non-GE) spread elsewhere in the Western United States and the Canadian province of British Columbia (Ellstrand 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 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 et al. 2006; Ellstrand et al. 2010).

While all plants that have been domesticated 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 et al. 2010). In general, there are few verified examples of crops where volunteer plants have directly evolved into competitive weeds. 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 3-17) (Ellstrand 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 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 3-17. 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
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 et al. 2010)

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 crosses, 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 crossing 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 become more difficult to control by herbicide options (Warwick and Stewart 2005). Consequently, management plans may need to employ diverse herbicides, carefully consider the herbicide resistance traits used in the rotation crop, and reflect more dependency on crop and herbicide rotations (Warwick and Stewart 2005).

GE traits that increase the fitness of crops, particularly in less domesticated varieties, have the potential to become problematic weeds. Consequently, these types of crop-trait combinations 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). 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).

3.4.2 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.

3.4.2.1 Tillage

Tillage is primarily used to control weeds and soil-borne pests and disease. Also, certain tillage practices may help to dry and warm the soil prior to planting. The tillage systems employed in the United States are conventional tillage, reduced tillage, and conservation tillage (defined to include no-till). These practices are characterized, in part, by the amount of plant residue that is left remaining on the field after harvest and the amount of soil disturbance. The development of and refinement of various tillage-seeding systems is an active area of research. What tillage practices are used and to what extent has substantial effects on soil quality, erosion, and the surrounding environment; tillage operations can also be costly and time-consuming for growers to implement (Brown et al. 2008; Wallander 2015; Harper 2017). Therefore, decisions concerning the amount and type of tillage to deploy are key considerations for growers and for policymakers who oversee agricultural and environmental programs. These decisions involve the consideration of a wide range of inter-related factors, such as desired crop yield, fuel and other input prices, weather and climate patterns, current and possible future commodity prices, air and water quality issues, the extent of weed and crop pests, and the erosional potential of a particular production area.

Conventional tillage involves intensive plowing leaving less than 15% crop residue in the field; reduced tillage leaves 15 to 30% crop residue; and conservation tillage involves leaving at least 30% crop residue (USDA-ERS 2000). No-till systems leave the crop residue on the production area, unless those residues are removed for other reasons such as biomass production (USDA-ERS 2000). Conventional tillage is associated with greater amounts of soil erosion and run-off than conservation tillage. Consequently, conventional tillage results in reduced soil quality and diminished water resources (USDA-ERS 2000). Reduced tillage lessens soil disturbance and erosional potential, and can in some cases improve soil quality. Conservation tillage systems, including no-till, are the least intensive and aims to improve or maintain soil quality and conserve topsoil (Fernandez-Cornejo et al. 2012; Roth 2015). Conservation tillage provides a variety of agronomic and economic benefits, such as reduction in fuel use due to fewer tillage passes over the field, preservation of soil organic matter, and reductions in soil erosion and water pollution (Fernandez-Cornejo et al. 2012; Roth 2015). Effective herbicide control is an important factor for farmers to employ when using conservation tillage. GE HR cropping systems improve weed management using herbicides and not surprisingly, a higher percentage of growers who have adopted GE HR crops use conservation tillage compared to non-adopters. In 2009, 44% of cropland devoted to major crops (corn, soybean, wheat, cotton, and rice) was farmed using conservation tillage (Horowitz et al. 2010). No-till farming, in particular, has recently been employed on around 35% of U.S. cropland (Horowitz et al. 2010).

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). Where herbicide control of weeds has become less effective, conservation tillage has declined (Price et al. 2011).

3.4.2.2 Pest and Weed Management

Management of plant pests, pathogens, and weeds is vital to sustaining maximum yield and product quality as their presence in a cropping system can result in yield losses on the order of 20% –75%, and impair crop products, which can reduce marketability. For example, Oerke (2006) estimated that, without pest control, production would decline worldwide by 54% for corn, 46% for soybeans, 75% for cotton, 58% for potatoes, and 30% for wheat (Oerke 2006). For most crops, weeds introduce the highest potential yield loss (around 30 – 40%), with losses to animals, plant pests, and pathogens being somewhat less. For example, for soybean in 2012, weeds accounted for 39% of total yield loss, followed by animals (29%), insects (28%), and plant diseases (4%) (USDA-NASS 2014a). Overall, average yield loss with no weed control in soybean is 49.5%, and corn 52% (Dille et al. 2015b, a). Such yield losses can translate into significant economic impacts. Based on WSSA analyses using data from 2007 to 2013, the potential loss in value for soybean and corn is $16 billion and $27 billion on an annual basis, respectively (Dille et al. 2015b, a).

Approximately 600 species of insects, 200 species of major weeds, and numerous species of bacteria, fungi, and nematodes are considered serious pests in agriculture. If such pests were not managed, crop yields per acre and crop product quality would decline, likely increasing production costs and food and fiber prices. Producers with greater pest problems would become less competitive (Fernandez-Cornejo et al. 2014d). The benefits of pesticides translate into lower production costs (reduced labor, fuel, and machinery used for pest control), higher crop yields and/or product quality, and increased net returns for farmers. Consequently, pesticides are a fundamental component of modern crop production for all farmers; those producing crops using organic, conventional, and GE cropping systems. While certain pesticides are used in organic cropping systems, this section focuses on pesticides used in GE and conventional cropping systems.

While the benefits of pesticides are well recognized, such benefits are accompanied by potential risks to human health and the environment. Human health risks can result from direct exposure of farm workers to pesticides or from consumer exposure to pesticide residues on foods.

Environmental risks can result from the off-site movement of pesticides and impacts on non-target species.

Pesticide use during field trials is regulated by the EPA. Any pesticide used must be registered with the EPA and applied pursuant to the EPA label requirements. The EPA also regulates the field testing of GE plants comprised of PIPs when plantings are larger than 10 acres, as well as testing of 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.[57] The EPA issues Experimental Use Permits (EUPs) for field testing of PIPs for areas larger than 10 acres (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 EUP under FIFRA. The regulations at 40 CFR 172.4 contain the requirements for applications for EUPs. The 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.

Pesticide use in relation to GE crops is of particular interest as there has been some debate as to whether GE crop plants have resulted in increased or decreased use of pesticides, and consequently, increased or decreased environmental and human health risks. Because some pesticides can be harmful to wildlife and humans, and insecticides and herbicides naturally select for resistant insect and weed populations, respectively, understanding the effect of a GE crop on pesticide usage has been and remains of interest to environmental and human health.

It is important to clarify, however, that in regard to potential harms to humans and wildlife, pesticide use data commonly referred to in the lay and peer reviewed literature citing the weight or volume of pesticide used conveys little meaningful information without understanding the toxicity of the pesticide being discussed, which varies widely among the pesticides used. Pesticide toxicity is dependent on the dose, duration, and frequency of exposure; dose being relative to the toxicity of (1) the active ingredient in a pesticide, (2) adjuvants (e.g., surfactants, defoaming agents, drift control agents), (3) combinations of both via synergistic interactions, and (4) environmental transport and fate. Pesticide toxicity is discussed in Section 3.4.2.2.4.

In general, evaluation of usage data on pounds or kilograms per acre can be misleading, as some pesticides, including herbicides, are effective at 1 pound/acre and others at 0.1 pounds/acre or less. An overall trend in decrease or increase in lbs per acre used or lbs per year used could simply reflect a change in the use of high-efficacy and low-efficacy pesticides, and not necessarily reflect an improvement from an environmental and human health perspective.

Bearing these factors in mind, insecticide and herbicide use relative to GE IR and HR crops are summarized below.

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[57] Current and previously registered plant-incorporated protectant registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

3.4.2.2.1 Overview

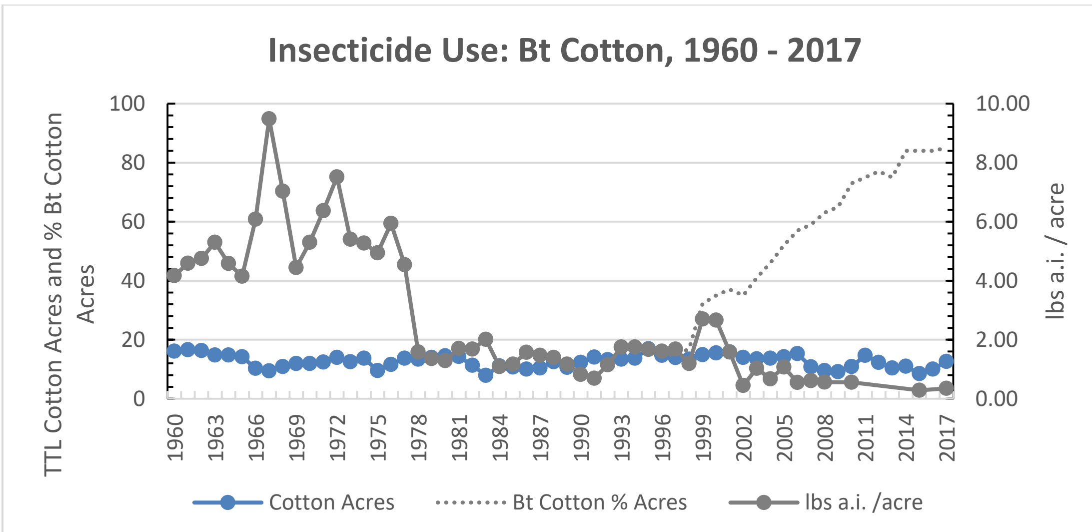
The types and quantities of pesticides applied by U.S. farmers have changed considerably over the last several decades (Fernandez-Cornejo et al. 2014d). This is in part a reflection of the wide-scale adoption of certain GE crop varieties over the last two decades. Proponents of GE crops suggest that overall pesticide use has decreased in these crops, while those critical of GE crops argue that they cause increased pesticide use. For example, a 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). On the other hand, Benbrook (2012) provided analyses suggesting that from 1996 – 2011, pesticide use increased by 183 million kgs (404 million pounds), or about 7% (Benbrook 2012). Other reviews of pesticide use in U.S. agriculture, and trends in increased or decreased pesticide use, have been conducted by the USDA and National Academy of Sciences, and that data is included here by reference (Fernandez-Cornejo et al. 2014d; Fernandez-Cornejo et al. 2014c; NAS 2016b; Kniss 2017).

Based on USDA-ERS data, overall pesticide use has declined in the United States since 1996, the first year GE crops were cultivated (Fernandez-Cornejo et al. 2014d). This is a trend that began occurring around 1980 (Fernandez-Cornejo et al. 2014d). Insecticide use by U.S. farmers has fallen while herbicide use has grown. Insecticide use was much higher in the 1960s and 1970s than in later years. It peaked at 158 million pounds in 1972, and has declined most years thereafter, ending at 29 million pounds in 2008. The introduction of HT crops in the mid-1990s augmented pest management options by permitting the use of more effective, "over-the-top" post emergent herbicides. Pounds of glyphosate per planted acre of soybeans, corn, and cotton rose in almost every year since 1996 while pounds of all other herbicides (per acre) fell (Fernandez-Cornejo et al. 2014d). Declines in overall pesticide consumption have also been accompanied by major changes in application techniques and stewardship efforts (e.g., integrated pest management, nutrient management, conservation tillage, precision agriculture) to maintain the sustainability of changing agricultural processes (McConnell et al. 2016). Pesticide use, however, varies widely among specific types of crops. More detailed analyses of the most recent data on pesticide use through 2017/2018 is presented below.

3.4.2.2.2 Insecticide Use with GE Crops

Based on USDA-NASS data, studies conducted by USDA-ERS (Fernandez-Cornejo et al. 2014b) and (Coupe and Capel 2015; Osteen and Fernandez-Cornejo 2016), and a report by the National Academy of Sciences (NAS) (NAS 2016b), insecticide use has declined with the adoption of Bt corn and Bt cotton (Fernandez-Cornejo et al. 2014d; Coupe and Capel 2015; Osteen and Fernandez-Cornejo 2016). For example, insecticide use for corn production, which peaked in the late 1970s and 1980s at 0.35 – 0.45 pounds active ingredient (a.i.) per planted acre, declined throughout the 1990s and 2000s to under 0.03 pounds a.i. per planted acre in 2017 (latest data) (Figure 3-16). Insecticide use for cotton, which peaked at 9.5 pounds a.i. per planted acre in 1967, has declined to less than 1 pound a.i. per planted acre (Figure 3-16). As of 2018, only 13% of U.S. corn acres, and 43% of cotton acres (2017) were treated with insecticides (USDA-NASS 2018c, 2019b). Insecticide use on corn and cotton are at near all-time lows of 0.02 - 0.03 lbs/acre, and 0.29 – 0.35 lbs a.i./acre, respectively (USDA-NASS 2019c).

Klümper and Qaim (2014) conducted a meta-analysis of 147 studies on pesticide use, yield, and farmer profits. They found that on average, globally, GE IR crops increased yield by 24.9%, reduced insecticide quantity by 41.7%, reduced insecticide cost by 43.4%, and increased farmer profits by 68.9%. Besides yield increases, which benefit farmers and land use requirements, as well as help support growing populations in developing countries, one of the main beneficial effects of GE IR crops in terms of environmental and human health impacts is the decline in insecticide use.



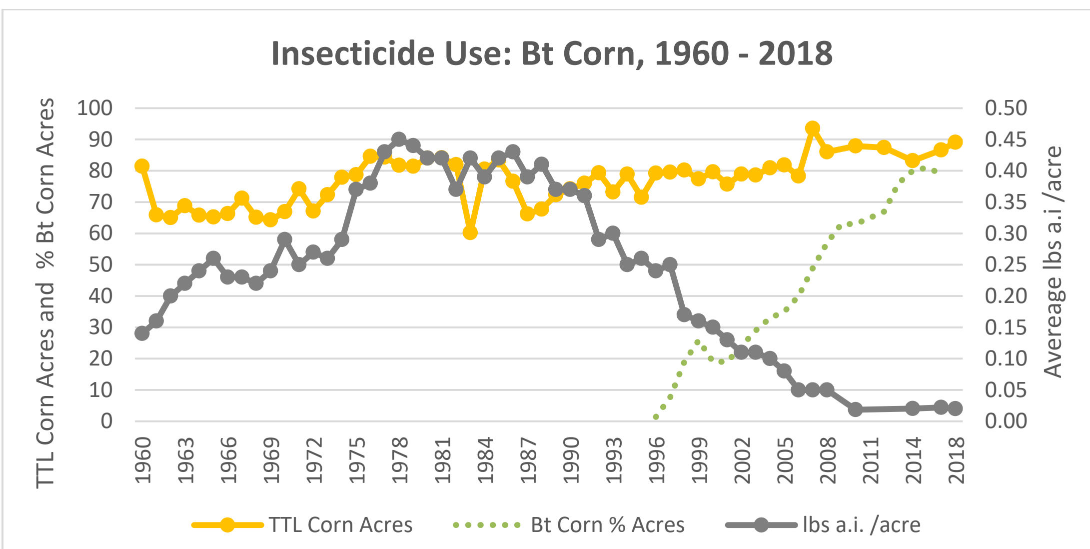


Figure 3-16. Insecticide Use in Bt Corn and Bt Cotton Production

Source: (Fernandez-Cornejo et al. 2014d; USDA-NASS 2019c)

In areas where cultivation of Bt corn and Bt cotton is high, the use of Bt crop varieties has also been associated with reduced insecticide use in adjacent cropping systems cultivating non-GE varieties, a result of the area-wide suppression of insect pest populations from use of Bt based cropping systems (NAS 2016b). For example, several studies have found that the use of Bt corn and Bt cotton are positively associated with the area-wide suppression of European corn borer and pink bollworm, respectively (e.g., see review by (Fernandez-Cornejo et al. 2014b)). Thus, cultivation of Bt crops can provide tangential benefits to adjacent farms by lessening the prevalence of certain insect pest populations and reducing the need for insecticide use in nearby cropping systems (NAS 2016b).

Due to the benefits provided by Bt based crops, there has been significant levels of adoption in the United States and around the globe (Head and Greenplate 2012). Bt corn and cotton have been found to provide not only effective pest control, but economic gains for farmers, along with environmental and worker health benefits via reductions in synthetic insecticide use (James 2014; Brookes and Barfoot 2015a).

While there are benefits with GE IR crops, they can create selection pressure for insect populations inherently resistant to transgenic Bt trait proteins (discussed further in 3.4.3–Pest and Weed Resistance). Consequently, the EPA requires implementation of rigorous insect resistant management (IRM) practices[58] to protect and properly steward Bt technologies for longevity in the marketplace (Head and Greenplate 2012).

Bt soybean has also been deregulated by APHIS, in 2011 and 2014 (USDA-APHIS 2020e). However these varieties were developed for deployment in South America. To date, there is no known commercial production of Bt soybean varieties in the United States.

3.4.2.2.3 Herbicide Use with GE Crops

Introduction

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. Several lists of agricultural weeds are provided on the USDA-NRCS website as well as the Weed Sciences Society of America website) (e.g., see (USDA-NRCS 2019; WSSA 2020)).

Weeds are common on all 400 million acres of U.S. cropland and almost 1 billion acres of range and pasture. Weeds can present significant challenges to efficient crop production, and can be difficult to control. As with plant pests and diseases, weeds can reduce crop yields and product quality, increase harvest costs, and reduce net returns. 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 result in economic losses ranging in the billions (Gianessi and Reigner 2007). Based on WSSA analyses using data from 2007 to 2013, potential loss in value for soybean and corn is $16 billion and $27 billion on an annual basis, respectively (Dille et al. 2015b, a). Management of weeds often requires significant resource inputs to produce maximum yields and net returns on crop production.

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. While tillage is an effective strategy to manage weeds, it can contribute to the erosion and compaction of soils, reducing the capacity of soils to absorb water,

[58] EPA - Introduction to Biotechnology Regulation for Pesticides: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides#resistance

and lead to runoff that can pollute surface waters with sediments and agronomic inputs. U.S. farmers began shifting to synthetic pesticides after their commercial introduction in the 1940's because they were inexpensive, effective, easy to apply, reduced labor costs, reduced the need for tillage, and increased crop yields (Fernandez-Cornejo et al. 2014d). Today, herbicides are a fundamental input for the control of weeds and will remain so for the foreseeable future. Herbicides are currently used on more than 90% of U.S. crop acreage (e.g., (USDA-NASS 2017, 2018c, b, 2019b)). Representative of the significance of weed management in crop production, agricultural expenditures on herbicides are currently around $5.1 billion annually (Atwood and Paisley-Jones 2017) .

Herbicide use in relation to GE crops has been and remains a topic of considerable debate, largely deriving from conflicting reports on herbicide use with GE crops. Depending on the source, agricultural biotechnology is either a fundamental component of sustainable agriculture that will help feed an ever expanding global population or symptomatic that the U.S. agricultural system is irreparably broken (Kniss 2016). Glyphosate has received particular scrutiny due to its association with the most dominant GE crop trait in corn and soybean, as well as its use in GE cotton.

In examining herbicide use it is important to clarify, as discussed in the introduction to this section, that simply looking at the total pounds per/year and pounds/acre of herbicide used, and trends in increase or decrease per year – evaluation of these metrics in isolation of other factors – is not very useful for assessment of human health or environmental risks. Such potential risks require evaluation of the pesticide active ingredient, its mode of action, potential toxicity of the a.i., as well as pesticide formulations as there may be synergistic effects that derive from such formulations. Nevertheless, as weight and use rates are some of the most commonly reported metrics, and due to comments received on the PEIS and other environmental assessments/impact statements, provided below are usage data on herbicides from the 1960s to 2017/2018.

The data provide here is largely based on USDA-NASS statistics for pesticide use. In terms of evaluating pesticide use; in 2018, for example, for corn, soybean, and cotton, there were a total of 75 unique herbicides in the USDA-NASS data sets, although some are different formulations of the same herbicide active ingredient (as shown in Table 3-18, Table 3-21, and Table 3-24 in the following sections). For example, there were 4 different glyphosate salts and 6 different formulations for 2,4-D, to include 3 salts. Considering the various formulations, there were a total 57 herbicide active ingredients used on these crops in 2018. Among the 75 unique herbicide a.i. formulations; 48 were used in corn, 37 in cotton, and 51 in soybean (see also (Kniss 2017)). It should be noted that while the USDA-NASS data sets are thorough, for some pesticides data is not available for each individual year, as some data was either not surveyed or sufficiently reported. However, most of the annual USDA-NASS data generally captures around 80-90% of acreage for a given crop during a given year. While the USDA-NASS survey estimates are subject to sampling variability, the charts and data discussed below provide a general approximation of pesticide use since 1960.

Overview

The quantity of herbicides applied to field, vegetable, and fruit crops increased sharply from the 1960s to the early 1980s, and has remained fairly consistent since the mid-1980s, with annual fluctuations (Figure 3-17). In 1952, only 5 – 10% of U.S. corn, wheat, and cotton acres were treated with herbicides. In 1964, the first year of USDA's national pesticide use survey, herbicides accounted for less than 25% of total pesticides used on major crops. From 1964 to 1982, annual herbicide use grew six fold, to 430 million pounds a.i., with herbicides being applied to around 90% of corn, cotton, and soybean acres (Fernandez-Cornejo et al. 2014d; Osteen and Fernandez-Cornejo 2016).

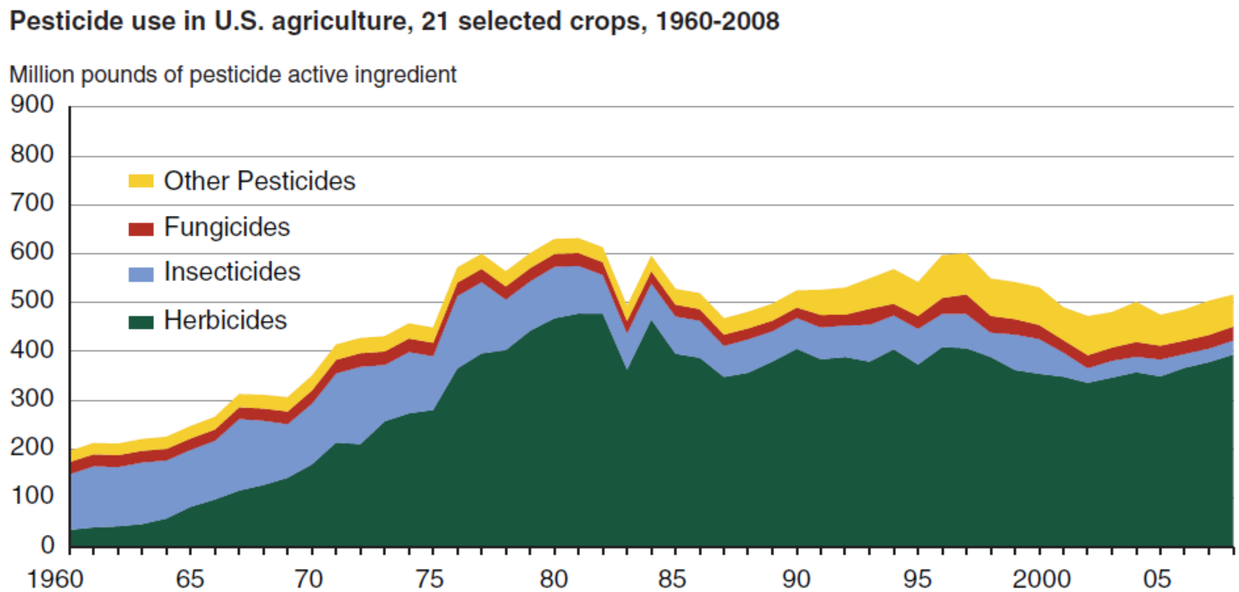


Figure 3-17. Pesticide Use in 21 crops: apples, barley, corn, cotton, grapefruit, grapes, lemons, lettuce, peaches, peanuts, pears, pecans, potatoes, oranges, rice, sorghum, soybeans, sugarcane, sweet corn, tomatoes, and wheat.

Source: (Fernandez-Cornejo et al. 2014d)

Major factors affecting overall herbicide use trends (as measured in lbs a.i./year and lbs a.i./acre) have been: (1) changes in crop acreage, which is influenced by economic and policy factors, (2) the replacement or discontinuance of older pesticides (MOAs) with newer ones (changes in per-acre application rates), contributing to changes in overall pesticide quantities, (3) the introduction and adoption of GE crops from 1996 onward, and (4) the emergence of weed populations resistant to various herbicide MOAs over the last several decades (discussed in Section 3.4.3 – Pest and Weed Resistance). For example, the increasing use of newer MOA herbicides (ALS, ACCase, and PPO inhibitors) during the 1980s and 1990s, along with declining crop acreage during the 1980s, contributed to declining herbicide use quantities from the mid-1980s to mid-2000s.

Four crops – corn, cotton, soybeans, and wheat – account for the bulk of herbicide use in the United States (95% – 97% of crops since 1971), and acreage planted to these crops is a significant factor accounting for changes in overall herbicide use patterns. In general, annual herbicide use in the United States fluctuates with the total acres planted for these four crops. Herbicide use patterns for corn, soybean, and cotton since 1960, the primary GE crops, are provided in Figure 3-18 and discussed further below.

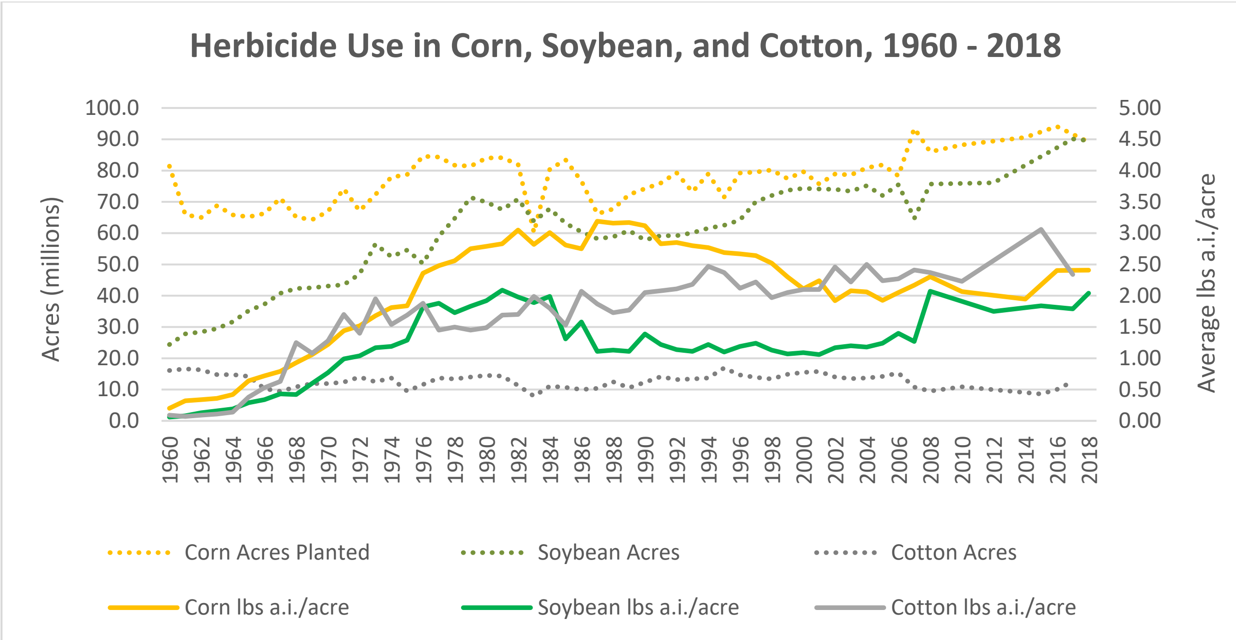


Figure 3-18. Herbicide Use in Corn, Soybean, and Cotton Production, Total Pounds Active Ingredient/Acre, and Acres, 1960 – 2018

Source: (USDA-NASS 2019c)

The widespread adoption of GE HR corn, cotton, and soybeans, which became commercially available in the mid-1990s, has had a major effect on herbicide use trends by encouraging the application of specific herbicides such as glyphosate. Between 1996 and 2018, the share of GE HR corn acreage rose from 3% to 90%, GE HR cotton acreage from 2% to 91%, and of GE HR soybean acreage from 7% to 94%; the majority of these being glyphosate-resistant. Increased use of glyphosate was an understandable result of U.S. farmers adopting glyphosate-resistant varieties of these crops. Fundamentally, adoption of GE glyphosate-resistant crops entailed increased application of glyphosate, which displaced use of many other widely-used older, and some newer, herbicides (Osteen and Fernandez-Cornejo 2016) (Figure 3-19).

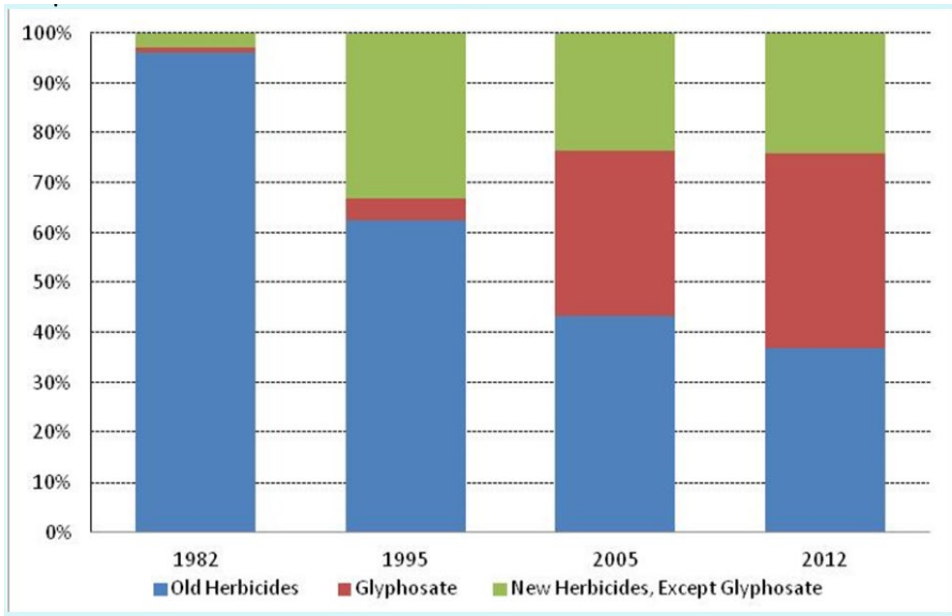


Figure 3-19. Glyphosate Use, 1982 – 2012

Glyphosate displaced both "old" MOA families used since the 1960s and 1970s (e.g., amino acid, microtubule, and photosynthesis inhibitors) and "new" MOA families introduced in the 1980's and 1990s (e.g., ALS, ACCase, and PPO inhibitors).

Source: (Osteen and Fernandez-Cornejo 2016)

Relative to adoption of GE HR corn, soybean, and cotton; overall herbicide use (in terms of lbs a.i./acre) on corn and cotton tended to increase during the 1996 – 2018 time frame, albeit slightly, while there has been a more marked increase in herbicide use with soybean (1996-2018) (Figure 3-20). Total annual per acre application rate for cotton herbicides has fluctuated around 2.0 (1998/1999) to a peak of 3.06 lbs a.i./acre (2015). Soybean evidences a distinct and steady increase from 1.10 lbs a.i./acre in 1995 to a peak of 2.04 lbs a.i./acre in 2018. Because glyphosate is applied at relatively higher per-acre rates (e.g., ~ 0.5 – 1.0 lb a.i./acre), relative to other previously-used herbicides, such as ALS, ACCase, and PPO inhibitors, increased glyphosate use accounts for most of the increase in pounds of herbicide applied in corn, soybean, and cotton crops during the 1997 to 2017/2018 time period. However, increased crop acreage and increases in herbicide resistant weed populations have also contributed.

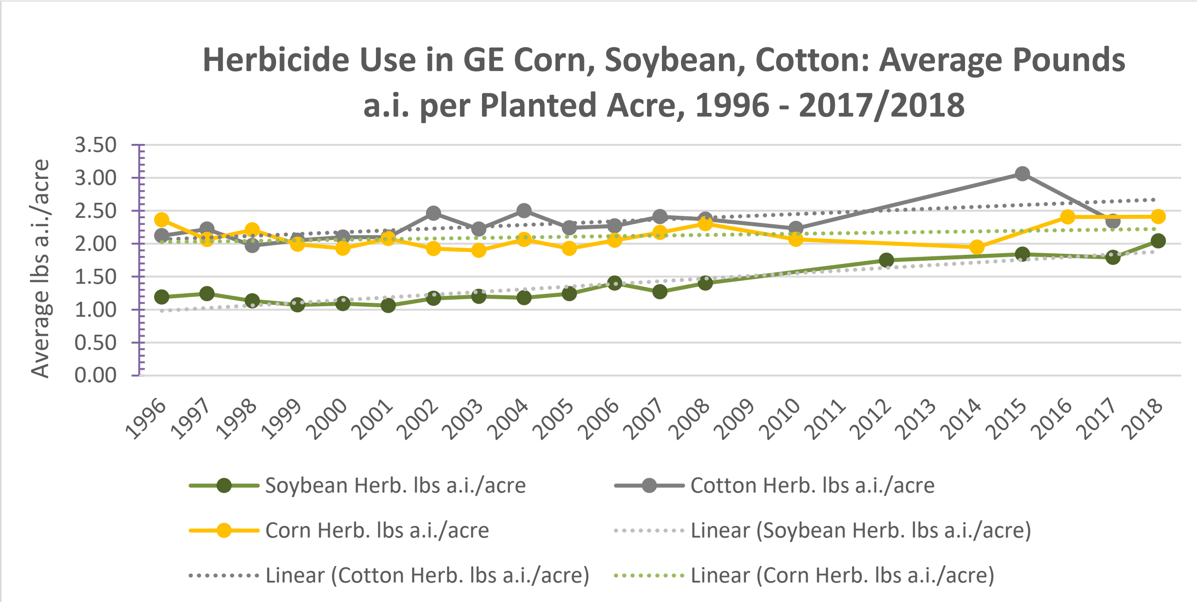


Figure 3-20. Herbicide Use in Corn, Soybean, and Cotton Production, 1995 – 2017/2018
Source: (USDA-NASS 2019c)

GE HR Corn

GE glufosinate and glyphosate resistant corn varieties were first deregulated in 1995 and 1997, respectively. The first 2,4-D and ACCase-inhibitor resistant corn was deregulated in 2014, and dicamba resistant corn in 2016 (Table 3-18).

Table 3-18. GE HR Corn: Deregulated Varieties

Petition	Applicant	Phenotype/Event	Effective
15-218-01p	Syngenta	IR and Glufosinate-Resistant/SYN-ØØØ98-3	2016
15-124-01p	Syngenta	Glufosinate and Glyphosate Tolerant/MZHG0JG	2015
15-113-01p	Monsanto	Dicamba and Glufosinate Tolerant/MON-87419-8	2016
13-290-01p	Monsanto	IR/Glyphosate-Tolerant/MON-87411-9	2015
11-342-01p	Genective	Glyphosate Tolerant/VCO-Ø1981-5	2013
11-244-01p	Pioneer	IR and Glufosinate Tolerant/DP-ØØ4114-3	2013
09-233-01p	Dow AgroSciences	2,4-D and ACCase-Inhibitor Tolerant/DAS-40278-9	2014
09-063-01p	Stine Seed Farm, Inc.	Glyphosate Tolerant/HCEM485	2013
07-152-01p	Pioneer	Glyphosate & Imidazolinone Tolerant/98140	2009
03-181-01p	Dow AgroSciences	IR and Phosphinothricin [glufosinate] Tolerant/6275	2004
00-136-01p	Dow AgroSciences	IR and Phosphinothricin Tolerant/1507	2001
00-011-01p	Monsanto	Glyphosate Tolerant/NK603	2000
98-349-01p	AgrEvo	Phosphinothricin Tolerant and Male Sterile/MS6	1999
97-342-01p	Pioneer Hi-Bred	Male Sterile and Phosphinothricin Tolerant/676, 678, 680	1998
97-265-01p	AgrEvo	Phosphinothricin* Tolerant and IR/CBH-351	1998
97-099-01p	Monsanto	Glyphosate Tolerant/GA21	1997
96-317-01p	Monsanto	Glyphosate Tolerant and IR/MON 802	1997
95-145-01p	DeKalb	Glufosinate Tolerant/B16	1995
94-357-01p	AgrEvo	Glufosinate Tolerant/T14, T25	1995

* Phosphinothricin = glufosinate

GE HR corn was first planted in 1997; as of 2000, 19.89 million acres were planted to GE HR corn (Fernandez-Cornejo et al. 2014b). GE HR corn adoption increased from 3% percent of planted acres in 1997 to around 90% in 2018 (Figure 3-21); the vast majority of this HR corn was glyphosate resistant. Overall, during the 1997–2018 time frame, herbicide use on corn has tended to increase, albeit modestly. From 1997 to 2014, total herbicide use in lbs a.i./acre actually tended to decline, fluctuating around 2.06 lbs a.i./acre (1.9 to 2.3 lbs a.i./acre). It increased to 2.40 lbs a.i./acre in 2016, and 2.41 lbs a.i./acre in 2018. Due to the increase in lbs a.i./acre during 2016-2018, the overall trend line increases as assessed from 1996.

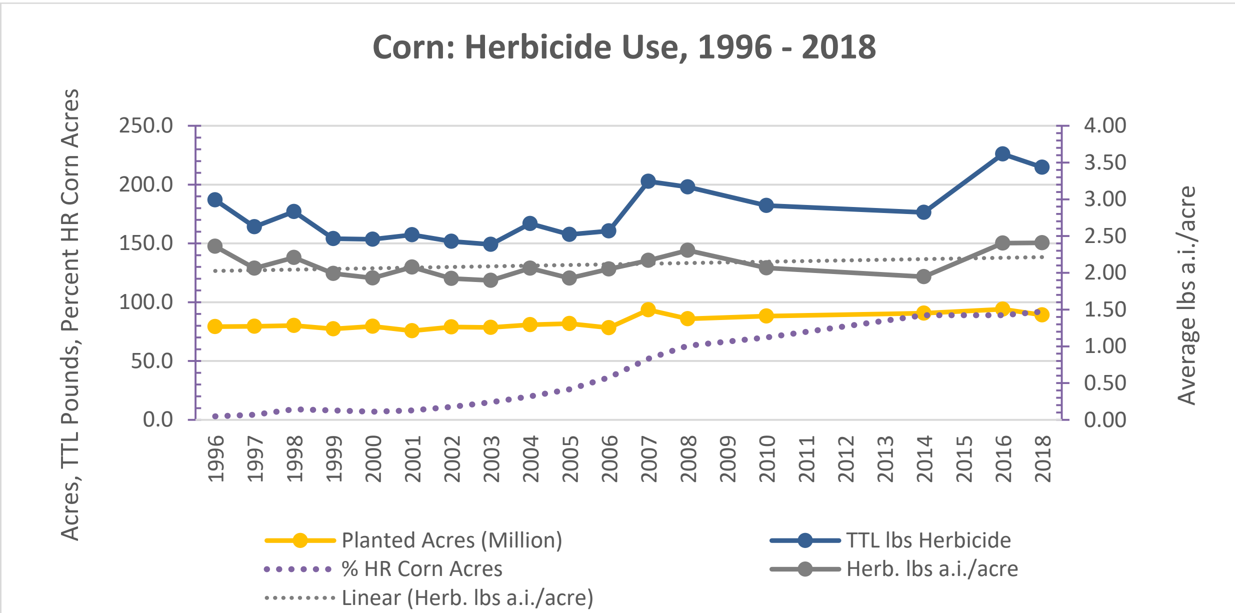


Figure 3-21. Corn: Herbicide Use, 1990 – 2018
Source: (USDA-NASS 2019c)

Commensurate with the adoption of GE glyphosate resistant corn, glyphosate (a.i.) use in corn increased from an average of around 0.03 lbs a.i./acre in 1995, to a peak (average) of 0.88 lbs a.i./acre in 2016 (Figure 3-22).

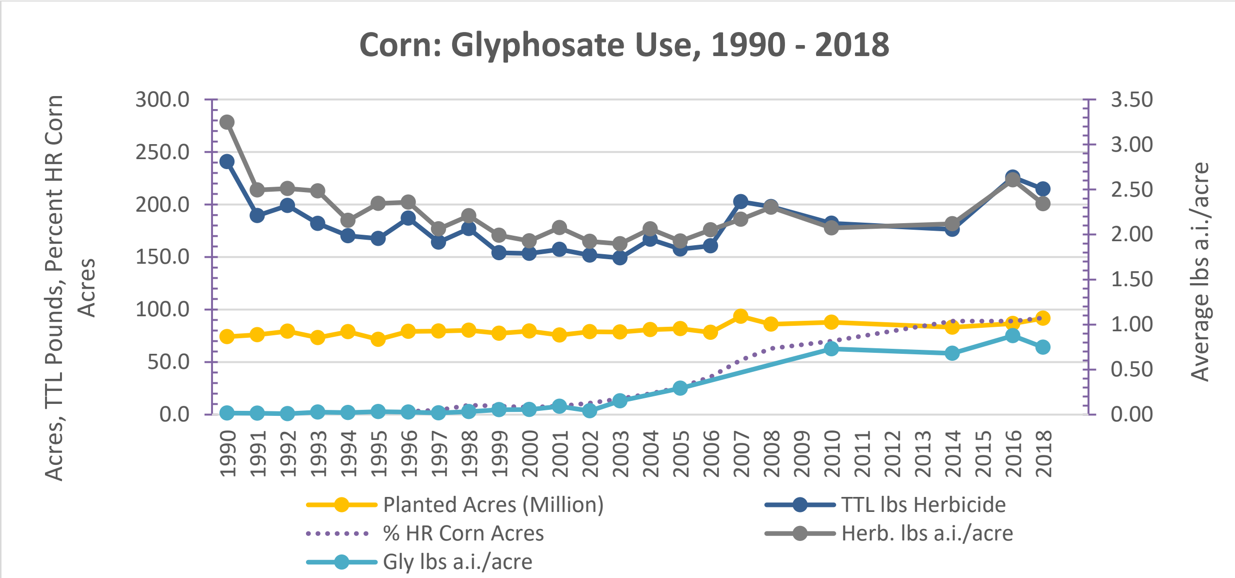


Figure 3-22. Corn: Glyphosate 1990 – 2018
Source: (USDA-NASS 2019c)

Where in 1968 glyphosate use was negligible, by 2008, glyphosate was applied on 50% of major U.S. crops (Figure 3-23) (Fernandez-Cornejo et al. 2014c). As of 2018, glyphosate was applied to around 76% of corn crops, and comprised 31% of total herbicide use in corn.

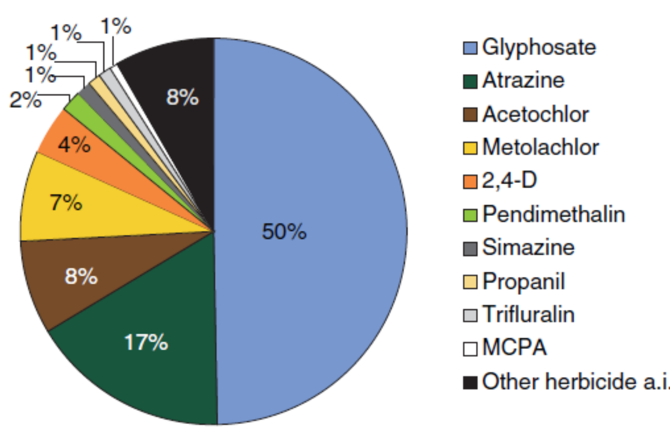


Figure 3-23. Herbicide Use – 21 Major Crops: Use by active ingredient, 21 selected crops in 2008, percent total pounds of a.i. applied
Source: (Fernandez-Cornejo et al. 2014d)

While glyphosate use increased, use of some of the other herbicides applied to corn has declined (Figure 3-24). For example, pendimethalin use declined from 2.6 million lbs a.i./yr (average of 0.022 lbs a.i./acre) to 342,000 lbs a.i./yr (average of 0.004 lbs a.i./acre) from 1997 to 2018. Due to their acute toxicity, alachlor and cyanazine (not shown) were phased out of use in the corn market. Atrazine use in corn production has remained fairly consistent, fluctuating around 45 to 60 million lbs a.i. annually.

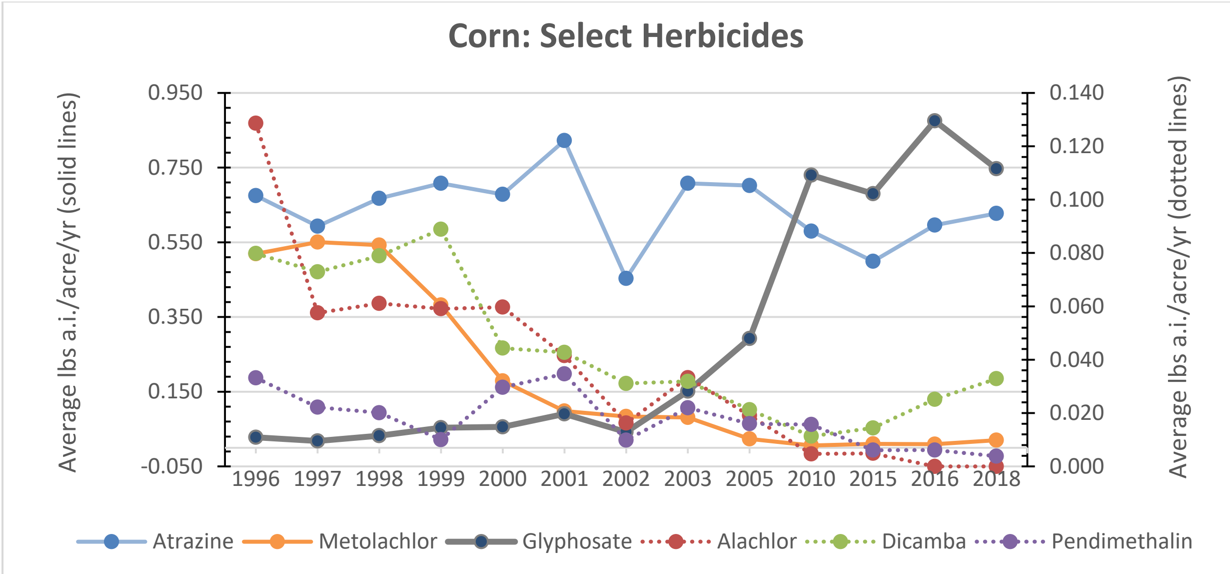


Figure 3-24. Corn: Herbicide Use, 1996 – 2018, Pounds a.i./acre per Year
Source: (USDA-NASS 2019c)

GE Glufosinate, Dicamba, and 2,4-D Resistant Corn

Apart from glyphosate, GE glufosinate, dicamba, and 2,4-D resistant corn varieties have been developed. Glufosinate resistant corn varieties were first deregulated in the mid- and late-1990s (see previous Table 3-1). More recently, the glufosinate and glyphosate resistant corn line, MZHG0JG was deregulated in 2015. 2,4-D and ACCase-inhibitor resistant DAS-40278-9 corn was deregulated in 2014. DAS-40278-9 corn (Enlist™ corn), in addition to 2,4-D, is resistant to "FOP" herbicides, such as quizalofop. Pioneer's corn line, event 98140, is resistant to imidazolinone herbicides including imazaquin, imazamethabenz-methyl, imazapyr, imazapic, imazethapyr, and imazamox in addition to glyphosate. Enlist™ corn became commercially available in the United States for the 2018 growing season (Dow AgroSciences 2018). Dicamba and glufosinate resistant MON-87419-8 corn was deregulated in 2016.

As glufosinate resistant corn varieties were first deregulated during the years 1995 through 2004, there was a minor increase in glufosinate use during this time. Glufosinate use in corn declined from 2004 to 2014, with an average increase of 0.002 lbs a.i./acre from 2014 to 2018 (Figure 3-25). Overall, use of glufosinate on corn, even with GE glufosinate resistant corn varieties available, has been relatively limited; presumably due to lesser efficacy and greater cost as compared with glyphosate.

There has seen a steady increase in use of 2,4-D in corn production since 2002, although this would not be associated with GE corn; the first 2,4-D resistant GE corn variety was deregulated in 2014, and only became commercially available in 2018. Since 2002, as glyphosate use increased in GE corn, use of dicamba and glufosinate declined up until around 2014; use of both has increased since 2014. Because dicamba resistant corn was only recently deregulated (2016), and dicamba resistant corn seeds were not yet commercially available in 2018, increased dicamba use observed from 2015-2018 occurred from application to non-GE corn.

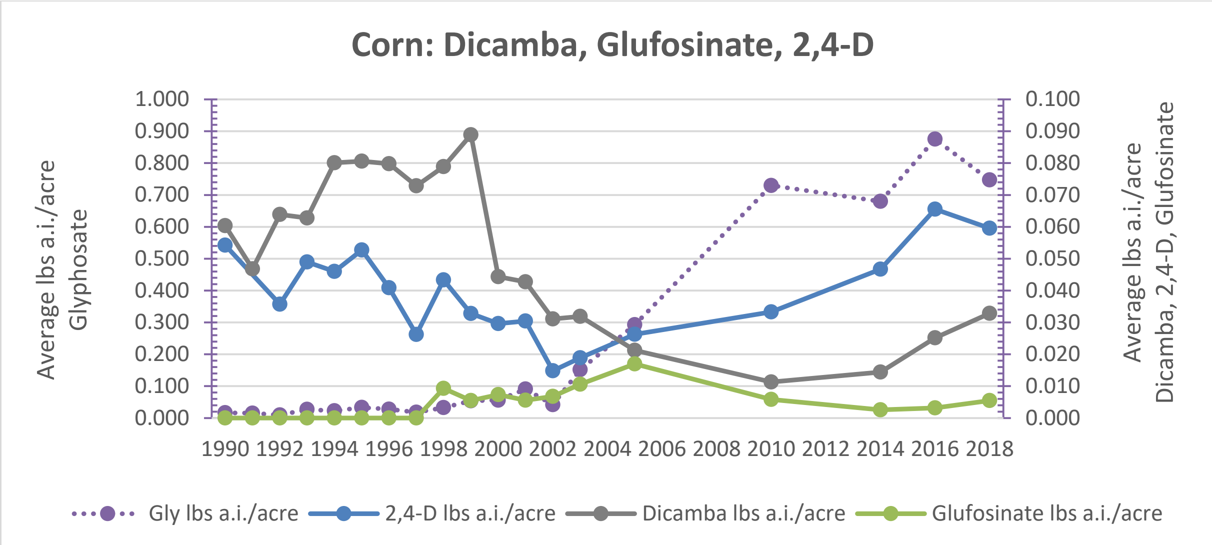


Figure 3-25. Corn: Glufosinate, 1990 - 2018
Source: (USDA-NASS 2019c)

Summary of Herbicide Use in Corn Production

As of the end of 2018, GE HR corn comprised about 80% of U.S. corn crops. Glyphosate was applied to 76% of corn crops, comprising 31% of total herbicide use. 2,4-D, dicamba, and glufosinate use with corn has been comparatively limited (Table 3-18, Table 3-19). While, during 2018, glyphosate was used on 76% of corn cropland, dicamba was used on 17% of corn cropland (1.4% of total herbicide use), 2,4-D was used on 12% of corn cropland (2.47% of total herbicide use), and glufosinate-ammonium on only around 1% of corn cropland (0.23% of total herbicide use).

Table 3-19. Herbicide Use in U.S. Corn Production – 2018

Herbicide a.i.	lbs a.i./Yr	Application Rate: lbs a.i./acre/Yr (Average)	Treated Acres, % of Area Planted	Portion of Total Herbicide Use
ATRAZINE	55,899,000	1.037	65	26.03%
ACETOCHLOR	38,757,000	1.433	33	18.05%
S-METOLACHLOR	28,259,000	1.198	29	13.16%
GLYPHOSATE ISO. SALT	27,691,000	0.993	34	12.90%
GLYPHOSATE POT. SALT	25,306,000	1.187	26	11.79%
GLYPHOSATE	10,081,000	1.018	12	4.69%
MESOTRIONE	4,177,000	0.121	42	1.95%
GLYPHOSATE DIM. SALT	3,508,000	1.158	4	1.63%
DIMETHENAMID-P	3,410,000	0.676	6	1.59%
2,4-D, 2-EHE	3,024,000	0.526	7	1.41%
2,4-D, DIMETH. SALT	2,284,000	0.546	5	1.06%
METOLACHLOR	1,817,000	1.392	2	0.85%
DICAMBA, DIGLY. SALT	1,348,000	0.312	5	0.63%
CLOPYRALID	859,000	0.082	13	0.40%
DICAMBA, DIMET. SALT	742,000	0.287	3	0.35%
TRIFLURALIN	678,000	1.655	(Z)	0.32%
DICAMBA, SODIUM SALT	660,000	0.103	8	0.31%
PARAQUAT	642,000	0.682	1	0.30%

Table 3-19. Herbicide Use in U.S. Corn Production – 2018				
Herbicide a.i.	**lbs a.i./Yr**	**Application Rate: lbs a.i./acre/Yr (Average)**	**Treated Acres, % of Area Planted**	**Portion of Total Herbicide Use**
SIMAZINE	572,000	1.107	1	0.27%
GLUFOSINATE-AMMONIUM	488,000	0.411	1	0.23%
TEMBOTRIONE	472,000	0.084	7	0.22%
ISOXAFLUTOLE	426,000	0.064	8	0.20%
PENDIMETHALIN	342,000	0.896	(Z)	0.16%
CLOPYRALID MONO SALT	301,000	0.082	4	0.14%
FLUMETSULAM	267,000	0.031	10	0.12%
DIFLUFENZOPYR-SODIUM	230,000	0.04	7	0.11%
BICYCLOPYRONE	226,000	0.031	9	0.11%
SAFLUFENACIL	220,000	0.055	5	0.10%
METRIBUZIN	159,000	0.212	1	0.07%
THIENCARBAZONE-METHY	123,000	0.022	7	0.06%
PYROXASULFONE	113,000	0.12	1	0.05%
DICAMBA, POT. SALT	106,000	0.202	1	0.05%
TOPRAMEZONE	91,000	0.018	6	0.04%
FOMESAFEN SODIUM	88,000	0.218	(Z)	0.04%
DICAMBA	73,000	0.181	(Z)	0.03%
RIMSULFURON	52,000	0.016	4	0.02%
FLUROXYPYR 1-MHE	41,000	0.083	1	0.02%
SULFENTRAZONE	35,000	0.153	(Z)	0.02%
FLUMIOXAZIN	33,000	0.165	(Z)	0.02%
BROMOXYNIL OCTANOATE	32,000	0.22	(Z)	0.01%
CLETHODIM	19,000	0.078	(Z)	0.01%
NICOSULFURON	19,000	0.051	(Z)	0.01%
THIFENSULFURON	19,000	0.014	2	0.01%
IMAZETHAPYR	9,000	0.02	1	0.00%
HALOSULFURON	7,000	0.032	(Z)	0.00%
PRIMISULFURON	4,000	0.021	(Z)	0.00%
FLUTHIACET-METHYL	3,000	0.008	(Z)	0.00%
DIQUAT DIBROMIDE	2,000	0.022	(Z)	0.00%
Total	**214,721,000**			

*Z = no data. Herbicides in bold type are used with GE HR corn varieties.

Source: (USDA-NASS 2019c)

GE HR Soybeans

Herbicide use on GE soybean crops has increased since 2006 (Figure 3-26). Herbicide a.i. per planted soybean acre has ranged from around 1 pound a.i./acre during the 1990s to 1.70 to 2.06 pounds a.i. since 2012 (see also previous Figure 3-18). In 1995, pendimethalin, trifluralin, and glyphosate were the most widely used herbicides in terms of average pounds a.i./acre applied. GE glyphosate resistant soybean seeds were commercially introduced in 1996. Glyphosate use averages around 0.56 pounds a.i. per acre in 2000, by 2014 HR seeds were planted on 94% of soybean acres, and average glyphosate use had risen to around 1.42 pounds a.i. per planted soybean acre. As of 2018, overall average glyphosate use on soybeans was 1.07 lbs a.i./acre/year (range from 0.49 for glyphosate ammonium salt to 1.53 for glyphosate potassium salt). The data in Figure 3-26 indicate that glyphosate use on soybean has been declining since 2012 and non-glyphosate herbicide use has been increasing. The overall average application for all herbicides on soybeans was 2.06 lbs a.i./acre (2018).

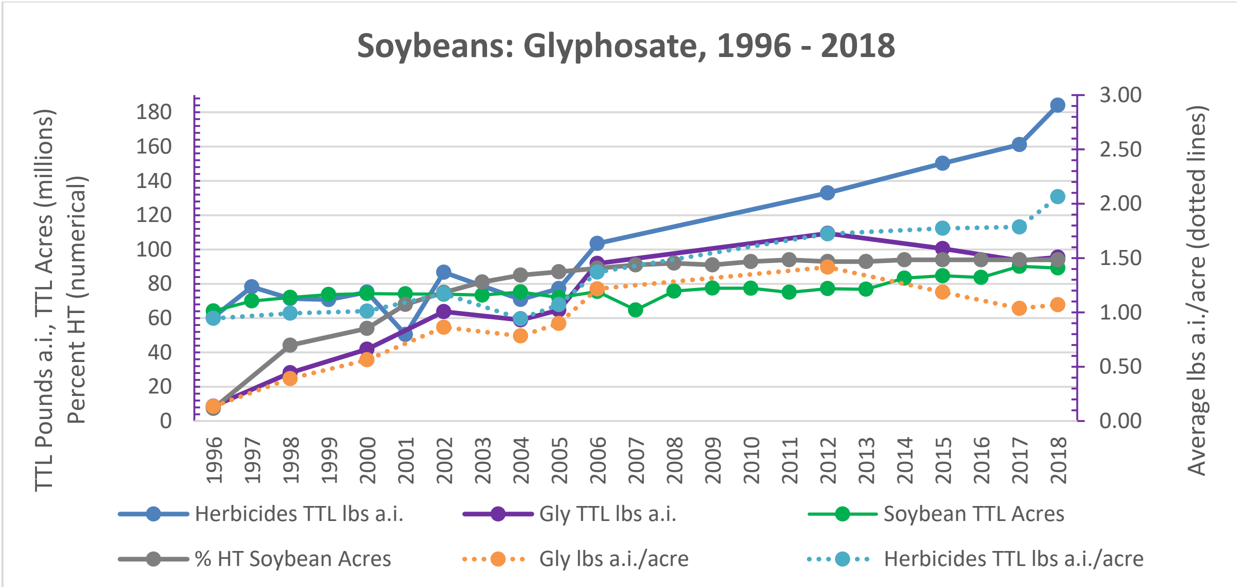


Figure 3-26. Soybeans: Glyphosate, 1996 – 2018
Source: (USDA-NASS 2019c)

As with corn, while glyphosate use increased, use of other herbicides applied to soybean declined (Figure 3-27). Chloramben was the first herbicide to dominate the soybean herbicide market (applied to 34% of soybean acres in 1968), providing effective control of grasses and broadleaf weeds. Metribuzin replaced chloramben use for broadleaf control, and was commonly combined in tank mixes with trifluralin to control grass weeds (Carpenter and Gianessi 1999). Trifluralin was applied to 22% of soybean acres in 1968, which declined to less than 1% in 2016. Parathion (not shown) was applied to around 3% of soybean acres in 1968, but its use declined due to its toxicity and classification as a Restricted Use Pesticide by the EPA. Linuron (not shown), while considered only slightly toxic (EPA toxicity class III), is applied to less than 1% of soybean acres, whereas in 1968 was the 3rd most frequently applied, at 8% of soybean acres (Fernandez-Cornejo et al. 2014d). Pendimethalin use declined from 13.8 million lbs a.i. to 1.02 million lbs a.i. from 1996 to 2018. Figure 3-27 provides a summary of the use of some of the primary herbicides that have been used in soybean production.

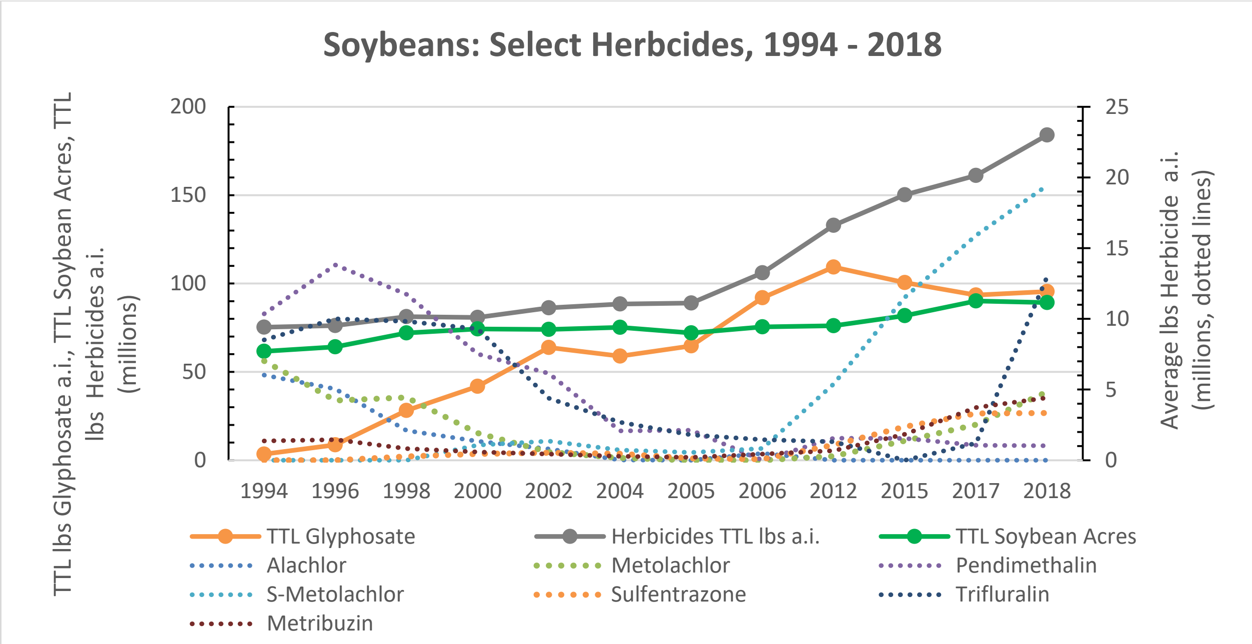


Figure 3-27. Soybeans: Herbicide Use, 1990 – 2018, Pounds a.i. per Year

Source: (USDA-NASS 2019c)

GE HR seed adoption was rapid and widespread among U.S. soybean farmers. By 2008, 92% of soybean acres were planted with GE HR seeds. GE HR soybean production sharply boosted glyphosate use on soybeans from a total of 9 million pounds a.i. applied in 1996 (0.14 pounds a.i. per planted acre) to a total of 109 million pounds a.i. applied in 2012 (peak: an average of 1.42 pounds a.i. per planted acre). Average pounds a.i. of all other herbicides applied to soybeans declined considerably from an average 1.05 pounds a.i. per planted acre in 1996 to 0.19 pounds a.i./acre in 2006 (Figure 3-28) (USDA-NASS 2018a). Since 2006, lbs a.i. of herbicides other than glyphosate have increased, while the use of glyphosate began to decline in 2012. While the reasons for this shift have not yet been the subject of qualitative or quantitative study, likely factors include the increase in glyphosate resistant weeds over the last two decades, availability and adoption of other GE HR soybean varieties, and best management practice recommendations to use other herbicide MOAs to control weeds and HR weeds.

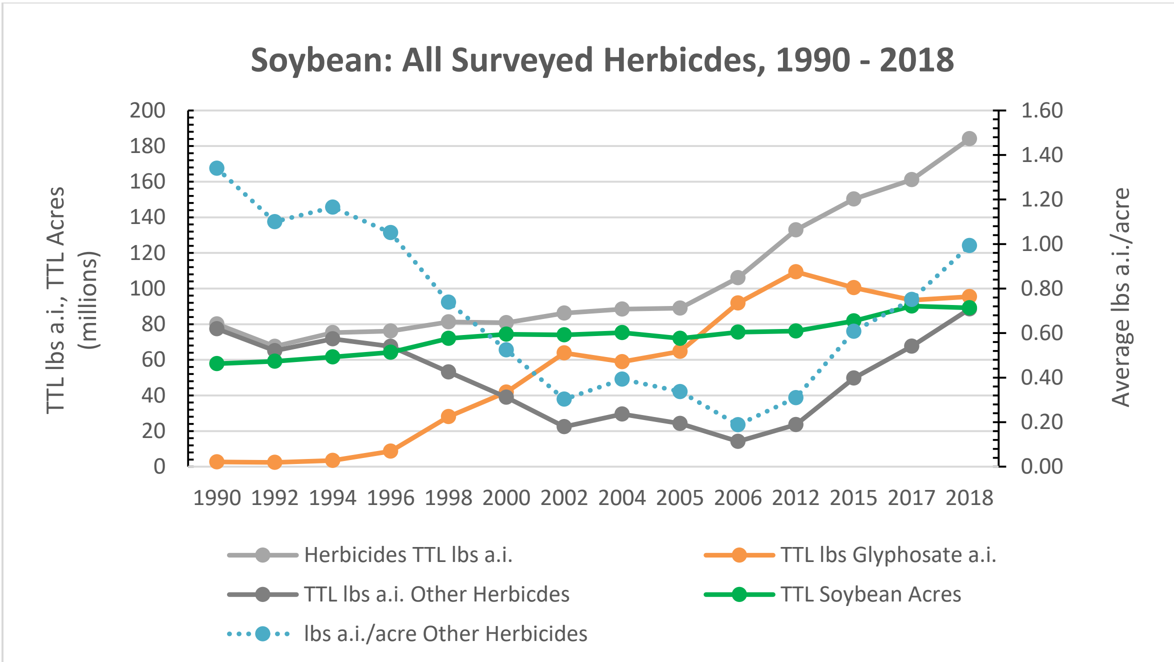


Figure 3-28. Soybeans: Herbicide Use, 1990–2018
Source: (USDA-NASS 2019c)

GE 2,4-D, Dicamba, and Glufosinate Resistant Soybean

GE 2,4-D resistant soybean was first deregulated in 2014, and dicamba resistant soybean was deregulated in 2015. Glufosinate resistant varieties of GE soybean were first deregulated in 1996 (Table 3-20).

Table 3-20. Deregulated GE HR Soybean Varieties

Petition Number	Applicant	Phenotype/Event	Effective
17-223-01p	Verdeca	High Yield, Glufosinate Resistant	2019
10-188-01p	Monsanto	Dicamba Resistant/MON 87708	2015
12-215-01p	Syngenta	HPPD and Glufosinate Resistant/SYHT0H2	2014
11-234-01p	Dow AgroSciences	2,4-D, Glufosinate, Glyphosate Resistant/DAS-444Ø6-6	2014
09-349-01p	Dow AgroSciences	2,4-D and Glufosinate Resistant/DAS-68416-4	2014
09-015-01p	BASF Plant Science	Imidazolinone Resistant/BPS-CV127-9	2014
09-328-01p	Bayer CropScience	Glyphosate and Isoxaflutole Resistant/FG7	2013
06-271-01p	Pioneer Hi-Bred Int.	Glyphosate & Acetolactate Synthase Resistant/DP-356Ø43-5	2008
06-178-01p	Monsanto	Glyphosate Resistant/MON 89788	2007
98-238-01p	AgrEvo	Phosphinothricin* Resistant/GU262	1998
98-014-01p	AgrEvo	Phosphinothricin Resistant/A5547-127	1998
96-068-01p	AgrEvo	Glufosinate Resistant/W62,W98,A2704-12,A2704-21,A5547-35	1996
93-258-01p	Monsanto	Glyphosate Resistant/40-3-2	1994

* Phosphinothricin = glufosinate

Enlist Duo, an herbicide product containing 2,4-D and glyphosate, was first registered in 2014 for use on GE corn and soybean crops in 6 states, and later in an additional 9 states. In 2017, the

EPA amended the registration to allow use on GE cotton in those 15 states and extend the use of Enlist Duo on GE corn, soybean and cotton to an additional 19 states. As evident, there was an increase in use of 2,4-D with soybean crops during 2004–2015; this increase occurred before the availability of GE 2,4-D resistant soybean crops (Figure 3-29). 2,4-D use on soybeans averaged 0.100 lb a.i./acre in 2015 (first year GE HR soybean crops were available), and 0.110 lb a.i./acre in 2017. Due to the lack of data and nascency of GE 2,4-D resistant soybean crops, evaluation of 2,4-D use in association with GE HR varieties is not possible. In 2018, 2,4-D was used on 17% of planted soybean acres, comprising around 4.64% of total herbicide use on soybean crops (See Table 3-21, Table 3-22).

The EPA first registered dicamba for applications post-emergent over-the-top (OTT) for soybean and cotton in 2016, as described in the Final Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean (available on regulations.gov, document ID: EPA-HQ-OPP-2016-0187-0959). Commensurate with registration of dicamba for use on GE HR soybean crops was an increase in use to an average of around 0.075 lbs a.i./acre in 2017, as compared to 0.002 lbs a.i./acre in 2015 (Figure 3-29). As of 2018, dicamba was used on 27% of planted soybean acres, comprising around 7.23% of total herbicide use on soybean crops (See Table 3-21).

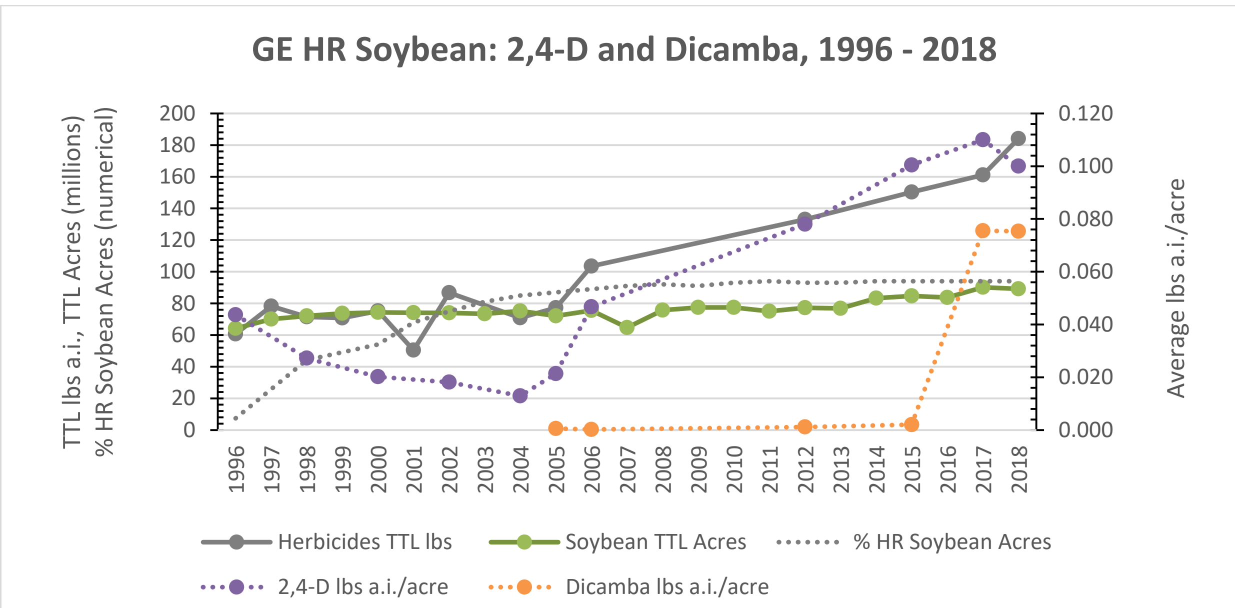


Figure 3-29. 2,4-D and Dicamba Use with GE HR Soybean, 1996—2018

Source: (USDA-NASS 2019c)

LibertyLink soybean (glufosinate resistant) was first introduced to market in 2009, although there is insufficient data on glufosinate use in soybean production to evaluate use trends; the earliest USDA-NASS data for glufosinate use in soybean is 2012, with subsequent data for 2015, 2017, and 2018 only. As of 2018, glufosinate comprised around 9.76 million lbs a.i. per year for soybean, at an average 4.73 lbs a.i. per total soybean acres (Figure 3-30).

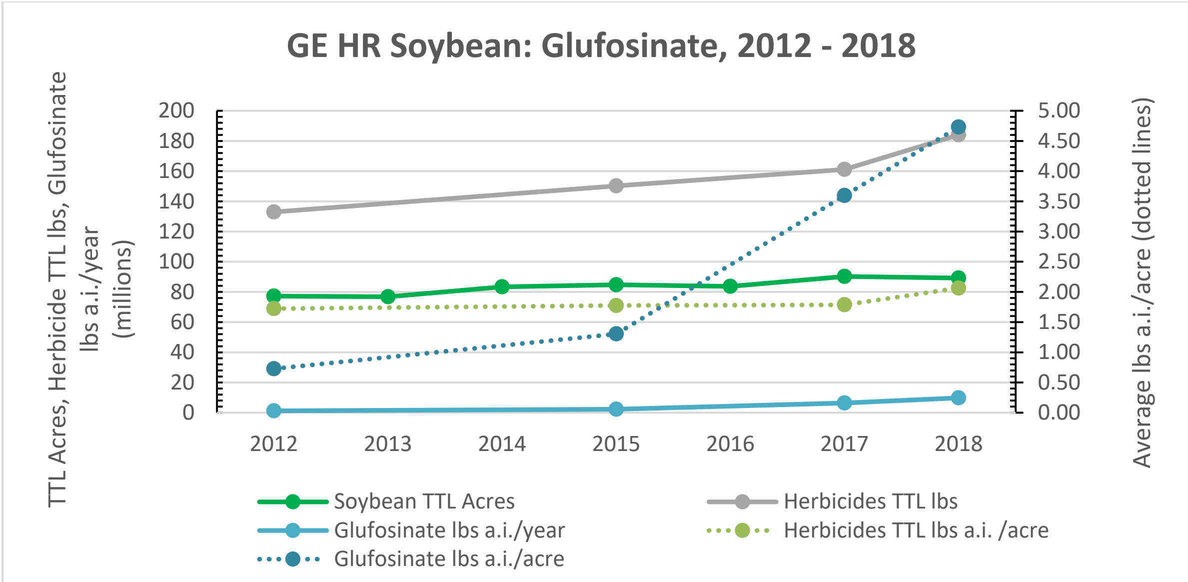


Figure 3-30. GE HR Soybean, Glufosinate Use, 2012—2018
Source: (USDA-NASS 2019c)

Summary of Herbicide of Use in Soybean Crop Production

As of the end of 2018, glyphosate was still widely used on soybean, comprising 57.3% of total herbicide use on soybean acres (Table 3-21). 2,4-D, dicamba, and glufosinate use with soybean has been comparatively limited. 2,4-D was used on 17% of soybean cropland (4.64% of total herbicide use), dicamba was used on 27% of soybean cropland (7.23% of total herbicide use), and glufosinate-ammonium on around 18% of soybean cropland (5.3% of total herbicide use. Isoxaflutole resistant soybean varieties are available, although the herbicide has not been registered for use on GE HR soybean, as of July 2019. A mesotrione resistant soybean variety is also available: AX-MESOTRIONE [EPA Reg. Number: 89167-51] can be applied pre-emergence to soybeans that are identified as mesotrione resistant.

Table 3-21. Summary: Herbicide Use in U.S. Soybean Production – 2018

	lbs a.i./Yr	Application: lbs a.i./acre/Yr (Average)	Treated Acres, % of Area Planted	% of Total Herbicide Use
GLYPHOSATE ISO. SALT	48,256,000	1.202	47	26.22%
GLYPHOSATE POT. SALT	36,651,000	1.527	28	19.91%
S-METOLACHLOR	19,439,000	1.283	18	10.56%
GLUFOSINATE-AMMONIUM	9,759,000	0.623	18	5.30%
GLYPHOSATE	7,098,000	1.105	7	3.86%
BAPMA SALT OF DICAMBA	6,572,000	0.572	13	3.57%
ACETOCHLOR	5,276,000	1.114	6	2.87%
DICAMBA, DIGLY. SALT	4,875,000	0.61	9	2.65%
METOLACHLOR	4,852,000	1.277	4	2.64%
2,4-D EHE	4,693,000	0.552	10	2.55%
METRIBUZIN	4,419,000	0.27	19	2.40%
FOMESAFEN SODIUM	3,643,000	0.234	18	1.98%
2,4-D DIMETH. SALT	3,592,000	0.562	7	1.95%
GLYPHOSATE DIM. SALT	3,484,000	1.147	4	1.89%

Table 3-21. Summary: Herbicide Use in U.S. Soybean Production – 2018				
	lbs a.i./Yr	Application: lbs a.i./acre/Yr (Average)	Treated Acres, % of Area Planted	% of Total Herbicide Use
PARAQUAT	3,457,000	0.611	7	1.88%
SULFENTRAZONE	3,339,000	0.195	20	1.81%
DIMETHENAMID-P	2,846,000	0.501	7	1.55%
PYROXASULFONE	1,570,000	0.136	13	0.85%
DICAMBA, DIMET. SALT	1,404,000	0.484	3	0.76%
CLETHODIM	1,398,000	0.109	15	0.76%
TRIFLURALIN	1,303,000	0.757	2	0.71%
PENDIMETHALIN	1,020,000	0.883	1	0.55%
FLUMIOXAZIN	720,000	0.089	9	0.39%
ATRAZINE	490,000	0.532	1	0.27%
IMAZETHAPYR	464,000	0.047	12	0.25%
ACIFLUORFEN, SODIUM	391,000	0.311	1	0.21%
DICAMBA, SODIUM SALT	305,000	0.26	1	0.17%
FLUAZIFOP-P-BUTYL	269,000	0.083	4	0.15%
FOMESAFEN	244,000	0.173	2	0.13%
SAFLUFENACIL	241,000	0.027	10	0.13%
GLYPHOSATE AMM. SALT	230,000	0.493	1	0.12%
2,4-D	212,000	0.531	(Z)	0.12%
LACTOFEN	198,000	0.173	1	0.11%
CLORANSULAM-METHYL	133,000	0.026	6	0.07%
CHLORIMURON-ETHYL	132,000	0.021	7	0.07%
DICAMBA	120,000	0.193	1	0.07%
QUIZALOFOP-P-ETHYL	42,000	0.052	1	0.02%
2,4-D ISOPROP. SALT	32,000	0.238	(Z)	0.02%
THIFENSULFURON	32,000	0.014	3	0.02%
DIFLUFENZOPYR-SODIUM	24,000	0.082	(Z)	0.01%
MESOTRIONE	22,000	0.064	(Z)	0.01%
IMAZETHAPYR, AMMON.	21,000	0.051	(Z)	0.01%
FLUMETSULAM	14,000	0.044	(Z)	0.01%
IMAZAMOX	13,000	0.052	(Z)	0.01%
TRIBENURON-METHYL	13,000	0.03	(Z)	0.01%
DICAMBA, ISO SALT	12,000	0.089	(Z)	0.01%
FLUMICLORAC-PENTYL	12,000	0.023	1	0.01%
OXYFLUORFEN	10,000	0.205	(Z)	0.01%
FLUTHIACET-METHYL	7,000	0.003	2	0.00%
RIMSULFURON	7,000	0.02	(Z)	0.00%
CARFENTRAZONE-ETHYL	5,000	0.025	(Z)	0.00%
Total	184,060,000			

*Z = no data

Herbicides denoted in bold type are those used with GE soybean varieties.

Source: (USDA-NASS 2019c)

GE HR Cotton

GE glyphosate resistant cotton was commercially introduced in 1996 and GE glufosinate resistant cotton in 2004. Sulfonylurea and bromoxynil resistant varieties were deregulated in the1990s, but never fully commercialized. More recently, dicamba and 2,4-D (2015) and isoxaflutole resistant (2018) varieties have been deregulated (Table 3-22). In 2016, the EPA first registered certain dicamba formulations for “over-the-top” use on dicamba resistant cotton and soybean plants during the 2017 growing season. Enlist Duo, an herbicide product containing 2,4-

D and glyphosate, was first registered in 2014 for use on GE corn and soybean crops in 6 states, and later in an additional 9 states. In 2017, the EPA amended the registration to allow use on GE cotton in those 15 states and extend the use of Enlist Duo on GE corn, soybean and cotton to an additional 19 states.

Table 3-22. GE HR Cotton, Deregulated Varieties

Petition Number	Applicant	Phenotype/Event	Effective Date
17-138-01p	Bayer	Glyphosate and Isoxaflutole Resistant	2018
13-262-01p	Dow AgroSciences	2,4-D and Glufosinate Resistant /DAS-8191Ø-7	2015
12-185-01p	Monsanto	Dicamba and Glufosinate Resistant /MON-887Ø1-3	2015
12-033-01p	Bayer	Glufosinate Resistant, IR/T303-3	2012
08-340-01p	Bayer	Glufosinate Resistant, IR/T304-40, GHB119	2011
06-332-01p	Bayer CropScience	Glyphosate Resistant /GHB614	2009
04-086-01p	Monsanto	Glyphosate Resistant /MON 88913	2004
02-042-01p	Aventis	Phosphinothericin Resistant /LLCotton25	2003
97-013-01p	Calgene	Bromoxynil Resistant and IR/31807, 31808	1997
95-256-01p	Du Pont	Sulfonylurea Resistant/19-51A	1996
95-045-01p	Monsanto	Glyphosate Resistant /1445, 1698	1995
93-196-01p	Calgene	Bromoxynil Resistant /BXN	1994

Phosphinothericin = Glufosinate

From the early 1960s to 1976, herbicide use per planted acre, driven largely by use of trifluralin and fluometuron, rose from less than 0.1 pounds a.i. per acre to 1.9 pounds a.i. per acre, respectively (Fernandez-Cornejo et al. 2014d). Herbicide use ranged from 1.5 to 2.5 pounds a.i. per planted acre in most years from 1982 to 1995. GE HR cotton adoption increased from 20% percent of planted acres in 2000 to around 82% in 2018. During the 1996–2018 time frame, herbicide use on cotton has tended to increase, albeit, as with corn, modestly (Figure 3-31). From 1996 to 2010, total herbicide use in average lbs a.i./acre remained fairly steady, fluctuating around 2.23 lbs a.i./acre (+/- 0.26). It increased to 3.06 lbs a.i./acre in 2015, declining to 2.34 lbs a.i./acre in 2017.

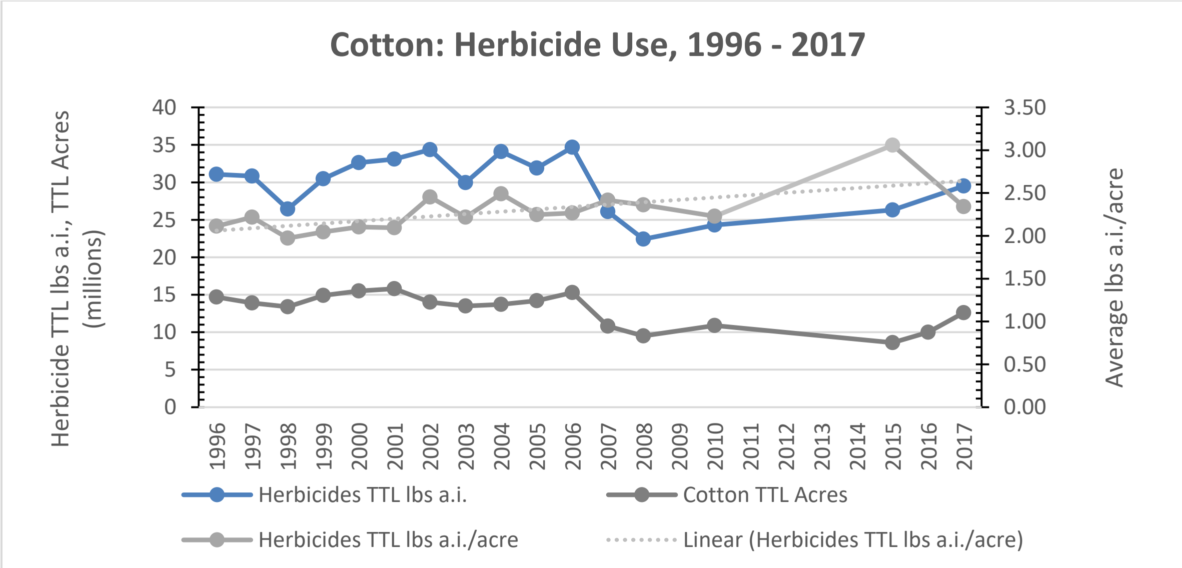


Figure 3-31. Cotton, Herbicide Use, 1996-2017
Source: (USDA-NASS 2019c)

GE glyphosate resistant cotton was quickly adopted by cotton farmers, accounting for approximately 10% percent of cotton acres after 1 year. As with corn and soybean, adoption of GE HR cotton understandably influenced the types of herbicides used on cotton crops. In 1996, trifluralin, MSMA, pendimethalin, and fluometuron were the dominant herbicides used in cotton production (Fernandez-Cornejo et al. 2014d). By 2018, by which time GE HR cotton was cultivated on 82% of cotton acres, glyphosate use accounted for 49% of herbicide use on cotton, and glufosinate 4%.

From 1995 – 2017 (latest data), average glyphosate use in cotton increased from an average of around 0.71 lbs a.i./acre to 1.14 lbs a.i./acre (Figure 3-32). Since 1995, total herbicide application has remained fairly constant at around an average of 2.0 – 2.4 lbs a.i./acre, although with a peak of 3.06 lbs a.i./acre in 2015.

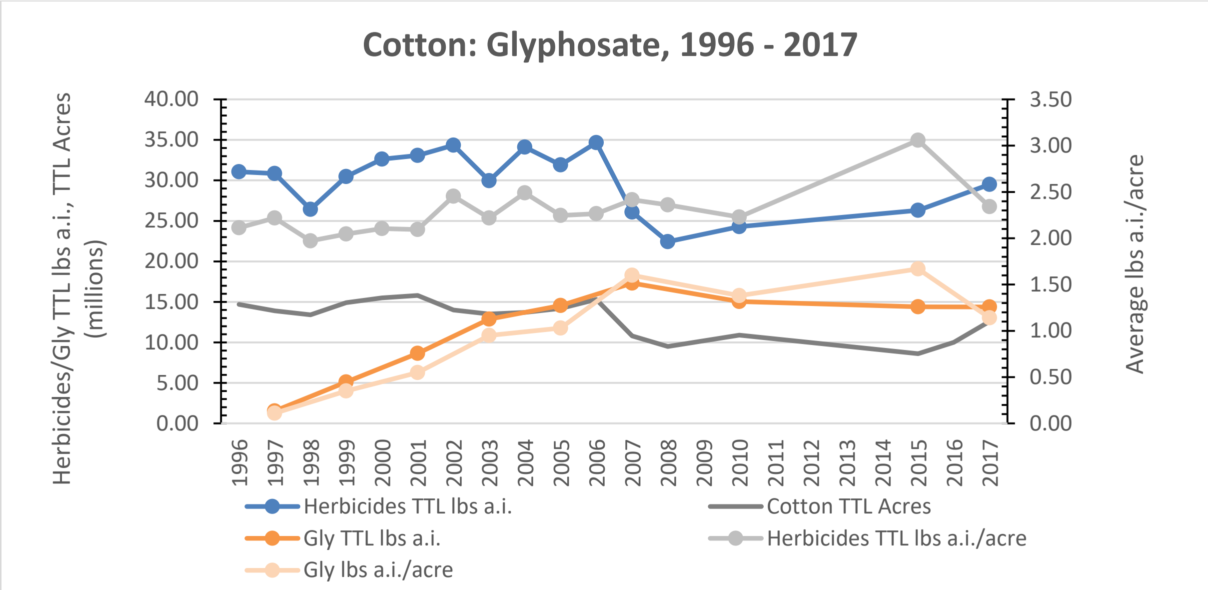


Figure 3-32. Cotton, Glyphosate Use, 1996 – 2017

Source: (USDA-NASS 2019c)

As with corn and soybean, while glyphosate use increased in cotton, use of some of the other herbicides applied to cotton declined (Figure 3-33). As examples, from 1995–2017, trifluralin use declined from 5.6 to 2.3 million lbs a.i./year, pendimethalin from 1.9 to 1.0 million lbs a.i./year, MSMA from 3.2 to 0.175 million lbs a.i./year, and fluometuron from 2.8 to 0.4 million lbs a.i./year.

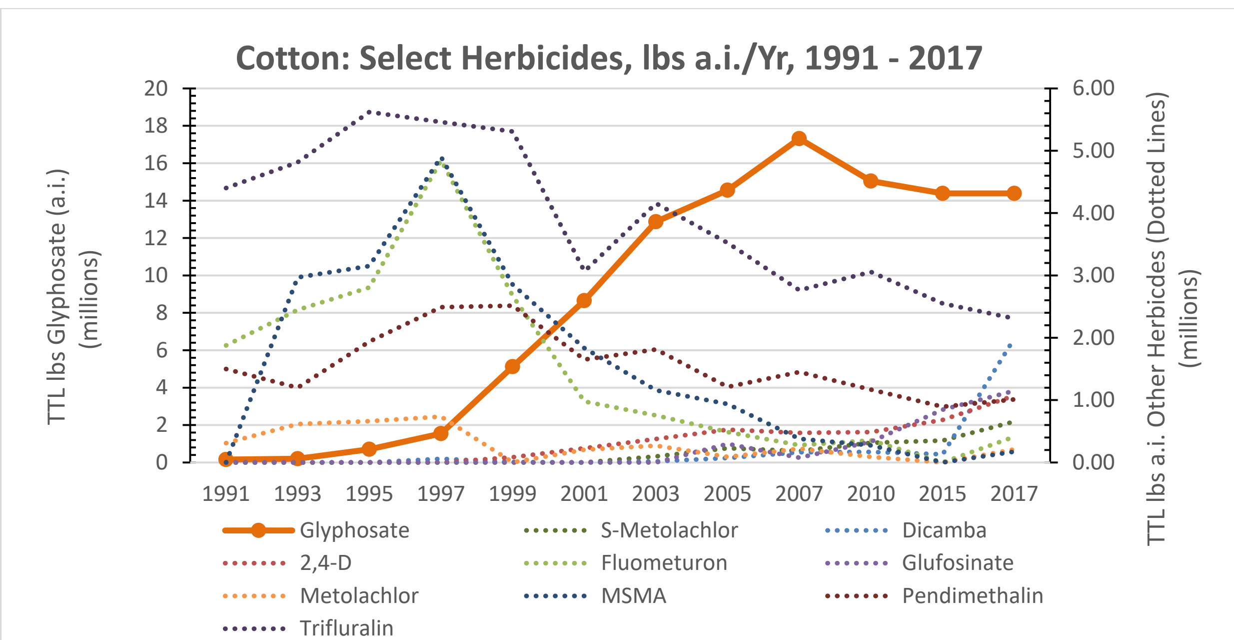


Figure 3-33. Cotton: Select Herbicides, 1991 – 2017

Source: (USDA-NASS 2019c)

Summary of Herbicide of Use in Cotton Crop Production

As of the end of 2018, glyphosate was used on 80% of cotton acres, comprising 48.7% of total herbicide use (Table 3-23). Dicamba was used on 33% of cotton cropland, comprising 6.74% of total herbicide use. 2,4-D and glufosinate use with cotton has been comparatively limited. 2,4-D was used on 12% of cotton cropland (3.64% of total herbicide use), and glufosinate-ammonium on around 17% of cotton cropland (3.89% of total herbicide use). Isoxaflutole resistant soybean varieties are available, although the herbicide has not been registered for use on GE HR cotton, as of July 2019.

Table 3-23. Herbicide Use in U.S. Cotton Production – 2017

	lbs a.i./Yr	Application: lbs a.i./acre/Yr (Average)	Treated Acres, % of Area Planted	Portion of Total Herbicide Use
GLYPHOSATE ISO. SALT	9,975,000	1.494	59	33.78%
GLYPHOSATE POT. SALT	4,144,000	2.068	18	14.03%
TRIFLURALIN	2,309,000	0.885	23	7.82%
S-METOLACHLOR	2,188,000	1.304	15	7.41%
GLUFOSINATE-AMMONIUM	1,150,000	0.592	17	3.89%
ACETOCHLOR	1,134,000	1.201	8	3.84%
DIURON	1,099,000	0.417	23	3.72%
PENDIMETHALIN	1,011,000	0.908	10	3.42%
2,4-D DIMETH. SALT	950,000	0.842	10	3.22%
DICAMBA, DIGLY. SALT	696,000	0.629	10	2.36%
DICAMBA; BAPMA	553,000	0.771	6	1.87%
DICAMBA, DIMET. SALT	466,000	0.522	8	1.58%
PROMETRYN	443,000	0.519	8	1.50%
FLUOMETURON	414,000	0.817	4	1.40%
FOMESAFEN SODIUM	319,000	0.21	13	1.08%
DICAMBA, SODIUM SALT	263,000	0.281	8	0.89%
DIMETHENAMID-P	250,000	0.69	3	0.85%
METOLACHLOR	211,000	1.689	1	0.71%
GLYPHOSATE	204,000	0.724	2	0.69%
MSMA	175,000	1.436	1	0.59%
FLUMIOXAZIN	121,000	0.081	13	0.41%
GLYPHOSATE DIM. SALT	65,000	0.821	1	0.22%
2,4-D CHOLINE SALT	61,000	0.773	1	0.21%
ATRAZINE	56,000	0.787	1	0.19%
CLETHODIM	48,000	0.19	2	0.16%
2,4-D EHE	47,000	0.817	1	0.16%
PYRITHIOBAC-SODIUM	44,000	0.096	4	0.15%
2,4-D	14,000	0.301	Z)	0.05%
DICAMBA	12,000	0.167	1	0.04%
CARFENTRAZONE-ETHYL	5,000	0.011	4	0.02%
PYROXASULFONE	4,000	0.078	(Z)	0.01%
SAFLUFENACIL	4,000	0.025	1	0.01%
THIFENSULFURON	3,000	0.015	2	0.01%
PYRAFLUFEN-ETHYL	2,000	0.003	5	0.01%
RIMSULFURON	2,000	0.017	1	0.01%
TRIBENURON-METHYL	1,000	0.011	1	0.00%

Table 3-23. Herbicide Use in U.S. Cotton Production – 2017				
	lbs a.i./Yr	Application: lbs a.i./acre/Yr (Average)	Treated Acres, % of Area Planted	Portion of Total Herbicide Use
TRIFLOXYSULFURON-SOD	1,000	0.009	1	0.00%
Total	29,529,000			

Herbicides denoted in bold type are those used with GE cotton varieties.

Source: (USDA-NASS 2019c)

GE HR Canola

Overall, herbicide applications in GE glyphosate- and glufosinate-resistant canola cropping systems have typically been less than that found in conventional cropping systems (Beckie H.J et al. 2011; Brookes and Barfoot 2015a; Brookes and Barfoot 2016). From 1996 – 2014, it is estimated that the use of GE HR canola resulted in a 25 million kg reduction in the amount of herbicide used in the United States (Brookes and Barfoot 2017b). In Canada, it is estimated the use of GE HR canola resulted in a 18.3 million kg reduction over the same period (Brookes and Barfoot 2017b).

GE HR Sugarbeets

GE sugarbeets became commercially available in 2006. As of 2012, around 97% of sugarbeet planted in the United States was GE glyphosate-resistant. In general, in regard to total lbs a.i./acre, herbicide use has increased with the introduction of GE glyphosate-resistant sugarbeet. Brookes and Barfoot (2017b) find that the use of GE glyphosate-resistant sugarbeet resulted in a net additional 1.8 million kg of herbicide active ingredient being applied to the sugarbeet crops globally, relative to the amount reasonably expected if this crop area had been planted to conventional sugarbeet (Brookes and Barfoot 2017b). Brookes and Barfoot (2017b) do not parse out the relative increase in the United States and Canada, separately.

The reported increase in lbs a.i./acre is attributed to glyphosate use rates being higher than the herbicides which it replaced. With the adoption of GE sugarbeet, there was a significant decline from around 10 applications of several different herbicide active ingredients to only around 2 or 3 applications of glyphosate (USDA-APHIS 2012b). However, due to the increased application rate for glyphosate, or rather, higher dose, there is an increase in total pounds a.i. applied per acre during a given growing season, relative to other herbicides, even though the number of herbicides and the number of applications of herbicide have decreased.

This considered, Kniss (2016) points out that GE glyphosate-resistant sugarbeet has resulted in highly effective weed control (Kniss 2016). According to the North Dakota/Minnesota sugarbeet grower survey (SR&EB 2017), before the adoption of GE sugarbeet many farmers listed weeds as their most serious production problem from year to year. After the adoption of GE glyphosate-resistant sugarbeet, weed problems declined. For example, in 1986, 39% of survey respondents reported weeds as being the most serious production problem in sugarbeet. In 2010, when 95% of sugarbeet acreage was GE glyphosate-resistant, 6% of respondents reported weeds as the most serious production problem (SR&EB 2017). Another reported benefit is that, by 2009, only two years after widespread adoption of GE sugarbeet, over 50,000 acres of sugarbeet fields were converted to some form of reduced or conservation tillage practices in Nebraska, Colorado, and Wyoming (Kniss 2016).

GE HR Alfalfa

Alfalfa is a perennial crop that can effectively suppress weeds when established. Historically, herbicide use on alfalfa has been more extensive in the west where weeds are easily spread through irrigation canals than in the east where alfalfa production is largely rain fed. Overall, herbicide was used on less than 20% of the alfalfa crop in 2011 when glyphosate resistant alfalfa became available after a court ordered injunction was dismissed. In 2014, USDA deregulated a new GE HR alfalfa variety, which is more easily digested by cattle (reduced lignin). The commercialization of this trait (stacked with HR alfalfa) is likely to further boost HR alfalfa adoption rates. Due to the recent and low level adoption of GE HR alfalfa, pesticide use data is insufficient to distinguish between non-GE and GE alfalfa varieties.

Summary of Herbicide Use on GE HR Crops

For GE corn, soybean, and cotton: Based on the USDA-NASS and other data reviewed, overall, during the 1997–2018 time frame, herbicide use on corn has tended to increase, albeit modestly. From 1997 to 2014, total herbicide use in lbs a.i./acre actually tended to decline, fluctuating around 2.06 lbs a.i./acre (1.9 to 2.3 lbs a.i./acre). It increased to 2.40 lbs a.i./acre in 2016, and 2.41 lbs a.i./acre in 2018. Due to the increase in lbs a.i./acre during 2016-2018, the overall trend line increases as assessed from 1996.

Similarly, from 1997–2017/2018, overall herbicide use (lbs a.i./acre) on cotton has shown a slight increase. However, during 1997–2010, herbicide use was relatively steady, fluctuating around 2.2 lbs a.i./acre. In 2015, herbicide use on cotton averaged 3.06 lbs a.i./acre, and in 2017, 2.34 lbs a.i./acre. Thus, a modest increase during the 21 year 1996—2017 period (Table 3-24). Soybean evidences a distinct and steady increase in herbicide applications from an average 0.94 lbs a.i./acre in 1996 to 2.06 lbs a.i./acre in 2018. Based on USDA-NASS data reviewed above, we find that aggregate herbicide use in GE corn, cotton, and soybean cropping systems increased around 1.16 lbs a.i./acre/year.

Table 3-24. Summary: Herbicide Use in Surveyed Corn, Cotton, and Soybean, 1996 – 2017/2018

	Corn			
	1996	**2017/2018**	**Diff.**	**% Change**
TTL lbs Herbicide a.i./yr (million)	186.98	214.72	27.74	14.84%
Acres (million)	79.2	89.13	9.93	12.54%
Average Herbicide lbs a.i./acre	2.36	2.41	0.05	2.12%
	1996-2002	**2003-2018**		
Herb. lbs a.i./acre (Ave)	2.08	2.12	0.04	1.92%
	Soybean			
	1996	**2017/2018**	**Diff.**	**% Change**
TTL lbs Herbicide a.i./yr (million)	76.16	184.1	107.94	141.73%
Acres (million)	64.2	89.6	25.4	39.56%
Average Herbicide lbs a.i./acre	1.19	2.05	0.86	72.27%
	1996-2002	**2003-2018**		
Herb. lbs a.i./acre (Ave)	1.13	1.51	0.38	33.63%

Table 3-24. Summary: Herbicide Use in Surveyed Corn, Cotton, and Soybean, 1996 – 2017/2018				
	Cotton			
	1996	2017/2018	Diff.	% Change
TTL lbs Herbicide a.i./yr (million)	79.2	89.13	9.93	12.54%
Acres (million)	14.7	12.6	-2.1	-14.29%
Average Herbicide lbs a.i./acre	2.11	2.34	0.23	10.90%
	1996-2002	2003-2018		
Herb. lbs a.i./acre (Ave)	2.14	2.4	0.26	12.15%

The data reviewed above on herbicide use in the United States is largely in agreement with studies conducted by the USDA and prior USDA scientists (Osteen and Fernandez-Cornejo 2013; Fernandez-Cornejo et al. 2014d; Osteen and Fernandez-Cornejo 2016), a recent report from the National Academy of Sciences (NAS 2016b), analyses by Coupe and Capel (2015), Brookes and Barfoot (2017b), and Perry et al. (2016).

Coupe and Capel (2015) reported somewhat similar findings; they found a reduction in the annual herbicide application rate to corn since the advent of GE HR corn, that the herbicide application rate is largely unchanged for cotton, and that herbicide use on soybean has increased (Coupe and Capel 2015). Their findings were based on data through 2009. More recent data indicates herbicide use in cotton has increased, albeit marginally, since 1996.

Perry et al. (2016) reported that for U.S. corn and soybean farmers, from 1998 to 2011, adopters of GE glyphosate-resistant soybeans used 28% (0.30 kg/ha, 0.27 lbs/acre) more herbicide than non-adopters, adopters of glyphosate-resistant corn used 1.2% (0.03 kg/ha, 0.027 lbs/acre) less herbicide than non-adopters, and adopters of GE insect-resistant (IR) maize used 11.2% (0.013 kg/ha, 0.012 lbs/acre) less insecticide than non-adopters (Perry et al. 2016). These findings are largely consistent with the data presented here.

Benbrook reported that, since 1996, herbicide use on corn has declined, with a modest increase in cotton and a more distinct increase in soybean (Benbrook 2012; Benbrook 2016). Benbrook (2012) also reported that, from 1996 to 2011, herbicide use increased as a result of GE cropping systems, by some 239 million kgs (527 million pounds) (Benbrook 2012).

Brookes and Barfoot evaluated pesticide use in GE cropping systems using methodology that compares pesticide use among GE and non-GE conventional crops, which differs from reporting of raw data as presented here. Nevertheless, their findings are worth noting (Brookes and Barfoot 2013b; Brookes and Barfoot 2016). One recent publication reported that for GE HR corn there has been a reduction in the volume of herbicide active ingredient use, around 9.9 %, between 1996 and 2014. For GE HR cotton, Brookes and Barfoot found that the use of glyphosate has resulted in a 1.8 million kg reduction in herbicide active ingredient use (-5.8% in the U.S.), relative to the amount reasonably expected if crop area had been planted to conventional corn and cotton (Brookes and Barfoot 2016). They report a decrease in herbicide active ingredient use for U.S. soybean crops (-3.5%), although they find the amount of herbicide active ingredient applied to global GE HR soybean crops increased by 7.8 million kg (+3.3%), relative to the amount reasonably expected if this crop area had been planted to conventional cultivars.

Similarly, they find that, over the period 2008–2014, the widespread use of GE HR technology in the United States and Canadian sugarbeet crops has resulted in a net increase in the total volume of herbicides applied to sugarbeet crops (+32.5%), relative to the amount reasonably expected if this crop area had been planted to conventional sugarbeet. As discussed above, GE HR canola use has resulted in a significant reduction (-19% in the United States) in the amount of herbicide active ingredient used relative to the amount reasonably expected if crop area had been planted to conventional canola.

Globally, Brookes and Barfoot find that in some countries there has been a net increase in the average amount of herbicide active ingredient applied to GE HR crops, and in others a net decrease, relative to use on conventional crops (Brookes and Barfoot 2016). They attribute this in part to development of glyphosate resistant weeds (Brookes and Barfoot 2013b; Brookes and Barfoot 2016).

The increased use of glyphosate on GE HR crops, increased crop acreage, displacement of other herbicides by glyphosate, and changes in use of various other herbicides contributed to increases in herbicide quantities used on corn, soybean, and cotton (Osteen and Fernandez-Cornejo 2016). For example, glyphosate formulations are applied at effective rates of around 1 lb a.i./acre, whereas certain herbicides such as nicosulfuron and rimsulfuron are applied at around 0.016 lbs a.i./acre, and clopyralid at around 0.09 lbs a.i./acre. Nicosulfuron and rimsulfuron have declined in use, and use of clopyralid has fluctuated, since the late 1990s. On the other hand, simazine, also a higher rate herbicide applied at around 1.2 lbs a.i./acre, increased in use from 2002 to 2010. Similarly, trifluralin, applied at around 1.3 lbs a.i./acre, atrazine (1.0 lb a.i./acre), acetochlor (1.4–1.7 lbs a.i./acre), and S-metolachlor (1.2–1.3 lbs a.i./acre) also increased in use since the advent of GE HR crops.

In summary, GE HR crops resistant to glyphosate increased the use of an herbicide with a higher application rate, relative to many other herbicides. This combined with increased use of other higher rate herbicides, decline in use of some herbicide with a lower per acre application rate, and increased acreage in corn and soybean, led to an increase in herbicide use in corn and soybean, as measured in lbs a.i./acre, and lbs a.i./yr. The same is true for cotton, except that cotton acreage actually declined from 1996 to 2017. The increase in herbicide use in these crops is perceived by some as an environmental and human health risk, which is not necessarily the case; environmental and human health risks depend on the potential toxicity of the specific herbicide active ingredient, herbicide formulations, and the hazards these pose to various taxa– discussed in the following section on herbicide toxicity (3.4.2.2.4).

Based on available data, GE HR corn, soybean, and cotton crops have had no discernible effect on the overall percentage of corn, cotton, and soybean acres treated with herbicides. By the mid-1980s, 10 years before the introduction of GE HR crops, over 90% of corn, cotton, and soybean acres were being treated annually. As of 1996, 97% of corn and soybean acres, and 93% of cotton acres, were treated with herbicides.

While certain GE crops have contributed to increased herbicide use in terms of lbs a.i./acre, as reviewed here and by others (Benbrook 2012; Benbrook 2016; Brookes and Barfoot 2016; Perry et al. 2016; USDA-NASS 2019c), increases in herbicide use have also occurred in non-GE wheat and rice. From 1990–2015, among GE HR corn, soybean, and cotton, and non-GE wheat, herbicide use increased more rapidly in non-GE spring and winter wheat as compared with GE HR corn, soybean, and cotton (Kniss 2017). In 1990, average herbicide use for spring and winter wheat was around 0.14 lbs a.i./acre, while in 2015 it was around 0.51 lbs a.i./acre (USDA-NASS 2019c). For rice, herbicide use averaged around 3.5 lbs a.i./acre in the early 1990s and declined to 2.64 lbs a.i./acre in 2006. Since that time, use rates have increased to 3.0 lbs a.i./acre (USDA-NASS 2019c).[59]

Where GE HR crops have had a distinct impact is on the types and mix of herbicide active ingredients used in corn, soybean, cotton, canola, and sugarbeet crops. A primary effect of GE HR crop adoption on herbicide use has been the substitution of primarily glyphosate for other herbicides, and to a lesser extent 2,4-D, glufosinate, and dicamba, in lieu of other herbicides. However, substitution of herbicides in GE HR crops may not always be the case. Stacked-trait varieties, which have become the most common GE varieties, may increase herbicide use. As of 2018, stacked-trait varieties comprised 80% of corn, and 82% of cotton acreage (Figure 3-34). For example, increased production of stacked-trait crops resistant to 2,4-D and glufosinate, or 2,4-D, glufosinate, and glyphosate, could potentially increase overall use of these herbicides in the United States.[60] For stacked-trait varieties, herbicide programs could combine current rates of glyphosate with additional use of dicamba and other herbicides.[61] These particular stacked-trait varieties may not necessarily involve a substitution of herbicide active ingredients, but may instead lead to additional herbicide use.

[59]https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Ag_Resource_Management/ARMS_2014_Rice_Highlights.pdf

[60] Stacked-trait soybean resistant to 2,4-D, glufosinate, and glyphosate [Dow AgroSciences, petition 11-234-01p] was deregulated in 2014, and stacked-trait cotton resistant to 2,4-D and glufosinate [Dow AgroSciences, petition 13-262-01p was deregulated in 2015.

[61] See Dow AgroSciences Petitions (09-233-01p, 09-349-01p, and 11-234-01p) for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and Soybean Varieties, Final Environmental Impact Statement—August 2014 [https://www.aphis.usda.gov/brs/aphisdocs/24d_feis.pdf]

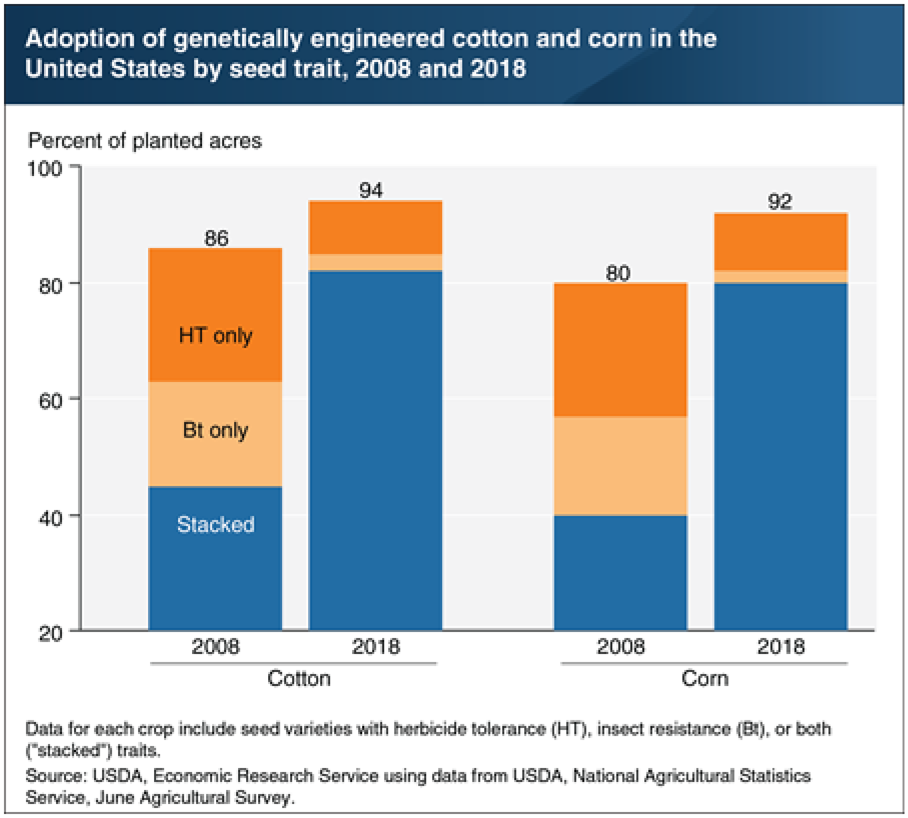


Figure 3-34. GE Stacked Trait Corn and Cotton, 2008–2018

In evaluating the relationship between GE HR crops and herbicide use patterns, it is a combination of inter-related factors that must be considered, not any single driver, when assessing herbicide use rates. Major factors affecting overall herbicide use trends since 1990 (as measured in lbs a.i./year and lbs a.i./acre) have been: (1) changes in crop acreage, which is influenced by economic and policy factors, (2) the replacement or discontinuance of older pesticides (MOAs) with newer ones (changes in per-acre application rates), influenced by pesticide regulation and grower choice, which contribute to changes in pesticide quantities,[62] (3) the introduction and adoption of GE HR crops, which influences the types of herbicides used, application rates, and herbicide quantities, (4) emergence of weed populations resistant to various herbicide MOAs over the last several decades (discussed below in Section 3.4.3 – Pest and Weed Resistance), and (5) the extent of implementation of highly recommended IWM practices for control of weeds.

While valuable to track and examine pesticide use on GE and conventional crops over time, simple determinations of whether total pounds/kilograms of herbicide a.i./year or a.i./acre/yr has increased or decreased provides but one of several metrics required for assessing human and environmental risks. In and of itself, assessing annual lbs and lbs/acre data is of little meaning, it provides no information about the risk synthetic chemistries may present to human health and

[62] Higher application rates indicate lower potency of the herbicide; more potent herbicides require a lower rate to achieve the desired degree of weed control. For example, metolachlor was supplanted by the lower-rate S-metolachlor, and cyanazine was phased out by the U.S.-EPA (in cooperation with DuPont) by 2002.

wildlife. It is the toxicity of pesticide active ingredients, synergistic effects of carriers/solvents, and inherent environmental fate and transport characteristics of active ingredients and other chemistries in the herbicide, which vary widely, that are the salient factors in assessing risks to humans and wildlife.

3.4.2.2.4 Herbicide Toxicity

Because herbicides are the most widely used pesticide in agriculture, and marginal increases in use over the past 2 decades have been in part associated with the use of some GE HR crops, attention is given here to the potential toxicity of herbicides used with GE HR crops. When evaluating the variety of different herbicides used in crop production, each with different use rates and toxicity profiles, simply reporting the weight of pesticide applied, as provided above, can be misleading. A recent National Academy of Sciences report strongly discouraged using such approaches: "Researchers should be discouraged from publishing data that simply compares total kilograms of herbicide used per hectare per year because such data can mislead readers" (NAS 2016b).

Glyphosate

The sharp increase in use of glyphosate in particular has received scrutiny due to its association with GE crops. The significant increase in glyphosate use, relative to a number of other herbicides on the market, generated concern among some scientists, policy-makers, and the general public. However, as analyses presented by Kniss (2017), the EPA (US-EPA 2015g, d), and others (Benbrook 2016; Brookes and Barfoot 2016; Perry et al. 2016) suggest, such increased use of an herbicide, including glyphosate, may not inherently increase risks for the environment, wildlife, or public health, as sometimes such shifts in usage can correspond with reduced environmental and human health risks (toxicity).

It is important to emphasize that the EPA evaluates the potential acute and chronic toxicity of a pesticide active ingredient via human health and environmental risks assessments. These assessment are conducted prior to a pesticide registration and inform the EPA label use requirements assuming it is authorized for use.[63] Pesticides can be hazardous if the recommended safe dose, duration, and frequency of exposure is exceeded. Adherence to the EPA pesticide label instruction is not only a legal requirement, it is fundamental to the safe use of the product. Information on the potential acute and chronic toxicity of each pesticide on the market is publicly available from various online resources, such as: (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 Action Network;[64] the Integrated Risk Information System;[65] Toxicology Data Network;[66] and, Agency for Toxic Substances and Disease Registry.[67]

Looking at the major crops on which herbicides are used – corn, soybean, cotton, wheat, rice: There are currently around 118 unique herbicide active ingredients used on these crops,

[63] EPA – Pesticides: http://www.epa.gov/pesticides
[64] Pesticide Action Network (PAN) Database: http://www.pesticideinfo.org/
[65] EPA – Integrated Risk Information System: http://www.epa.gov/iris
[66] National Institutes of Health, Health & Human Services – Toxicology Date Network: http://toxnet.nlm.nih.gov/
[67] Agency for Toxic Substances and Disease Registry: http://www.atsdr.cdc.gov/

collectively (Kniss 2017; USDA-NASS 2019c). As of 2019, there were around 48 different herbicide (a.i.) formulations used in commercial corn production, around 51 different herbicides (a.i.) applied to soybean, 37 applied to cotton, 7 to rice, and around 44 to spring and winter wheat (USDA-NASS 2019c).

An environmental impact quotient has been widely used in GE crop studies, and while useful in some respects, there are inherent limitations using the environmental impact quotient for risk assessment (Peterson and Schleier 2014; Kniss and Coburn 2015). Consequently, Kniss (2017) evaluated the relative toxicity of herbicides being used on GE HT corn, soybean, and cotton, and non-GE rice and wheat, using a hazard quotient approach (Kniss 2017), which is also employed by the EPA. In the hazard quotient approach, the toxicity of a pesticide represents the hazard and the amount of pesticide active ingredient applied represents an estimate of exposure, so that the resulting hazard quotient provides an estimate of risk. High hazard quotient values indicate a relatively more toxic combination of herbicides.

From 1990 – 2014, Kniss (2017) estimates that acute herbicide toxicity has decreased 88% in corn. Much of the reduction in acute toxicity was due to phasing out of alachlor and cyanazine from the corn market. In 1990, alachlor (acute LD50 of 150 mg/kg) and cyanazine (acute LD50 of 182 mg/kg) accounted for 85% of the total acute hazard quotient. As a result of significant use of atrazine and to some extent mesotrione, the chronic hazard quotient increased 7% in corn, though it has trended downward slightly in recent years (Kniss 2017).

For soybean, from 1990 to 2015, chronic and acute herbicide toxicity in soybean was estimated to decrease 78% and 68%, respectively. Most of the reduction in the chronic hazard quotient has been due to reduction in linuron use, while most of the acute hazard quotient reduction was due to reduction in alachlor use (Kniss 2017).

For cotton, the acute hazard quotient has decreased 65% from its peak in 1994 to its lowest point in 2003. After 2004, acute toxicity increased, but in 2015 was still substantially lower than any acute hazard quotient value observed before 2001. Much of the reduction in cotton acute hazard quotient was due to phasing out of the herbicide cyanazine, which made up 60% to 70% of the acute hazard quotient between 1990 and 1998. The chronic hazard quotient for cotton increased between 1990 and 2015, although the increase has been driven almost completely by a single herbicide, diuron, which was responsible for 89% of the chronic hazard quotient in cotton (Kniss 2017).

Overall, the acute toxicity of herbicides used in the United States has decreased over the last 20 to 25 years for the major GE crops – corn, soybean, and cotton (Brookes and Barfoot 2016; Perry et al. 2016; Kniss 2017). While potential chronic toxicity has decreased for soybean, it has increased for cotton, and there has been a marginal increase for corn, due to the use of diuron, and atrazine and mesotrione, respectively (Kniss 2017). The largest decreases in hazard were a result of discontinuation of several products with relatively high toxicity, including alachlor, cyanazine, and molinate. The EPA's decisions to discontinue these products has had a beneficial effect on pesticide applicator health risks, and potential environmental impacts.

Increased glyphosate use in association with GE crops has spurred debate about its safety. APHIS reviewed 10 studies on glyphosate health effects (particularly as to whether it causes cancer) summarized below. Of the 10 studies, 7 did not report a linkage between glyphosate use and cancer.

The World Health Organization International Agency for Research on Cancer (IARC) classified glyphosate as "probably carcinogenic to humans." In arriving at this classification, IARC characterized evidence of carcinogenicity in humans as "limited," based on the data available for non-Hodgkin lymphoma (NHL). IARC considered the evidence of carcinogenicity in experimental animals as "sufficient." The latter determination was based on the occurrence of renal tubule carcinoma, hemangiosarcoma, and pancreatic islet-cell adenoma in rodents, as well as mechanistic evidence (Chang and Delzell 2016). Glyphosate has an approximate acute LD50 of around 4,320 mg/kg to 5,037 mg/kg in male rats. This renders glyphosate less acutely toxic than 94% of the herbicides used on corn, soybean, cotton, rice, and wheat (Kniss 2017). Glyphosate is an EPA Category IV pesticide, which is the least toxic category (40 CFR 156.62). Glyphosate is estimated to have a lower chronic toxicity[68] than 94% of herbicides used on corn, soybean, cotton, rice, and wheat. Based on the acute and chronic toxicity data for glyphosate, if glyphosate were not used, environmental and human health risks could potentially increase as other herbicides with greater acute and chronic toxicity could be used in its stead (Kniss 2017; USDA-NASS 2019c). Thus, if glyphosate use were discontinued (as proposed in the EU) the resulting displacement of glyphosate by other herbicides could present acute and chronic health risks to the public and pesticide applicators, as over 94% of other herbicides are considered more acutely and chronically toxic than glyphosate (Peterson and Hulting 2004; Kniss 2017).

In general, most studies agree that, overall, there has been a shift to less toxic herbicide use in the United States (Fernandez-Cornejo et al. 2014d; Brookes and Barfoot 2016; NAS 2016b; Perry et al. 2016; Kniss 2017). Because glyphosate is considered less toxic and persistent than 94% of other herbicides applied to corn, soybean, cotton, and wheat, and bearing in mind the vast majority of corn, soybean, cotton, canola, and sugarbeet acres are planted with GE seed, the net impact of GE glyphosate resistant crops has been considered an improvement in environmental quality and a reduction in human health risks.

The above considered, there is debate and uncertainty as to the risks chronic exposure to glyphosate may present to human health. The International Agency for Research on Cancer (IARC) in 2015 classified glyphosate as "probably carcinogenic to humans" (Group 2A). The European Food Safety Authority (EFSA) concluded that glyphosate is unlikely to represent a carcinogenic hazard to humans from dietary exposure to residual pesticide content (EFSA 2015). In 2016 the Joint FAO/WHO Meeting on Pesticide Residues in food concluded that 'glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet' (FAO/WHO 2016). The EPA has concluded its regulatory review of glyphosate (US-EPA 2020b). After a thorough review of the best available science, as required under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA has concluded that there are no risks of concern to human health when glyphosate is used according to the label and that it is not a carcinogen (US-EPA 2020b). These findings on human health risk are consistent with the conclusions of science reviews by many other countries and other federal agencies, including the U.S. Department of Agriculture, the Canadian Pest Management Regulatory Agency, the Australian Pesticide and

[68] No observable effect level (NOEL) from 24-month chronic rat studies.

Veterinary Medicines Authority, the European Food Safety Authority, and the German Federal Institute for Occupational Safety and Health. .

Zhang et al. (2019) conducted a meta-analysis that includes the most recent update of the Agricultural Health Study (AHS) cohort published in 2018 along with five case-control studies. Using the highest exposure groups when available in each study, they report the overall meta-relative risk (meta-RR) of NHL in glyphosate based herbicide (GBH)-exposed individuals was increased by 41% (meta-RR = 1.41, 95% confidence interval, CI: 1.13-1.75). For comparison, they also performed a secondary meta-analysis using high-exposure groups with the earlier AHS (2005), and calculated a meta-RR for NHL of 1.45 (95% CI: 1.11-1.91), which was higher than the meta-RRs reported previously. To contextualize their findings of an increased NHL risk in individuals with high GBH exposure, they reviewed publicly available animal and mechanistic studies related to lymphoma. They documented further support from studies of malignant lymphoma incidence in mice treated with pure glyphosate, as well as potential links between glyphosate/GBH exposure and immunosuppression, endocrine disruption, and genetic alterations that are commonly associated with NHL or lymphomagenesis. Overall, in accordance with findings from experimental animal and mechanistic studies, they assert their meta-analysis of human epidemiological studies suggests a compelling link between exposures to GBHs and increased risk for NHL (Zhang et al. 2019)

Leon et al. (2019) concluded that "We did not observe an association between risk of NHL overall and ever use of glyphosate, a broad-spectrum herbicide used in agriculture and other settings." "Whereas the lack of association of ever/never use of glyphosate with NHL overall in our analysis is consistent with a recently published analysis from Andreotti et al. (2018) reporting no association between lifetime days or intensity-weighted lifetime days of glyphosate use and NHL (440 exposed cases), our mHR observed for Diffuse large B-cell lymphoma [DLBCL] with ever/never use of glyphosate for the three cohorts combined is higher than that for AHS alone."

The German Federal Institute for Risk Assessment (BfR) was commissioned by the German government and the European Food Safety Authority (EFSA) to review the IARC assessment. In its assessment report, BfR reached the conclusion that "If used properly and for its intended purpose, glyphosate is not carcinogenic." (BfR 2019). The BfR assessment was supported by all European Union member states except one (Sweden), and by EFSA.

Mink et al. (2012) conducted a qualitative systematic review, without a meta-analysis, of epidemiologic studies of glyphosate and various cancers, including NHL. Taking into account potential sources of error, including selection bias, confounding, and especially exposure misclassification, the authors concluded that they "found no consistent pattern of positive associations indicating a causal relationship between total cancer (in adults or children) or any site-specific cancer and exposure to glyphosate."

Based on a systematic review and meta-analysis of glyphosate exposure and risk of lymphohematopoietic cancers, on balance, the existing epidemiologic evidence does not favor a causal effect of glyphosate on non-Hodgkin lymphoma NHL, Hodgkin lymphoma (HL), multiple myeloma MM, leukemia, or any subtype of these malignancies (Chang and Delzell 2016).

Based on glyphosate use and cancer incidence in the Agricultural Health Study (AHS): Among 54,251 applicators, 44,932 (82.8%) used glyphosate, including 5,779 incident cancer cases (79.3% of all cases). In unlagged analyses, glyphosate was not statistically significantly associated with cancer at any site. However, among applicators in the highest exposure quartile, there was an increased risk of acute myeloid leukemia (AML) compared with never users (RR = 2.44, 95% CI = 0.94 to 6.32, Ptrend = .11), though this association was not statistically significant. Results for AML were similar with a five-year (RRQuartile 4 = 2.32, 95% CI = 0.98 to 5.51, Ptrend = .07) and 20-year exposure lag (RRTertile 3 = 2.04, 95% CI = 1.05 to 3.97, Ptrend = .04) (Andreotti et al. 2018).

Glufosinate

Phosphinothricin, also known as glufosinate, to which canola, corn, cotton, and soybean have been genetically engineered to be resistant, is a naturally occurring compound. It was isolated from the soil bacteria in the genus *Streptomyces*. It is formulated into products that are typically used as non-selective, foliar-applied herbicides. Products may be registered for pre-plant and post-emergence control of grass and broad leaf weeds in crops and in certain non-crop sites (US-EPA 2016c). Glufosinate has an acute LD50 of 1910, which is EPA category III – of relatively low toxicity.

Herbicides containing the active ingredient glufosinate were first registered by the EPA in 1993. These products have been used on over thirty crops, and for other approved uses, between 1998 and to the present. Glufosinate-containing herbicides are currently registered for use on various non-GE crops, including apples, berries, citrus, currants, grapes, grass grown for seed, potatoes, and tree nuts (US-EPA 2016c). Glufosinate-containing herbicides are currently registered for use on rice in the United States, but they are not used domestically for that purpose. Non-crop uses of glufosinate include weed control on golf course turf, residential lawns, industrial and residential landscape plantings, utility and roadside rights-of-way, and timber site preparation for tree plantings (US-EPA 2016c). The EPA is currently reviewing glufosinate and issued preliminary ecological and human health risk assessments in 2016 (US-EPA 2016c).

Dicamba and 2,4-D

Dicamba[69] and 2,4-D[70] have been widely used in agriculture for over 40 years, and EPA risk assessments of current formulations have classified both herbicides as being relatively environmentally benign. Both, being plant hormone (auxin) regulators, have low to moderate acute and chronic toxicities to mammalian, bird, and fish model organisms; degrade fairly rapidly in the soil; and are not known to bioaccumulate. 2,4-D generally has low toxicity for humans, except for certain acid and salt forms can cause eye irritation. 2,4-D generally has moderate toxicity to birds and mammals, is slightly toxic to fish and aquatic invertebrates, and is practically nontoxic to honeybees. However, the ester forms of 2,4-D can be highly toxic to fish and other aquatic life, hence, following of label use requirements is imperative. Aquatic animals are more sensitive to 2,4-D as water temperature rises. Dicamba's toxicity to honey bees ranges

[69] National Pesticide Information Center, Dicamba, Technical Fact Sheet: http://npic.orst.edu/factsheets/archive/dicamba_tech.html#toxbox

[70] National Pesticide Information Center, 2,4-D, Technical Fact Sheet: http://npic.orst.edu/factsheets/archive/2,4-DTech.html#ecotox

from moderately toxic to practically non-toxic. It is not expected to be a hazard to other beneficial insects.

By design, both dicamba and 2,4-D are extremely toxic to broadleaf plants. For many terrestrial and aquatic plant species, the EPA assessments rank the ecotoxicological risks for both dicamba and 2,4-D well above their set levels of concern. Based on risk assessments comparing a suite of 12 herbicides, the risk to terrestrial plants for dicamba and 2,4-D is around 75 and 400 times greater than glyphosate, respectively (Mortensen et al. 2012).

Furthermore, both dicamba and 2, 4-D are more volatile than glyphosate and so damage to broadleaf crops from spray drift is a concern. Both Monsanto (developer of dicamba resistant crops) and Dow (developer of 2, 4-D resistant crops) have registered low volatile formulations of dicamba and 2, 4-D respectively. Extensive damage from dicamba drift has been reported each year dicamba resistant crops have been grown (Bradley 2018). In 2015, dicamba resistant crops were available for planting but low volatile formulations were not yet registered by the EPA for use. Growers illegally sprayed dicamba resistant crops with high volatile formulations not registered for this use and crop damage ensued from drift. The following year, low volatile formulations of dicamba were registered and available for use but drift still remained a problem, according to the EPAs web site.[71] In 2017, the EPA reached an agreement with manufacturers on measures to further minimize the potential for drift to damage neighboring crops from the use of dicamba formulations used to control weeds in GE cotton and soybeans. The registrants voluntarily agreed to registration and labeling changes including making these products restricted-use, record keeping requirements, and certain additional spray drift mitigation measures. Manufacturers have agreed to a process to get the revised labels into the hands of farmers in time for the 2018 growing season. When the EPA registered these products, it set the registrations to automatically expire in two years to allow the EPA to change the registration, if necessary. The EPA has monitored the success of these changes to help inform their decision whether to allow the continued over-the-top use of dicamba beyond the 2018 growing season. In 2018, EPA extended the registration for two years for over-the-top use (i.e. use on growing plants) of dicamba to control weeds in fields for cotton and soybean plants genetically engineered to resist dicamba. This decision was informed by extensive collaboration between EPA, the pesticide manufacturers, farmers, state regulators, and other stakeholders. The registration includes label updates that add protective measures to further minimize the potential for off-site damage. The registration will automatically expire on December 20, 2020, unless EPA further extends the registration

3.4.3 Pest and Weed Resistance

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 weed resistance. However, it is not a direct correlation; development of (selection for) resistant populations depends on various factors, such as insect and weed characteristics, pesticide chemical properties and MOA, and cultural practices. Cultural practices would include crop rotation, tillage

[71] https://www.epa.gov/ingredients-used-pesticide-products/registration-dicamba-use-genetically-engineered-crops

practices, continuous or repeated use of a single herbicide versus use of several herbicides that have differing MOAs, and use of chemicals at the recommended dosage.

3.4.3.1 Pest Resistance Management

As reviewed above in Section 3.4.2.2, GE IR based crops can reduce the need for chemical insecticides 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 long-term use could promote the development of insect populations resistant to the IR trait.

It has long been recognized that continued exposure of crop pests to pesticides through aerial or ground applications can result in the development of resistant (adaptation) populations. This is, likewise, an important issue for GE plants, and other organisms with pest resistant traits. A 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 some Bt crops due to developed resistance to Bt derived plant incorporated protectants (PIPs) has been reported for 5 of 13 major pest species examined, compared with resistant populations of only one pest species in 2005 (Tabashnik et al. 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 et al. 2013).

While the use of Bt crops has been effective as part of integrated pest management programs used in commercial crop production, their efficacy will wane if pest resistance is selected to the mechanism of action of the particular Bt Cry protein[72] through exposure. Thus, where and when not judiciously used, GE IR crops may see a decline in efficacy over time, while also contributing to increasingly limited pest management options. This limitation would be especially problematic in organic agriculture where Bt insecticide is one of the few pesticides compliant with 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 IRM strategies are employed to minimize the selection of resistant insect populations.

Genes and or gene products introduced into plants that confer resistance to pests are known as PIPs. 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.[73] Current GE IR crops that contain EPA regulated PIPs include Bt potato, corn, cotton, and soybean (US-EPA 2015e). Not all PIP plants produce a protein as is the case for GE plum conferring resistance to the plum pox virus.

[72] Bacillus thuringiensis (Bt) strains synthesize crystal (Cry) and cytolytic (Cyt) proteins that are toxic to certain orders of insects.
[73] NOTE: EPA does not regulate the GE plant itself, only the inserted PIP gene(s)/protein(s).

Due to concerns regarding the selection of insects that are resistant to GE plants expressing PIPs, the EPA has established mandatory insect resistance management (IRM) practices for specific crop types, which include the incorporation of structured or natural refuges[74] to reduce the likelihood of pest resistance development (US-EPA 2015b). As part of this program, in January of 2015 the EPA proposed a framework to reduce corn rootworm resistance (US-EPA 2015a). 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 under public review on a continual basis. The EPA's docket for general information on insect resistance management can be found under docket number, EPA-HQ-OPP-2011-0922.[75]

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 2010), 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 et al. 2013).

3.4.3.2 Weed Resistance Management

Herbicide Resistant Weeds

Herbicide resistant weeds are not subject to regulation under 7 CFR part 340 unless the herbicide resistant weed poses a plant pest risk. Similarly, the selection of herbicide resistant weeds through herbicide use is not regulated by the USDA; rather, herbicide use is regulated by the EPA. 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.

Concomitant with the use of herbicides to manage agricultural weeds has been the selection of herbicide resistant weed populations. It is well recognized that the singular, long-term use of an herbicide will likely promote the selection of resistant weed populations (Owen 2011; Vencill et al. 2012). 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. This is not unique to GE crops; herbicide resistance has routinely occurred with conventional crops and herbicides since the introduction of herbicides in the 1950s (Figure 3-35).

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[74] 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.

[75] http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2011-0922

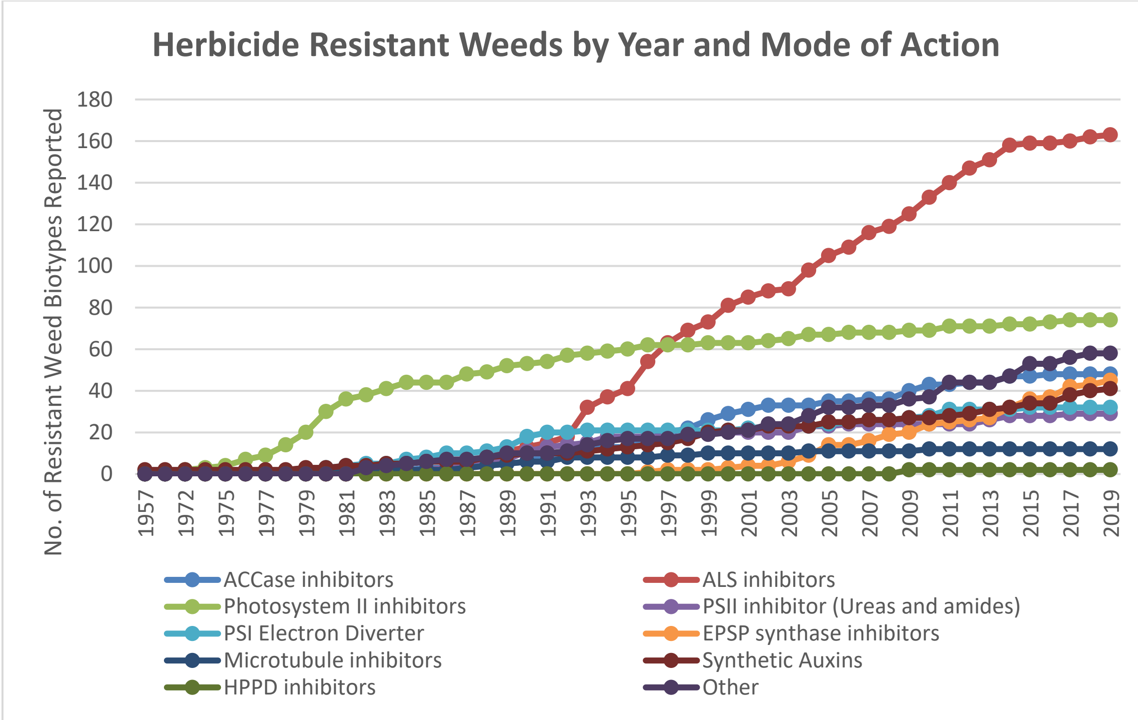

Figure 3-35. Increase in the Development of Herbicide Resistance: Herbicide Modes of Action The herbicide groups with the most herbicide resistant weeds are acetolactate synthase (ALS) inhibitors (e.g., imidazolinone and imazethapyr); ACCase inhibitors (e.g., phenylpyrazoline); triazine based photosynthesis II inhibitors (e.g., atrazine); synthetic auxins (e.g., dicamba, 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 2020)

Whether among GE or non-GE crops, the tendency for the selection of herbicide resistance is dependent on the type, quantity, and modes of action of herbicides used in crop production, the plant/weed species present in the area where the herbicides are applied, and weed management practices employed. Selection of herbicide resistant weed biotypes is a consequence of basic evolutionary processes driven by selection pressure. Herbicide resistant weed populations are selected when a plant naturally resistant to the herbicide active ingredient survives, reproduces after exposure to an herbicide, and passes the resistant trait on to future generations of the plant. With repeated herbicide use, selection pressure for resistant weed biotypes can be significant, and resistant biotypes flourish by deposition of naturally resistant seed in the soil seed bank.

Weed management decisions are a vital aspect of this process, as certain weed management practices impart strong selection pressures[76] on weed communities, which can result in shifts of weed species at the local level (Owen 2011; Owen 2012; Vencill et al. 2012). Fundamentally, overreliance on a single weed management strategy, particularly utilization of a single herbicide

[76] 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.

mode of action, can cause intense selection pressure on weed populations. Over time, with no change in weed control strategies, the weed population selected will be for those species naturally resistant to an herbicide MOA. In this context, selection pressure is the extent to which plants are either eliminated or favored by environmental conditions and herbicide exposure (Vencill et al. 2012).

As of 2019, forty eight states report the presence of herbicide resistant (HR) weed populations. The top 15 herbicides (a.i.) with resistant weed populations are summarized in Figure 3-36. Weed populations resistant to specific modes of action are summarized in Table 3-25. Development of resistance has occurred most frequently with the long-used triazine, atrazine, and the acetolactate synthase (ALS) inhibitors imazethapyr, tribenuron-methyl, imazamox, and mesosulfuron-methyl. For glyphosate, which is most commonly used on GE HR crops, there are currently 48 unique cases of resistant weeds worldwide. For two other herbicides used on GE HR crops, there is one species resistant to glufosinate and two species resistant to dicamba (Heap 2020).

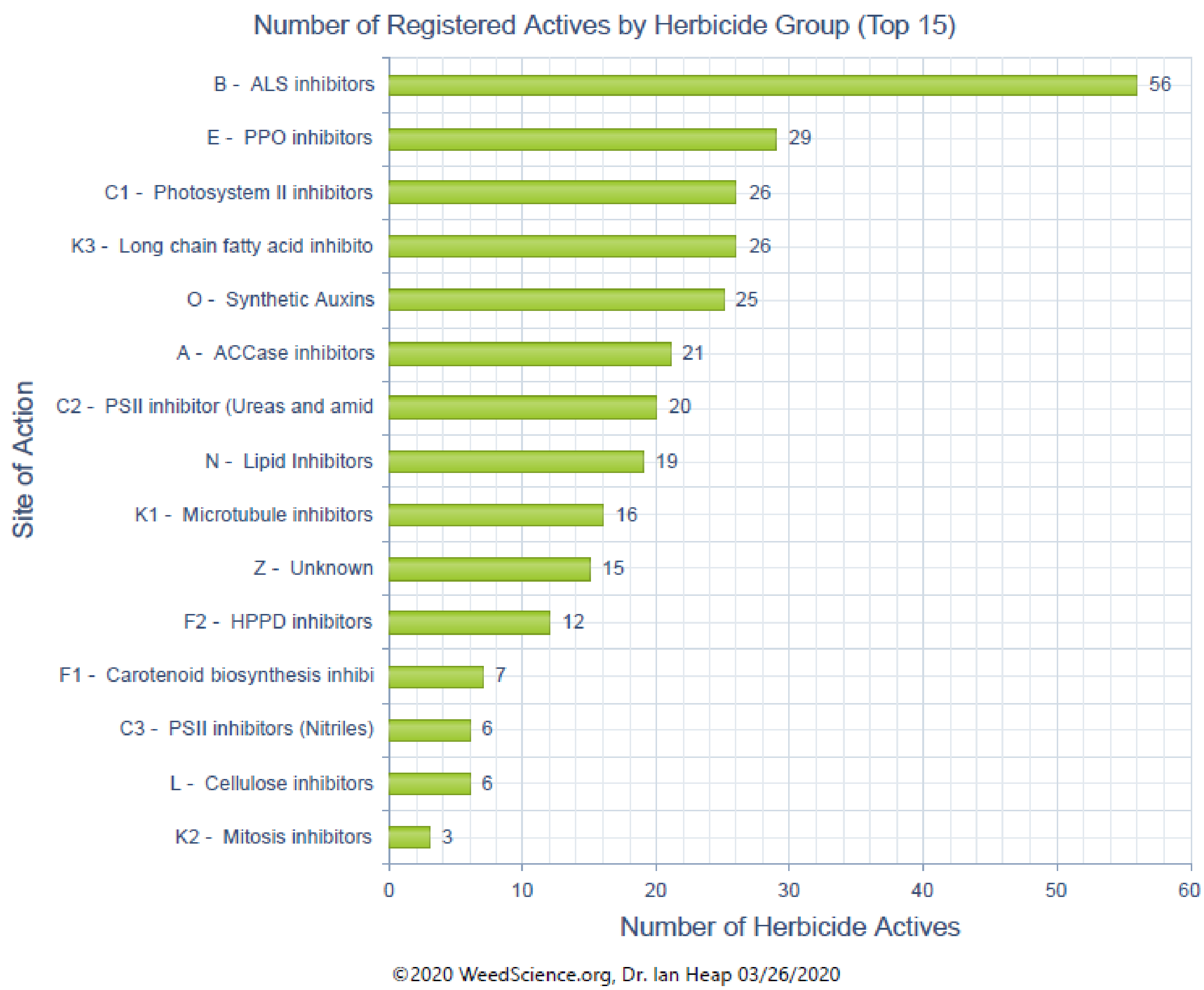

Figure 3-36. Top 15 Herbicides and the Number of Herbicide Resistant Weed Species, 2020 - Globally

Source: (Heap 2020)

Table 3-25. Herbicide-Resistant Weeds by Mode of Action, 2020						
	Herbicide Group	**HRAC Group**	**Example Herbicide**	**Dicots**	**Monocots**	**Total**
1	ALS inhibitors	B	Chlorsulfuron	101	64	165
2	Photosystem II inhibitors	C1	Atrazine	51	23	74
3	ACCase inhibitors	A	Sethoxydim	0	49	49
4	EPSP synthase inhibitors	G	Glyphosate	24	24	48
5	Synthetic Auxins	O	2,4-D	33	8	41
6	PSI Electron Diverter	D	Paraquat	22	10	32
7	PSII inhibitor (Ureas and amides)	C2	Chlorotoluron	11	18	29
8	PPO inhibitors	E	Oxyfluorfen	10	3	13
9	Microtubule inhibitors	K1	Trifluralin	2	10	12
10	Lipid Inhibitors	N	Triallate	0	10	10
11	Carotenoid biosynthesis (unknown target)	F3	Amitrole	2	5	7
12	Long chain fatty acid inhibitors	K3	Butachlor	1	5	6
13	PSII inhibitors (Nitriles)	C3	Bromoxynil	3	1	4
14	Carotenoid biosynthesis inhibitors	F1	Diflufenican	3	1	4
15	Glutamine synthase inhibitors	H	Glufosinate-ammonium	0	4	4
16	Cellulose inhibitors	L	Dichlobenil	0	3	3
17	Antimicrotubule mitotic disrupter	Z	Flamprop-methyl	0	3	3
18	HPPD inhibitors	F2	Isoxaflutole	2	0	2
19	DOXP inhibitors	F4	Clomazone	0	2	2
20	Mitosis inhibitors	K2	Propham	0	1	1
21	Unknown	Z	Endothall	0	1	1
22	Cell elongation inhibitors	Z	Difenzoquat	0	1	1
23	Nucleic acid inhibitors	Z	MSMA	1	0	1
	Total			256	239	495

This table lists the number of species resistant to each mode of action. Please note that many species have evolved resistance to more than one mode of action, so the grand total represents unique cases of resistance (species x MOA), not the number of distinct species.

Source: (Heap 2020)

Over 80 HR weed species have been reported in the United States (Heap 2020). Because many of these HR weeds are resistant to more than one herbicide mode of action (MOA), as of 2019, there were 165 unique cases of HR weeds (weed species x MOA). Weed species resistant to multiple herbicide MOAs are becoming more widespread and diverse (Figure 3-37). As of 2019, there were 104 species resistant to 2 MOAs, 64 species resistant to 3 MOAs, 32 species to 4 MOAs in the United States (Heap 2020). Various species have evolved resistance to 5 or more MOAs (Figure 3-37). A detailed and continuously updated list of herbicide resistant weed biotypes is maintained on the International Survey of Herbicide Resistant Weeds website (Heap 2020).

Weeds have developed resistance to the majority of herbicide MOAs that are currently available, complicating the weed control options available to growers. There have been no herbicides with completely novel MOAs developed and commercialized in recent decades (Duke 2012).

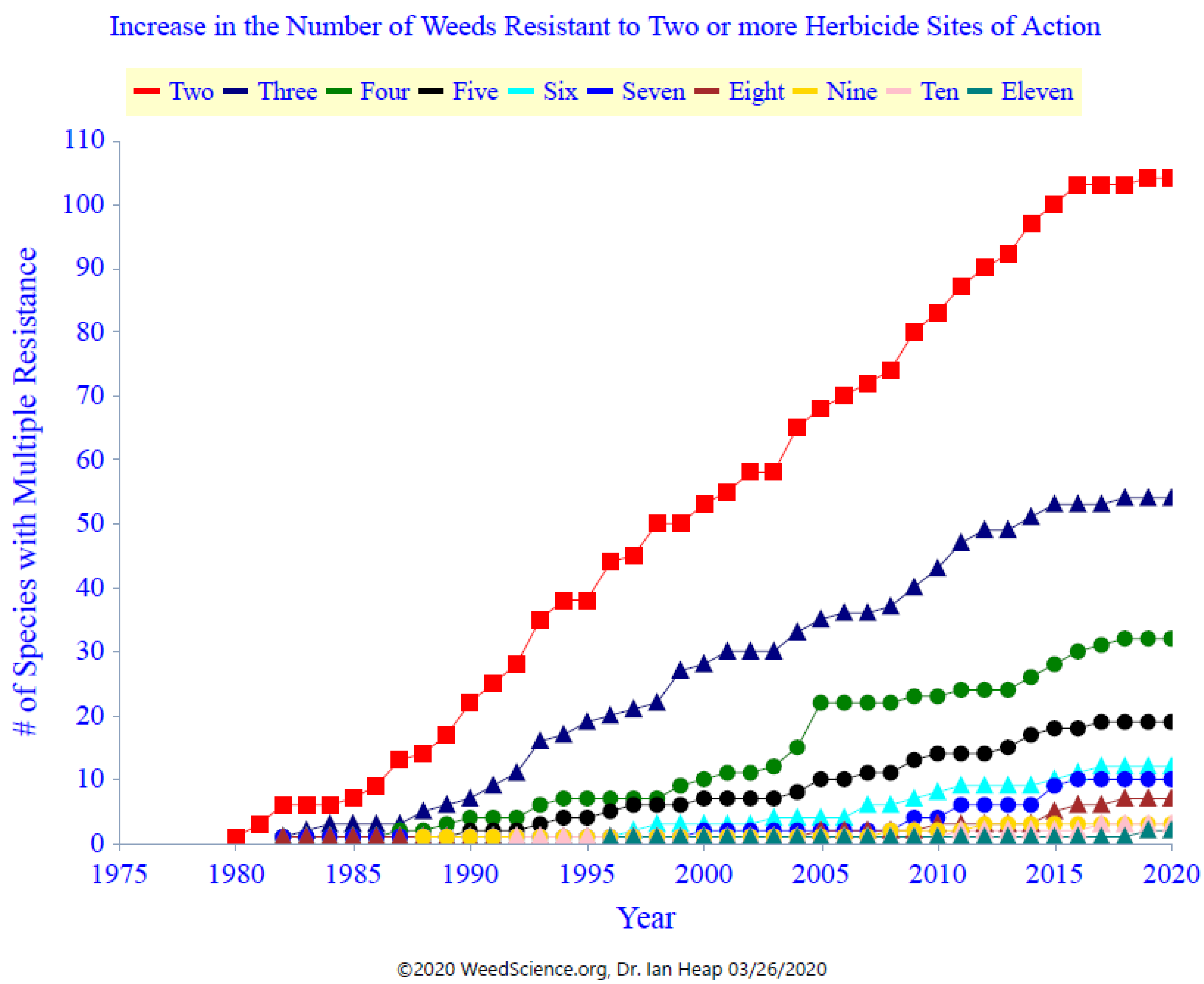

Figure 3-37. Weeds with Resistance to Multiple Herbicide Modes of Action
Source: (Heap 2020)

As discussed previously in Section 3.4.2.2.3 – Herbicide Use, while GE crops have contributed to the selection of resistant weed biotypes, they are not a singular cause. For instance, increased herbicide use in recent years (since 1990), and thereby selection for HR weeds, has been occurring in non-GE wheat. There has also been increased herbicide use in non-GE rice, with more resistant weed varieties in rice than in GE soybean. Herbicide use intensity, as measured by the number of herbicide applications being made to each field, has increased in corn, soybean, cotton, rice, spring wheat, and winter wheat, regardless of whether they were GE or non-GE (Kniss 2017). Among GE HT corn, soybean, and cotton, and non-GE rice and wheat, herbicide use increased faster in rice, spring wheat, and winter wheat as compared with GE HT corn, soybean, and cotton (Kniss 2017). Some researchers have blamed glyphosate-resistant crops and the resulting evolution of glyphosate-resistant weeds for increasing herbicide use in maize, soybean, and cotton (Benbrook 2016). While this explanation is plausible for these three glyphosate-resistant crops, it cannot explain the similar trends for increasing herbicide intensity in rice and wheat, since no glyphosate-resistant cultivars are commercially available for those crops. The claim that glyphosate-resistant crops are the primary driver of increasing herbicide use is at odds with the empirical data. As (Kniss 2017) states, "the broader problem of herbicide-resistant weeds (rather than the artificially narrow focus on glyphosate) may certainly have played a role in increasing herbicide use for all of the crops in this analysis. The most likely explanation, though, is probably a combination of inter-related factors and is far more complex than any single driver." Herbicide use trends in wheat, corn, rice, and soybean (discussed in Section 3.4.2.2.3), are reflected in the prevalence of resistant weed biotypes among these cropping systems (Figure 3-38).

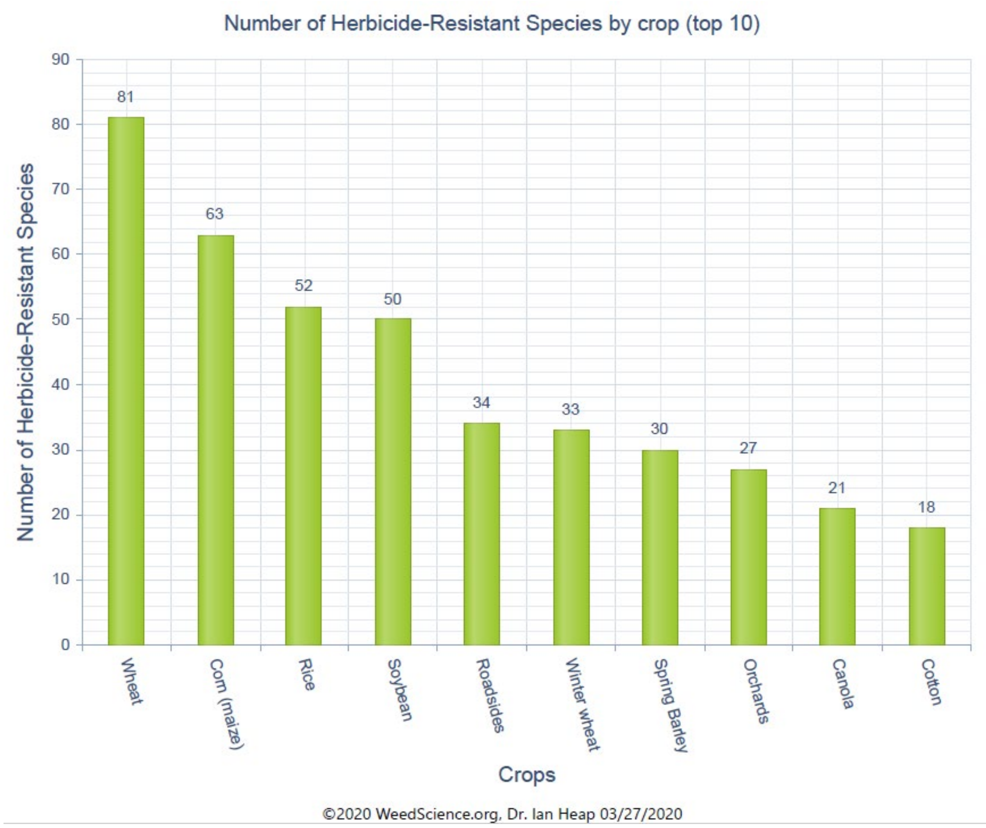

Figure 3-38. Number of Herbicide-Resistant Weeds by Crop Type, 2020

Source: (Heap 2020)

When glyphosate-resistant crops were first commercialized in the United States, neither the USDA nor the EPA required resistance-management plans to delay the evolution of glyphosate-resistant weeds (NAS 2016b). In general, at that time, herbicide-resistant weed management was not widely practiced. The repeated use of glyphosate on glyphosate-resistant crops, which were adopted rapidly and widely, quickly led to selection for weed populations naturally resistant to glyphosate (NAS 2016b). More recently EPA has undertaken a more active role in herbicide resistance management with the issuance of guidance (US-EPA 2017c). It requires reporting to the EPA of any new herbicide resistant weed populations, provides growers and users with detailed information and recommendations to slow the selection and spread of herbicide resistant weeds, and provides a mechanism to identify case specific measures that are deemed appropriate to reduce the risk of selection and spread of weeds such as disallowing reapplications of the herbicide on the same crop in the following year or time limited registration. There are new requirements to include on the label the MOA of the herbicide, application parameters, and recommendations for best practices for weed management. There is also an education component that includes distribution of local resistance management plans.

Herbicide Resistance Management Strategies

Strategies for the effective management of herbicide resistant weeds, and preventing their development, remains a debated topic. Over-reliance on and the inefficient use of herbicides has sparked debate on how to best incorporate herbicides into sustainable weed management systems (Mortensen et al. 2012; Harker et al. 2017; Kniss 2017). The need for control of development of herbicide resistant weed populations has been addressed in part by the development and adoption of stacked-trait varieties of GE crop plants, which allow use of multiple herbicides with varying MOAs. GE varieties incorporating three or four traits are now common. While this is an emerging and widely practiced strategy, the efficacy of this approach, due to the nascency of these types of GE crops, and need for proper implementation of the cropping strategy, is not well established.

In general, there is disagreement in the weed-science research community about the benefit of stacking multiple HR traits and spraying multiple herbicides for resistance management (NAS 2016b). Critics of this strategy assert that this technology will allow herbicides to be used over vastly expanded areas, and will likely create three interrelated challenges for sustainable weed management. One, that stacked-trait HR crops are likely to increase the severity of resistant weeds. Two, that stacked-trait HR crops will facilitate a significant increase in herbicide use, with potential negative consequences for environmental quality. Three, that this strategy will deter further research into integrated weed management (Mortensen et al. 2012). Others acknowledge that stacking is unlikely to prevent HR weeds from eventually being selected (Evans et al. 2015), but nevertheless see a benefit in stacking multiple HR traits from the expected delay in the time for resistant weeds to be selected.

Most scientist and agronomists advise that weed management involves more than herbicide diversity; that there needs to be greater diversity in crop rotation, which tends to decrease the dominance of individual weed species, and often leads to the use of herbicides with different MOAs (Owen 2011; Shaner and Beckie 2014; Harker et al. 2017). Many weed scientists argue that more research on herbicide alternatives is required, that research on allelochemicals and biofumigants, diverse crop rotations, higher crop seeding rates, intercropping, competitive cultivars and planting patterns, physical weed control, weed seed destruction, and reducing weed seed and vegetative propagule dormancy is crucial for the sustainable management of weeds (Harker et al. 2017). In regard to stacked-trait GE HR varieties, more research at the farm level and in experimental plots and biochemical, genomic, and population genetic research are needed to decrease the uncertainty and develop better resistance-management approaches (NAS 2016b). Fundamentally, absolute reliance on herbicides to solve all weed problems is economically and environmentally unsustainable (Gill and Holmes 1997; Zimdahl 2007; Owen 2011; Vencill et al. 2012).

Strategies for managing and avoiding the selection of HR weed populations are becoming increasingly well-developed for use in U.S. agriculture. Crop producers are advised to use, integrated weed management (IWM) practices to address HR weed management concerns. These practices are strongly recommended by the crop protection and crop seed industries, the USDA, university extension services, the EPA, state departments of agriculture, Weed Science Society of America (WSSA 2016), and others (Weller et al. 2010; Owen 2011; Owen 2012; Vencill et al. 2012). IWM includes timely herbicide applications, use of herbicides with multiple MOAs, crop rotation, cover crops, various tillage practices, weed surveillance, and hand-pulling (Owen 2011; Garrison et al. 2014; CLI 2020a). It is important that growers use herbicides with diverse mechanisms of action in an IWM program to delay the selection of HR weeds (Wilson et al. 2009; Shaw et al. 2011; Vencill et al. 2012).

Developers of GE HR varieties provide stewardship and IWM guidance to crop producers (e.g., (Bayer-CropScience 2016; Pioneer 2016)) that is in accordance with and responsive to the EPA requirements and WSSA recommendations. In 2017, as noted above, the EPA issued PR Notice 2017-2, *Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship* (US-EPA 2017c). PRN 2017-2 indicates that the EPA is providing HR weed management guidance for herbicide labeling, education, training, and stewardship for herbicides undergoing registration review and for label registration (i.e., new herbicide active ingredients, new uses proposed for herbicide-resistant crops, or other case-specific registration actions). 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 that work with USDA (IPM 2020).

There is some evidence that HR 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 et al. 2015). While IWM can generally be successful in deterring herbicide resistance in the short term while reducing weed infestations and maintaining crop yield potential, it may take many years to affect the weed seed bank. 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 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 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.

Fundamentally, sustainable weed management will only be achieved if there is diversity in both the agroecosystem and in the herbicide and non-herbicide tools employed for weed control (IWM) (Shaner and Beckie 2014). However, grower management of herbicides may not align with what weed scientists recommend for optimal management of development of resistant weed populations. Growers may not adopt recommendations they perceive as being too expensive, time consuming, or complicated (Shaner and Beckie 2014). Because of the inherent economic risks in farming, it may be difficult for some growers to think long-term when the economic viability of their farm enterprise is at stake (Shaner and Beckie 2014). Moreover, growers who rent or lease land, may have less incentive for land stewardship, including adoption of IWM practices, than growers that own the land (Shaner and Beckie 2014).

3.4.4 GE Forest and Orchard Trees

GE fruit trees have been and are developed for commercial food markets (e.g., apple, plum, orange). GE trees are also being explored for use in commercial forestry and for ecological restoration purposes (e.g., eucalyptus, pine). APHIS has authority to regulate a GE tree when such a tree is a 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 (USDA-APHIS 2020a).

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.

3.4.4.1 Orchard Trees

Various GE orchard and plantation trees have been developed and field tested, including apple, avocado, banana, European plum, papaya, lime, and grapefruit. As of 2018, the GE orchard trees of apple (non-browning trait), plum (plum pox virus resistant), and papaya (papaya ringspot virus resistant) have been deregulated under 7 CFR part 340. GE ringspot virus resistant papaya is in commercial production in Hawaii, commercial production of GE non-browning apple has begun with sales of fruit in the Midwest in 2017 (Okanagan 2017), and plum 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. Crosses 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, cherry, or diploid plum. Cross-compatibility with the Damson plum species (*P. spinosa*) has been reported with hybrid progeny displaying various levels of fertility (Nielsen and Olrik 2001).

Isolation distances between the GE orchard trees 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 et al. 2011). For plum and papaya, gene flow dramatically decreases at distances over 1300 ft/400 m (Mendoza et al. 2008; Scorza et al. 2013a).

Whereas measures are taken to ensure isolation distances from non-GE orchard trees during field trials of flowering fruit trees, the potential harm from gene flow is considered during the petition for nonregulated status. If no harms to plant health are identified, the GE crop can be deregulated with no further restrictions imposed on the growth of that crop.

Fruits arise from maternal tissue and therefore are not genetically modified by gene flow from pollen, though the seeds contained within the fruit can be GE due to gene flow. Detection of biotech traits in seeds could impact the value of the fruit in the GE sensitive marketplace though the fruit itself lacks GE traits. In this way, GE fruit trees have the potential to cause economic harm to the corresponding non-GE crops. Environmental impacts for the virus resistant papaya and plum are beneficial in that they can prevent feral populations from contributing to the spread of virus (USDA-APHIS 2007, 2009). The non-browning trait in apple is thought to be neutral; it does not provide a fitness advantage or disadvantage to the apple and therefore is not expected to cause adverse impacts to feral apple populations through gene flow (USDA-APHIS 2014c).

3.4.4.2 Commercial Forestry

Several varieties of GE forestry trees have been field tested under APHIS authorization, including American elm, loblolly pine, hybrid pitch x loblolly pine, poplar, and eucalyptus. To date, GE trees for commercial forestry purposes have not been issued determinations of nonregulated 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, introduce sexual sterility to prevent pollen-mediated gene flow, improve fiber/wood product quality, expand the range of climate conditions under which a commercial tree species can be cultivated, and/or 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) (Chen et al. 2001; Verma and Dwivedi 2014; Zhou et al. 2017).

3.4.4.3 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.[77] The American Chestnut Research and Restoration Project (SUNY-ESF 2019) 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 trees may also be developed to remove environmental contaminants from soils and wetlands where other forms of cleanup may be prohibitively expensive (Van Aken 2008; Yadav et al. 2010).

3.4.4.4 Field Tests

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, there may exist substantial populations of sexually compatible relatives in the wild and the GE tree itself could likely persist outside areas of commercial cultivation without human intervention. 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 et al. 2010).

APHIS has authorized field tests of eucalyptus, poplar, white spruce, and sweetgum, as well as non-forest trees including papaya, apple, walnut, and plum (see (USDA-APHIS 2020a)). Prior to authorizing field tests, APHIS evaluates whether the field test is confined by assessing a number of factors, 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 et al. 2013). In cases where flowering could potentially overcome the confinement conditions, an environmental analysis would be prepared to consider the environmental impacts.

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, 2012c). Such conditions might require flower buds be removed prior to flowering, that flowering trees must be male sterile, trials to be conducted in areas isolated from sexually compatible relatives, or that field sites are removed from potentially affected threatened and endangered (T&E) species and critical habitats. Permit applicants must indicate how the GE trees will be devitalized upon completion of field testing, and how they will ensure that any underground plant parts capable of vegetative propagation are 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.

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[77] 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.

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 (USDA-APHIS 2017a).

3.4.5 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 regulatory requirements and restrictions in other countries 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 rose (*Rosa hybrida*). A flower color modified petunia was developed in 1987 (Meyer et al. 1987) and bred into commercial petunia lines (Oud et al. 1995), though the varieties were not intentionally released. However in 2017, The Finnish Food Safety Authority discovered that orange petunias for sale in Finland were GE and lacked the proper authority for release (EVIRA 2017). This prompted an international effort to test all petunia varieties in commerce. Over 120 varieties were discovered to have a GE trait that required authorization for entry into and field release within the United States (USDA-APHIS 2017b). The petunia industry has voluntarily removed GE petunias from commerce (USDA-APHIS 2017d).

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, whether the trait would increase the invasive potential of sexually compatible wild relatives if gene flow were to occur (Chandler and Sanchez 2012), and whether the GE trait would lead to the widespread dissemination of plant pests. For field testing of GE ornamentals, the same confinement requirements as prescribed for crop plants apply.

3.4.6 GE Insects and Invertebrates

APHIS has authorized the field testing of GE insects that are plant pests. In all cases these are insects that are being developed to use as biocontrol agents. Among those field tested were diamondback moth (a pest of cabbage type crops), pink bollworm (a pest of cotton), western orchard predatory mite (a beneficial mite that consumes mites such as spider mite and a pest of apples and pears), and a beneficial nematode, *Heterorhabditis bacteriophora*, that controls numerous insect pests.

There are innovative projects with insects involving biotechnology that has not yet been field tested. One project funded by DARPA is named the The Insect Allies program[78] and seeks to evaluate whether insects may be used as vectors to facilitate the spread of GE plant viruses that

[78] https://www.darpa.mil/program/insect-allies funded by DARPA

can help manage or eradicate certain plant pests as well as stress caused by abiotic factors. Another project aims to use gene drives to control plant pests. The gene drive is an emerging technology that promotes the preferential inheritance of a gene of interest, thereby increasing its prevalence in a population (Emerson et al. 2017). Gene drive systems are capable of altering the traits of wild populations and associated ecosystems (Esvelt et al. 2014). Buchman et al. (2018) have shown in a laboratory under highly contained conditions that a gene drive system based on the *Medea* gene can control Spotted wing fruit fly, *Drosophila suzukii* (Buchman et al. 2018).

Biotechnology is also being explored as a means to control insects that spread human diseases such as malaria (Kyrou et al. 2018), Zika virus (Oxitec 2017), and dengue (Oxitec 2017). The FDA and EPA have primary responsibility for regulating GE mosquitos under the FFDCA and FIFRA respectively. If a mosquito-related product is intended to function as a pesticide by preventing, destroying, repelling, or mitigating mosquitoes for population control purposes, the product is regulated by the EPA under FIFRA (US-FDA 2017). Mosquito-related products that are intended for other uses, including preventing mosquito-borne disease in humans or animals or to reduce the virus or pathogen load in a mosquito, are regulated by FDA under the FFDCA.

3.4.7 GE Microorganisms

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, 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, though they are extensively used in contained facilities for the production of food substances, pharmaceuticals, and industrial compounds.

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 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, respectively.

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 2015f):

- 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 19,500 environmental releases of GE organisms as of July 2018 (USDA-APHIS 2020a). These releases have encompassed more than 100 different types of GE organisms, and include row crops, trees, turf grasses, and ornamental plants. 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 creeping 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 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 et al. 2011).

For those GE plants that 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 plants have resulted in adverse environmental impacts that are unique or differ from conventional cropping systems (i.e., (Sanvido et al. 2007; Brookes and Barfoot 2013b; Klümper and Qaim 2014). Hybrids of GE plants x wild relative species that have disrupted ecosystems (altered population structures or 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 2010; NAS 2016b). The use of pesticides 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 2010). For example, 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 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 et al. 2010; Brookes and Barfoot 2010; Tuomisto 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 require continuous research and innovation (FAO 2014a). 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 and timing and quantity of agronomic inputs such as insecticides, herbicides, fertilizers and irrigation).

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 2014a). 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 2014a). 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 altered regional weather patterns on crop production (e.g., drought, pest infestations) (Backlund et al. 2008; Brevik 2013; Hatfield 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 2015a), all agricultural production, GE and non-GE alike, can result in well-understood environmental impacts as described throughout this PEIS. 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 2014a). 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

Overview

In an agricultural setting, concerns regarding soils are the potential for agronomic practices and inputs to affect soil fertility; erosional capacity; off-site transport of sediments, pesticides, and fertilizers; and disturbance of soil biodiversity. Tillage, cover crops, crop rotation, and pesticide and fertilizer inputs can influence the biological, physical, and chemical properties of soil and have a substantial impact on soil fertility, crop yield potential, and soil erosion (Baumhardt et al. 2015a). Soil quality loss occurs through declines in soil organic matter, vital minerals (magnesium, calcium), essential nutrients (nitrogen, phosphorus, potassium), soil biota, and physical alteration of soil structure (compaction). 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. Among these, tillage is the primary practice that can facilitate topsoil loss via wind and water erosion; a process that can take centuries to reverse. Moisture, soil organic matter, and carbon loss can also be exacerbated by tillage (VandenBygaart et al. 2015).

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). Consequently, maintaining soil fertility and precluding soil erosion is a basic requirement of sustainable 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.

Concerns regarding soil quality are the same for all cropping systems, GE and non-GE alike. The following discussion focuses primarily on the chemical and physical aspects of agricultural soils – namely erosion. 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 section below (3.6.4).

Soil erosion

Historically, conventional tillage has served as a primary tool for incorporating crop residues, controlling weeds, and suppressing soil borne diseases. Such practice, however, has not always resulted in effective soil management and has contributed to substantial soil erosion in some areas of the United States. Soil erosion not only increases fertilizer requirements and production costs, it leads to impaired air and water quality. Soil erosion occurs in all areas of the United States, but is more concentrated in those regions where the percentage of total area in cropland is highest and a larger proportion of the land is highly erodible (Magleby et al. 1995; USDA-NRCS 2010; Baumhardt et al. 2015b). Excessively eroding cropland soils are concentrated in the Midwest, Southern High Plains of Texas, and Northern Plain States (Figure 3-39). Where soil erosion occurs through natural processes, the rates of which are determined by soil type, local ecology, and weather, certain tillage and cover crop practices have substantial impacts on the erosion potential of soils. Because susceptibility to erosion is a key concern on more than half of U.S. cropland (USDA-NRCS 2010), soil management and conservation are important components in crop production.

Since 1985, conservation programs have specifically targeted highly-erodible lands in the United States and soil erosion has significantly declined (USDA-NRCS 2010). Since this time growers have increasingly implemented conservation tillage practices and reduced-tillage practices (USDA-NRCS 2006b; CTIC 2015). Farmers are also encouraged to adopt cover crops to conserve soils and soil quality (SARE 2016). Since the mid-1980s, as conservation tillage and no-till practices increased, total soil loss on erodible croplands in the United States decreased from 462 million tons per year to 281 million tons per year, or by 39% as of 2005 (USDA-NRCS 2006d). In the United States, no-till increased from less than 6% in 1990 to almost 24% in 2008, and conservation tillage increased from about 26% to 42% during the same time period (Baumhardt et al. 2015a).

In terms of the relationship between GE cropping systems and tillage, GE HR cropping systems are generally associated with conservation tillage practices. Farmers who use conservation tillage are more likely to adopt GE HR crop varieties than those who use conventional tillage, and those who adopt GE HR crop varieties are more likely to practice conservation tillage than those who use non-GE seeds (Fernandez-Cornejo et al. 2012). Since 2000, corn, cotton, soybean, and wheat acreage under conservation tillage (mulch, ridge, and no till) has increased; the former three crops are primarily GE varieties (Osteen et al. 2012). While both GE crops and the percentage of cropland farmed with no-till and reduced-till practices have concurrently increased over the last two decades, a direct causal relationship between conservation tillage and GE cropping systems is difficult to determine (NAS 2016b). The adoption of no-till and reduced-till practices began in the 1980s, with the rate of adoption increasing over the years due to a combination of factors: the advent of relatively lower cost and effective herbicides, developments of other technologies that facilitate direct seeding, and, in the United States, soil conservation policy introduced with the Food Security Act of 1985 (NAS 2016b). Hence, the initial expansion of no-till and conservation tillage predate the release of the first GE HR crops in the late 1990s (NAS 2016b).

While a distinct causal relationship between GE HR crops and the adoption of conservation tillage practices by growers has not been clearly established, GE HR crops are recognized as facilitating reduced-till and no-till cropping systems (Fernandez-Cornejo et al. 2012). GE HR systems can employ non-residual, broad-spectrum, foliar applied herbicides as a 'burndown' pre-seeding treatment, followed by an 'over the top' post-emergence treatment once the crop has become established. This has proven to be an effective and commercially attractive weed control system for many crop producers (Beckie H.J et al. 2011; Brookes and Barfoot 2015b): The agronomic and economic advantages provided by certain GE HR crops have, in part, contributed to their widespread adoption, which is, in turn, associated with utilization of reduced-till and no-till cropping systems (Beckie H.J et al. 2011; Gusta et al. 2011; Brookes and Barfoot 2015b). In general, the reduction in need for tillage that is facilitated by post-emergence, broad-spectrum herbicides has had both direct and indirect beneficial environmental impacts by facilitating reduction in soil losses and improving soil moisture and carbon retention (Gusta et al. 2011; VandenBygaart et al. 2015).

Fundamentally, land management practices used in crop cultivation can impact 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 2015b). These land management practices are common to, and differ little among GE and non-GE cropping systems. Based on extant data, the current reduced and no-till practices that are predominant in U.S. crop production are considered beneficial to cropland soils (relative to conventional tillage), limiting the impacts of crop production on soil erosion and soil quality in these areas.

In general, as conservation tillage practices increase, total soil loss on erodible croplands in the United States decreases. As of 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. Commensurate with an increased adoption of conservation tillage practices, soil erosion on U.S. cropland decreased 44% between 1982 and 2012. Water (sheet and rill) erosion declined from 1.59 billion tons per year to 0.96 billion tons per year, and erosion due to wind decreased from 1.38 billion tons per year to 0.71 billion tons per year (USDA-NRCS 2015c)(Figure 3-39, Figure 3-40, Figure 3-41). For wind erosion, rates reduced from 3.63 ±0.07 to 2.20 ±0.06 over the same time period (USDA-NRCS 2015c). Any decrease in erosion of cropland carries with it a corresponding decrease in runoff and introduction of non-point source (NPS) pollutants such as sediments, fertilizer, and pesticides into water bodies.

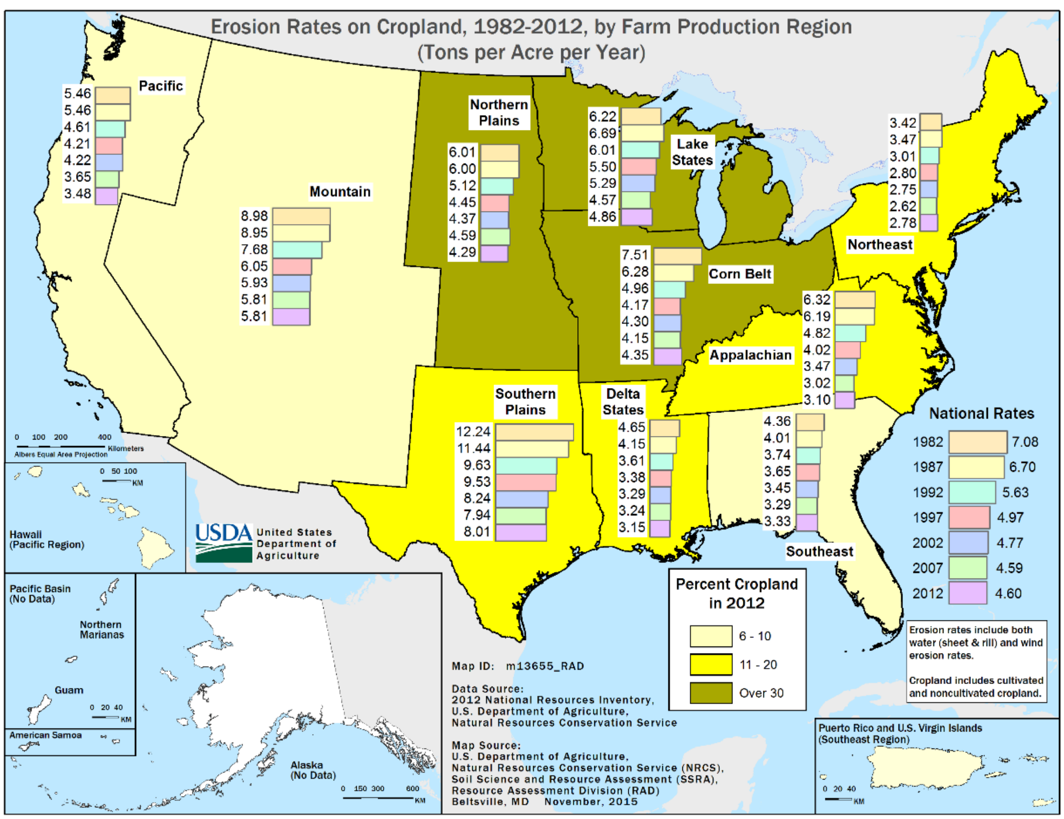

Figure 3-39. Locations of U.S. Croplands Subject to Erosion
Source: (USDA-NRCS 2015a)

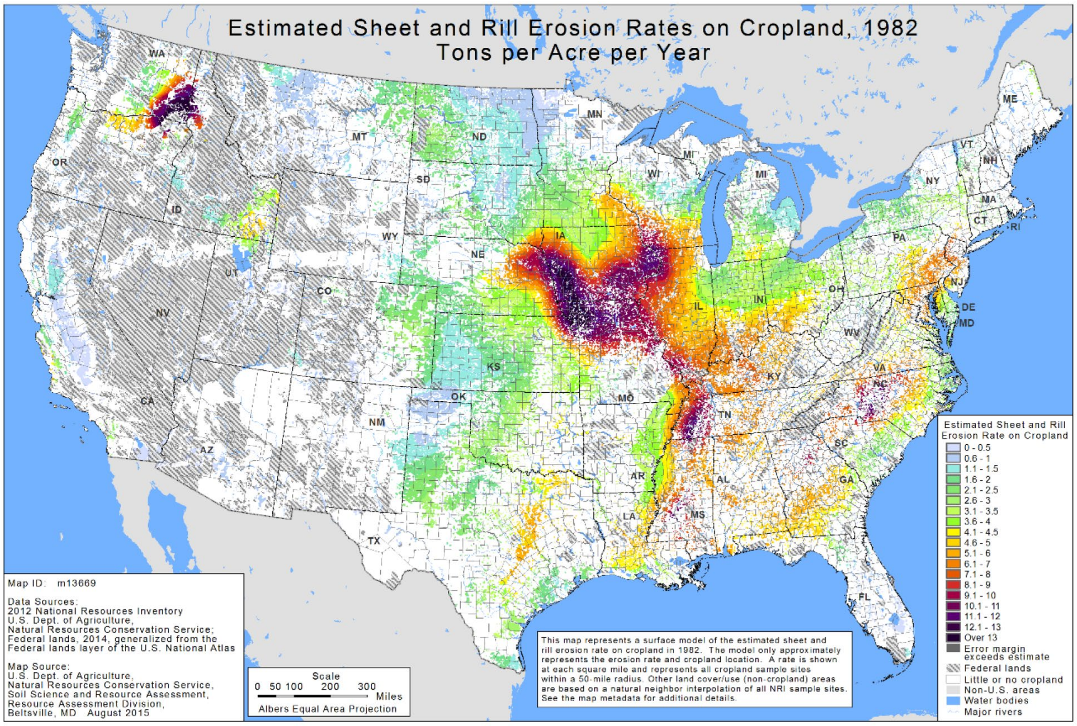

Figure 3-40. Sheet and Rill Erosion, 1982

Source: (USDA-NRCS 2015c)

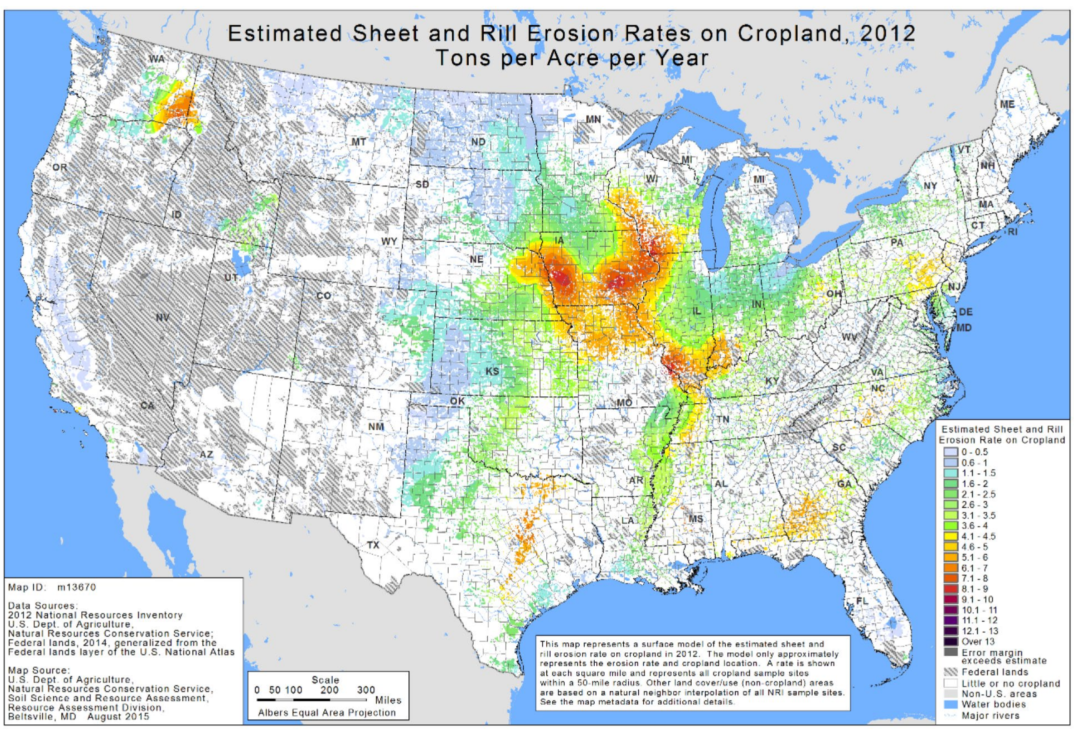

Figure 3-41. Sheet and Rill Erosion, 2012

Source: (USDA-NRCS 2015c)

While erosion rates have steadily declined, in part due to USDA erosion management programs, the development of HR weed populations (Section 3.4.3.2 – Weed Resistance) have forced growers in some areas to include or intensify tillage in order to sustain maximum yields and net returns from 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). The management of HR weeds has emerged as a determining factor in the type of tillage growers will employ: this in turn can impact soil quality and erosional capacity.

For all cropping systems, GE and non-GE alike, 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).[79] 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-Farm Service Agency and USDA-NRCS.[80] State agencies likewise provide assistance in development and implementation of soil conservation plans.

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, or fertilizer); regional climate and weather patterns; and the agronomic practices employed in management of crop residues (US-EPA 2005; Parris 2011; US-EPA 2017b, 2018d). 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 (e.g., proteins or genetic material) into aquatic ecosystems and its potential effect on water resources or the deployment of crops that are better able to scavenge water or use available 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 132 million acre feet in 2015 (latest USGS data), accounting for 42% of the Nation’s total freshwater withdrawals (Dieter et al. 2018). For the 17 contiguous Western states, which account for approximately 74% of irrigated acres, withdrawals of 107.4 million acre feet comprised nearly 81% of the Nation’s irrigation withdrawals (Dieter et al. 2018) (USDA-ERS 2015a).

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

[79] USDA-NRCS: Highly Erodible Land Conservation Compliance Provisions.
http://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/alphabetical/camr/?cid=nrcs143_008440
[80] USDA News Releases - Release No. 0155.14:
http://www.usda.gov/wps/portal/usda/usdahome?contentid=2014/07/0155.xml&contentidonly=true

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 3-42) (Dieter et al. 2018). 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).

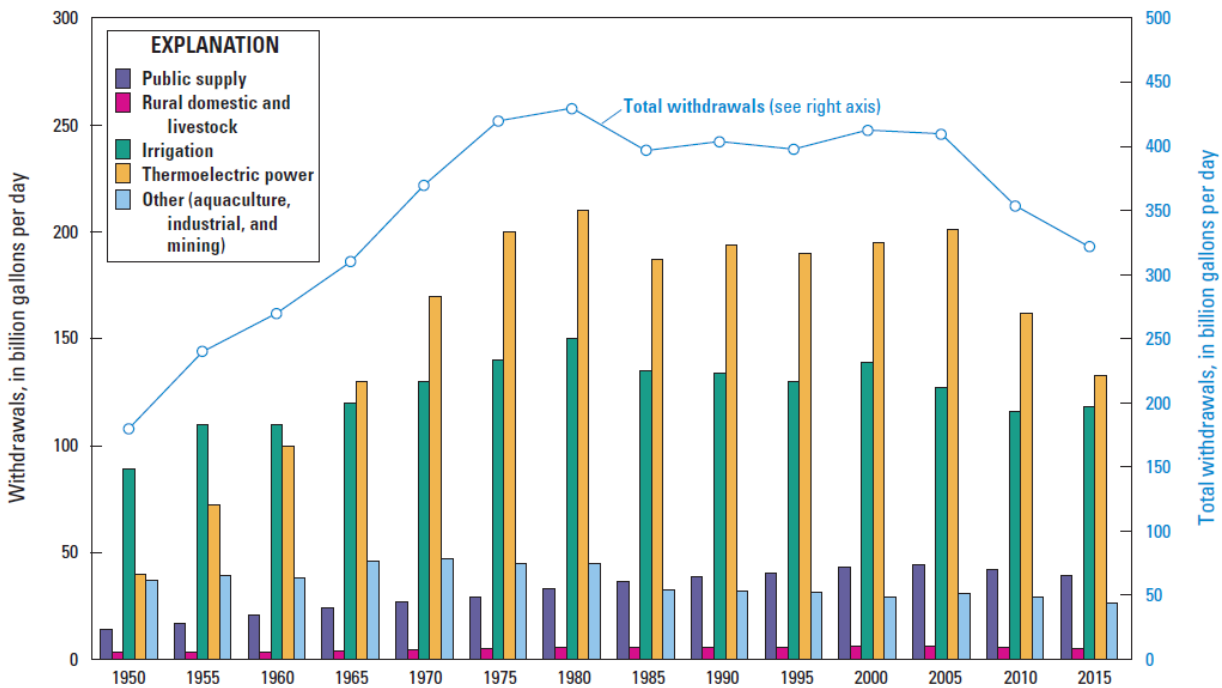

Figure 3-42. Trends in Total Water Withdraws for All Purposes, 1950-2015

Source: (Dieter et al. 2018)

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 3-43). In general, the amount of 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 are increasingly implemented on farms across the United States (Schaible and Aillery 2012).

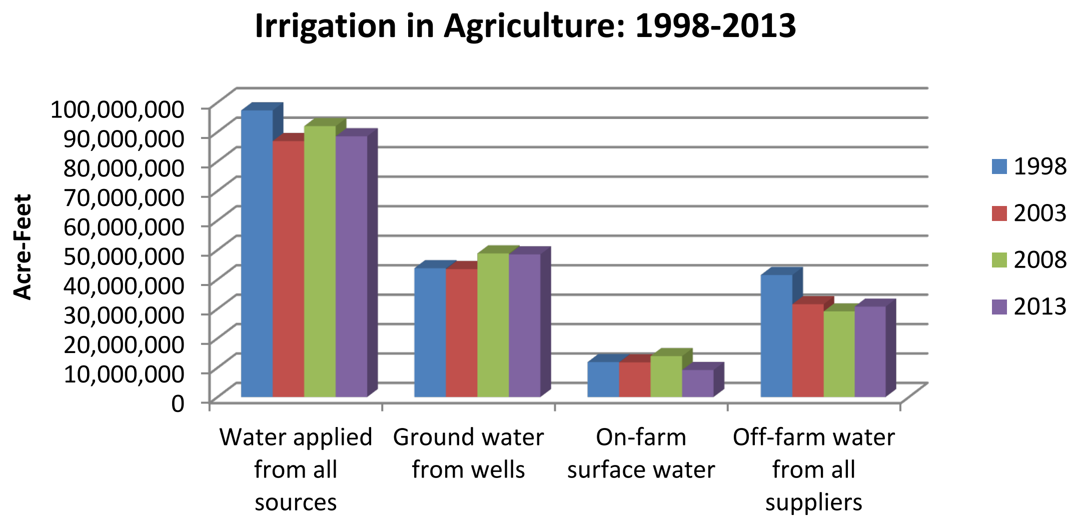

Figure 3-43. Sources and Volume of Irrigated Agriculture, 1998 – 2013
Source: (USGS 2015)

Irrigated farmland is concentrated largely in the Western United States, which reflects regional and local weather patterns and geology (Figure 3-44). 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%), sugarbeets (32%), dry edible beans (29%), and barley (26%). In addition, about 80% of all land in orchards and berries is irrigated (USDA-NASS 2012).

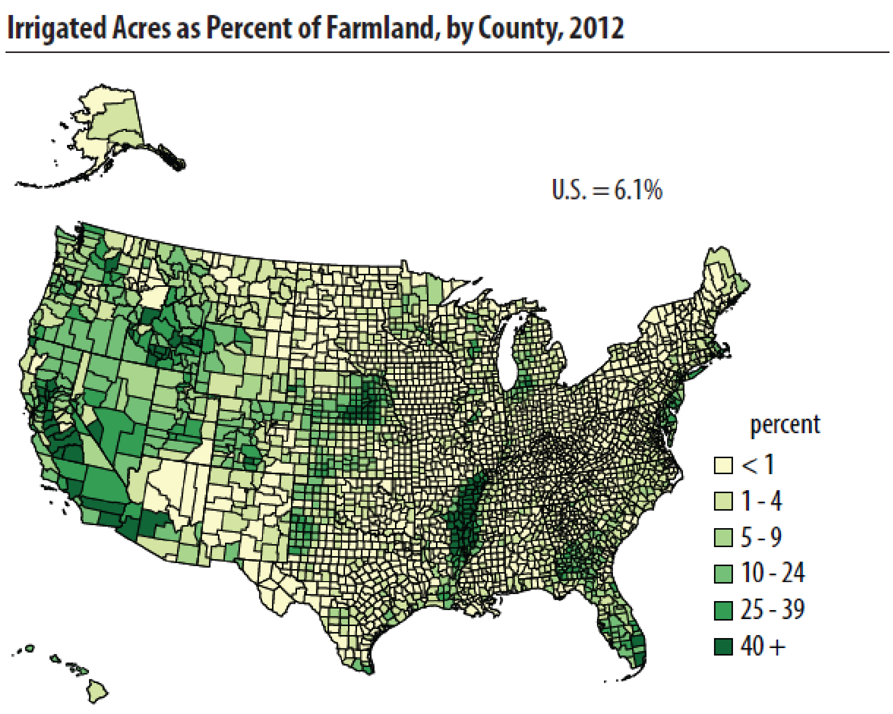

Figure 3-44. Irrigated U.S. Farmland: 2012
Source: (USDA-NASS 2014b)

The geographic distribution of total surface and groundwater withdrawals for irrigation during 2015 (latest data) is shown in Figure 3-45. 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 of less than 20 inches, which is generally considered the minimal sufficiency to support crops without supplemental water (Dieter et al. 2018). Surface water represents the primary source for irrigation in the arid West, and the 17 Western states cumulatively account for 91% of total surface-water irrigation withdrawals and 71% of total groundwater irrigation withdrawals (Figure 3-46) (Dieter et al. 2018). This is indicative of both historic and likely future trends in irrigation withdrawals.

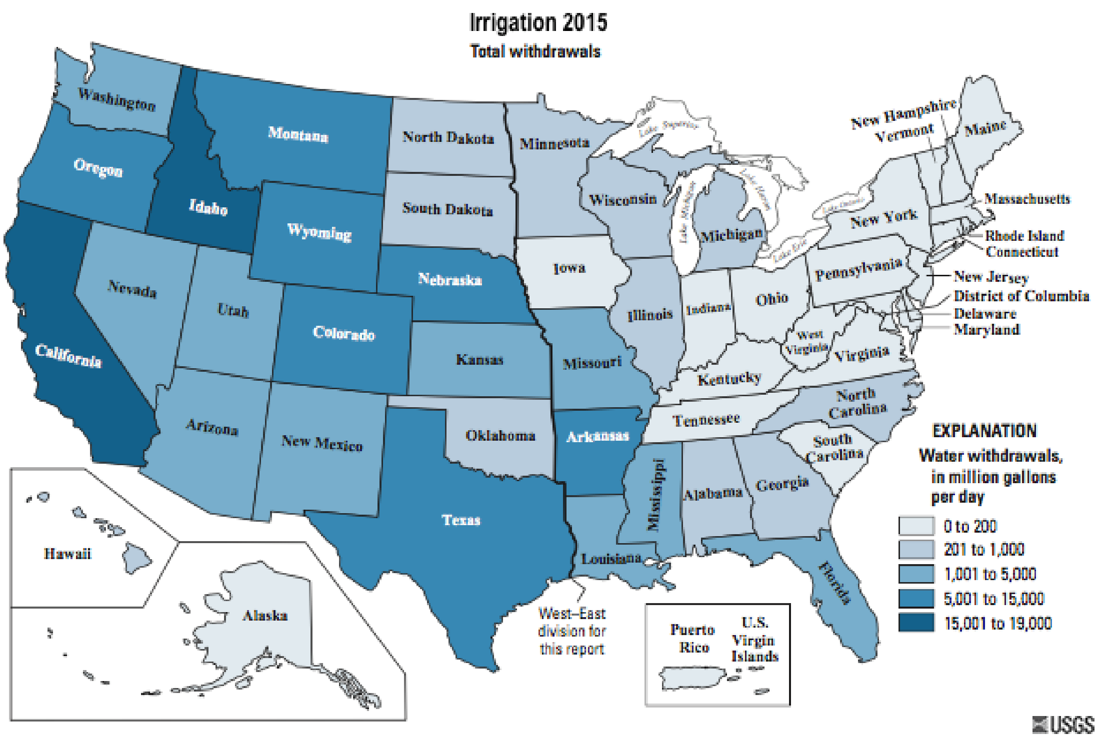

Figure 3-45. Geographic Distribution of Total Surface-Water and Groundwater Withdrawals for Irrigation, 2015
Source: (Dieter et al. 2018)

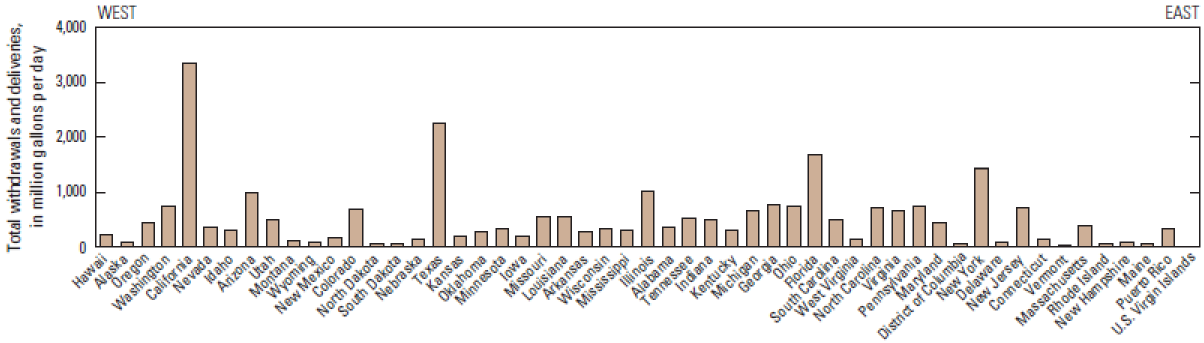

Figure 3-46. Irrigation Withdrawals: Regional Distribution in the United States, 2015

Source: (Dieter et al. 2018)

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. 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 et al. 2012). While irrigation has become more water and energy efficient, water scarcity will likely prove a challenge for agriculture in the 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 2010).

3.5.2.2.2 Variability in Supply

As global mean temperature increases, the availability of water supplies across much of the West are expected to become more variable due to reduced snowpack, 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 users over-drafting water stored in aquifers and reservoirs. While droughts exacerbate supply scarcity, water demands are expected to continue to expand and result in reallocations among competing users, namely industry, agriculture, and municipalities (Wiebe and Gollehon 2006; Osteen et al. 2012). For example, from December 2011 to March 2017, the state of California experienced one of the worst droughts to occur in the region on record (NIDIS 2018).

Any reduced water supplies due to changes in patterns of precipitation, as well as 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 (Water-flow needs for fish and wildlife habitat and other ecosystem benefits), 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 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 et al. 2012). Population growth, Native American water-right claims, water quality improvement initiatives, water related environmental priorities, altered weather patterns, 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 tolerance and salt tolerant plants. GE drought tolerant plants under development may have different water requirements than plants lacking drought tolerant traits. The development of drought tolerant 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 are expected to occur in the future.

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 2019b).

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 streams and rivers, nutrients third, and pesticides sixteenth (Table 3-26) (US-EPA 2018a). 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,[81] 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.

Table 3-26. Causes of Impairment in Assessed Rivers and Streams, 2015

Cause of Impairment Group	Miles Threatened or Impaired
Pathogens	187,872
Sediment	138,874
Nutrients	118,831
Organic Enrichment/Oxygen Depletion	98,037
Temperature	94,448
Metals (other than Mercury)	94,384
Polychlorinated Biphenyls (PCBs)	82,311
Mercury	72,554
Habitat Alterations	63,019
Turbidity	47,750
Cause Unknown	45,318
Cause Unknown - Impaired Biota	44,900
Flow Alteration(s)	41,329
Salinity/Total Dissolved Solids/Chlorides/Sulfates	38,072
pH/Acidity/Caustic Conditions	33,740
Pesticides	18,069

Source: (US-EPA 2018a)

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

[81] Hypoxia means low dissolved oxygen concentrations. Anoxia means a total depletion of dissolved oxygen. Both conditions are harmful to aquatic biota.

meet market demand and support societal needs. Nitrogen, phosphate, and potassium 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 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 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 et al. 2011). Agricultural nutrient losses to streams are a primary concern in the Midwest (Ribaudo 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 2006d).

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 contained one or more pesticides that exceeded a chronic aquatic-life benchmark (ALB). By representing the potential toxicity of pesticides in streams and rivers, ALB toxicity criteria provides a measure of water quality impacts on aquatic life. Across these streams, there were 13 pesticides that exceeded chronic ALBs at more than 5 percent of stream sites (Stone et al. 2014). Two of the pesticides were herbicides (metolachlor and atrazine) and the remainder insecticides (Stone et al. 2014).

Where pesticides remain an issue in agricultural production, the impact of crop production on freshwater systems has declined over the last decade. A 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,[82] 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 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.[83] 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.[84] Therefore, it is unlikely that any PIP registered for commercial uses would present a significant risk to aquatic organisms. Tank et al. (2010) observed that maize detritus is common in low gradient stream channels, and Cry1Ab proteins persist in maize leaves and can be measured in the water column even 6 months after harvest. They concluded that Cry1Ab proteins, are widely distributed and persistent in the headwater streams of a Corn Belt landscape (Tank et al. 2010). Rosi-Marshall et al. (2007) first reported in laboratory feeding trials that consumption of Bt corn byproducts reduced growth and increased mortality of a non-target stream insect, the leaf-shredding trichopteran, *Lepidostoma liba*, while other invertebrate taxa that they examined showed no negative effects. Subsequently the same research team (Chambers et al. 2010) used field studies to assess the influence of Bt maize detritus on benthic macroinvertebrate abundance, diversity, biomass, and functional structure *in situ* in 12 streams adjacent to Bt maize or non-Bt maize fields. They found no significant differences in total abundance or biomass between Bt and non-Bt streams. Though their *in situ* findings did not support their laboratory results (Chambers et al. 2010), they concluded "this is likely because the streams we studied in this region are highly degraded and subject to multiple, persistent anthropogenic stressors (e.g., channelization, altered flow, nutrient and pesticide inputs). Invertebrate communities in these streams are a product of these degraded conditions, and thus the impact of a single stressor, such as Bt toxins, may not be readily discernable." Thus, to the extent that Bt detritus has an effect on aquatic organisms, its effect is undetectable over the background of other effects on these organisms.

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[82] Bacillus thuringiensis (Bt) strains synthesize crystal (Cry) and cytolytic (Cyt) proteins that are toxic to certain orders of insects.
[83] 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
[84] EPA - Introduction to Biotechnology Regulation for Pesticides; https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides#data-requirements

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. The EPA's National Pollutant Discharge Elimination System 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 2015b, d; USDA 2015)). 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 regulations 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 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 2014b).

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. 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. Selection 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 impacts 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 2010).

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. The EPA designates a region as being in attainment for a criteria pollutant if atmospheric concentrations of that pollutant are below the NAAQS or as being in nonattainment if criteria pollutant concentrations violate the NAAQS. States enforce the NAAQS through creation of state implementation plans, which are designed to achieve EPA-established NAAQS.

Crop production practices can generate air pollutants that can potentially affect the environment and human health and can challenge regional NAAQS. These emission sources include: smoke from crop 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 et al. 2009; US-EPA 2013b).

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 impacts on non-target species. Herbicide loss through volatilization can be significant, up to 25 times larger than losses from surface runoff (Gish et al. 2011). While pesticide regulations and requirements for the use of EPA registered pesticides, are the same for both GE and non-GE cropping systems, the timing of the use of pesticides on GE crops may be different, resulting in applications during periods later in the growing season when temperature conditions are more likely to result in increased volatilization.

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.[85] 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 2020c)). 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

[85] EPA - What EPA is Doing to Reduce Pesticide Drift; https://www.epa.gov/reducing-pesticide-drift/what-epa-doing-reduce-pesticide-drift

environmental and human health concern, there are ongoing efforts to reduce the run-off, volatilization, and leaching of pesticides into environmental media (US-EPA 2019a, 2020c).

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 2012a).

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 of chemicals or fertilizer in irrigation systems), and conservation irrigation (USDA-NRCS 2006d, c).

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 Section 3.2 – Major Land Uses in the United States.

3.6.1 Animal, Fungal, and Microbial Communities

The animal, fungal, and microbial kingdoms are integrally related, and the structure and function of various communities of biota among these are interdependent. Viruses, for the purposes of the PEIS, 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 et al. 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 et al. 2005). Some of these beneficial species include the convergent lady beetle, carabid beetles, parasitoid wasps, and predatory mites (Landis 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 Section 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 et al. 2016; Trapero 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 targeted plant pests but may be impacted by the GE trait that confers resistance against a plant pest.

Detailed information on wildlife species in the Major Land Resource Areas discussed above (see Figure 3-7) 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 2006a). 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 PEIS 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 (Rodenhouse et al. 1993; Schoonover et al. 2005; Morandin and Kremen 2013; Bohnenblust et al. 2016).

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 impacts 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 Section 4.3.5 - Agricultural Weeds and HR Weed Management.

The transport and environmental release of regulated GE organisms may be authorized for any area of the United States or its territories. A list of plant species potentially affected by such transport and release is beyond the scope of this PEIS. NRCS provides an extensive list of plants in their online PLANTS Database,[86] 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, and plant species proposed for listing, are discussed in chapter 6 of this PEIS.

3.6.3 Plant Pests and Disease

Various species of animals, fungi, and bacteria provide essential services in the sustainable production of agricultural crops (e.g., 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.[87] Estimated losses from pests and disease are $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 2012). 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 2012). For example, it has been estimated that approximately 65% of U.S. crop losses are due to non-native introduced pests and disease (Fletcher 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 cultivation of a particular crop variety, crop rotation, adjustment of planting dates, and other cultural practices. 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

[86] http://plants.usda.gov/java/

[87] 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]."

minimizing potential crop losses and crop management costs, and achieving maximal crop yields.

Most the pest resistant GE plants field tested have been Bt corn, soybean, cotton, and potato developed for resistance to insects of the orders Lepidoptera, Diptera, Coleoptera, Hymenoptera, Homoptera, Orthoptera and Mallophaga (USDA-APHIS 2020a). 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, virus resistant cassava/yucca, and citrus resistant to the bacteria that causes citrus greening.

GE microbial pesticides have been developed in 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 natural isolates and those produced through techniques of modern biotechnology.

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, including the utilization of biotechnology to develop GE varieties resistant to pests or disease. Consequently, future APHIS review for authorization of movement and field testing under 7 CFR part 340 could consider GE plants developed for resistance to these pests and diseases as well as resistance to pests and diseases in less major crop plants

3.6.3.1 Corn

There are numerous arthropod pests of corn production (Table 3-27), 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 3-27. 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)
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 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 3-28. Major soybean production states are Illinois, Indiana, Iowa, and Minnesota.

Table 3-28. 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 axonopodi*s 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
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 et al. 2010; Whitworth et al. 2015; ISU 2016; UoI 2016; UoM 2016)

3.6.3.3 Cotton

Cotton pests and diseases are listed in Table 3-29. The state with the highest cotton production is Texas, followed by Georgia (USDA-NASS 2019c).

Table 3-29. 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*)	
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, b; UGA 2016; UoA 2016)

3.6.3.4 Potato

Potato pests and diseases are listed in Table 3-30. Major potato-producing states are Colorado, Idaho, Michigan, Minnesota, North Dakota, Oregon, and Washington.

Table 3-30. 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*)	
Potato Spindle Tuber Viroid (Member of Pospiviridae)	
Potato Virus A,M, X, Y (Members of Potyviridae, *Carlavirus*)	
Tobacco Rattle Virus (*Tobravirus*)	

Source: (Johnson et al. 2010; Radcliffe 2010)

3.6.3.5 Forest Related Insect Pests and Diseases

As with commercial crop production, insect pests and diseases can cause catastrophic forest loss. For example, in 2011, tree mortality caused by insect pests 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 3-31.

Table 3-31. 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

There has been some concern that GE organisms, namely GE crop plants, can adversely affect non-target terrestrial and aquatic invertebrates, amphibians, and soil bacteria community structures (Lancaster et al. 2010; Allegrini et al. 2015). Non-target species include any species that may be unintentionally affected by the importation, interstate movement, containment, restricted field testing, or unrestricted environmental release of GE organisms. 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 (such as small mammals and nematodes), pollinators (such as bees, birds, and butterflies), predator species (such as beetles), decomposers (such as earthworms, insects, and soil microorganisms), and plant symbionts (such as rhizobacteria). Effects on soil microorganisms are covered in section 3.6.5-Soil Biota. Effects on

Non-target Invertebrate Populations

For invertebrate populations, the potential for adverse impacts is largely limited to GE plants comprised of PIPs and GE microbial pesticides. 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, insect resistance and herbicide resistance traits have been the most widely used, and are likely to remain the more commonly utilized GE organism-trait-MOA combinations for conferring resistance to pests. The most commonly grown GE PIPs in the United States are IR cotton (85%) and corn (82%) (USDA-ERS 2019). A few other GE traits, such as virus resistant papaya, virus resistant squash, and fungal resistant potato, are cultivated; however, disease resistant crops are produced on a relatively small number of acres worldwide.

There has been considerable focus on the non-target 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 falls into streams or other waterways. Many studies have been done on the currently available PIPs to examine direct toxicity to non-target insects (Marvier 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. Those used in GE plants to date are highly specific to target insects, harmless to vertebrates and plants, and biodegradable (Bravo et al. 2007; Koch 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 et al. 2012).

With GE IR crop plants, predator-prey relationships in the local environment can be 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 if the structure of the vegetation on which non-target species feed is changed (Lundgren 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 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.

PIPs may also be based on RNA interference (RNAi) technology. The potential hazards posed by 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 the food webs of non-target species that could be affected, and lack of models that accurately predict the potential field-level effects from GE plants or other organisms containing an RNAi PIP (Lundgren and Duan 2013).

Many studies indicate that Bt pollen and nectar from deregulated Bt plants 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). 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.[88] In general, extensive investigation has not identified any significant adverse effects of GE Bt crop varieties on non-target insects and other species (Koch et al. 2015).

To date, significant adverse effects on non-target invertebrate communities that are singularly attributed to the commercial use of GE IR crop plants have not been identified (Naranjo 2009;

[88] 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

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 planted 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 et al. 2008; 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 where resistant populations of target insects may be selected through the use of the IR crops. Consequently, insect resistance management has emerged as a basic practice in the production of GE IR crops.

Monarch Butterfly

HR crops containing a glyphosate resistance trait are among the most commonly deployed GE crops. These crops include HR soybean (94% percent of land in soybean production), HR cotton (91% percent of land in cotton production), and HR corn (90% percent). Glyphosate is a very effective herbicide in eradicating milkweed, which can be a problem weed in corn. There has been debate on the role of glyphosate on the decline of monarch butterfly populations. In general, there is as yet no consensus among researchers that increased glyphosate use is associated with decreased monarch populations (Brower et al. 2012a; Brower et al. 2012b; Davis 2012; Ries et al. 2015; Inamine et al. 2016; Pleasants et al. 2016; Stenoien et al. 2016; Agrawal 2017; Saunders et al. 2018). On one side, a group argues that the Midwest milkweed represents an important food resource for monarch larvae and that glyphosate effectiveness in eradicating this food source harms the monarch butterfly population. The group aims to mitigate this harm by reintroducing milkweed plantings into the Midwest on a grand scale. The other side argues that other factors, such as habitat fragmentation and the unavailability of late season nectar plants, are likely responsible for the observed decline in migratory monarch populations (Agrawal 2017). The latter group suggests that wide-scale planting of milkweed is not going to increase populations or save monarch populations from demise and therefore is a waste of resources (Maeckle 2016). The NAS study on GE crops concluded, “Studies and analyses of monarch dynamics reported as of March 2016 have not shown that suppression of milkweed by glyphosate is the cause of monarch decline” (NAS 2016b).

Due to the population decline, the NRCS and others – including the USFWS – have developed a collaborative landscape level partnership to benefit the monarch butterfly (*Danaus plexippus plexippus*) through the design and application of selected NRCS conservation practice standards and enhancements. [89] These conservation practice standards and enhancements are applied by NRCS when providing technical and financial assistance to eligible landowners using its Farm Bill authorities. Other actions implemented by the NRCS include the conversion of suitable monarch butterfly habitat types to other land uses, including crop production; and implementation of certain conservation practice standards and enhancements as part of the application of pesticides/herbicides to benefit the monarch butterfly, including but not limited to Integrated Pest Management and Herbaceous Weed Control.

Amphibians

[89] https://www.fws.gov/savethemonarch/pdfs/MonarchConferenceReport2016.pdf

Worldwide, amphibians are dramatically declining, with more than one-third of all known species threatened with extinction (Wagner et al. 2013). Many ascribe this decline to environmental contaminants, including herbicides. While glyphosate itself does not appear to be toxic to amphibians, certain surfactants used in glyphosate formulations, polyethoxylated tallowamine or polyethoxylated alkylamine, can have lethal and sub-lethal effects on amphibians (Wagner et al. 2013). In contrast, glyphosate formulated for use in aqueous environments is practically nontoxic to amphibians (Wagner et al. 2013). Herbicide use is one among many contributing factors to ongoing global amphibian declines (Boone et al. 2007). The role of glyphosate herbicides remains difficult to assess as field data remain sparse and abnormal population changes have been suggested to often result from multiple interacting causes such as pesticides, habitat destruction, UV-B, and altered weather patterns (Wagner et al. 2013).

In general, the increased use of glyphosate-based herbicides cannot be held responsible for most amphibian population and species losses during the last few decades (Wagner et al. 2013). The majority of population declines in developed countries occurred in the 1960s to 1970s (Houlahan et al. 2000), partly due to the intensification of agriculture in general (Wagner et al. 2013) prior to the commercialization of glyphosate in 1974 (Dill et al. 2010). A new wave of dramatic declines and extinctions of amphibians has been witnessed over the last 3 decades (Mendelson et al. 2006), but these have largely taken place in pristine and remote areas of the tropics (Wagner et al. 2013). Glyphosate-based herbicide use as a causative factor can be ruled out because other potential causes have been identified (e.g., habitat destruction and emerging infectious diseases (Wagner et al. 2013). Tree frogs are the anuran family most sensitive to glyphosate-based herbicides, but their disappearance cannot be causatively linked to increasing glyphosate-based herbicide or other pesticide use. The same holds for the observed disappearance of other sensitive species in agrarian landscapes. While glyphosate-based herbicide use is increasing, farming has been intensified in general and tree frog populations are affected by a multitude of other factors (such as landscape fragmentation) (Wagner et al. 2013). In general, there is no temporal evidence of any association between glyphosate-based herbicide use and observed amphibian declines (Wagner et al. 2013). Rather, Hayes et al (2010) suggests the widely used herbicide Atrazine, an endocrine disruptor, likely affects amphibian populations through a combination of effects and is a likely contributor to global amphibian declines (Hayes et al. 2010).

3.6.5 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 Section 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, soil fungi, and microorganisms (i.e., carbon, nitrogen, phosphorus cycling). Third, climate (Brevik 2013) influences 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 et al. 2004; Gupta et al. 2007). This is particularly relevant as most GE organisms to date 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 et al. 2004; Icoz and Stotzky 2008; Kremer and Means 2009; Carpenter 2011; Kremer 2014; Turrini et al. 2015)).

Most of the scientific literature on this topic 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 et al. 2008); and (2) the potential effects of 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, both direct effects from the gene product itself, and whether there may be pleiotropic effects,[90] because the trait is known to influence the expression of other genes, are considered.

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 EPSPS*)[91] derived from the CP4 strain of the naturally occurring soil bacterium, *Agrobacterium* (Funke et al. 2006). Once incorporated into the plant genome, the gene product, CP4 EPSPS, confers resistance to the inhibitory effects of glyphosate. EPSPS is not unique to *Agrobacterium*; it is an enzyme widely prevalent in plants, bacteria, and fungi. Similarly, the phosphinothricin N-acetyltransferase (*pat*) gene from naturally occurring isolates of *Streptomyces viridochromogenes* and *bialaphos resistance* (*bar)* gene from naturally occurring isolates of *Streptomyces hygroscopicus*, provide GE plant resistance to the herbicide glufosinate. A further example is a GE plant engineered with a *dicamba monooxygenase (DMO)* 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 *Epsps* 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 PAT and EPSPS in GE plants has not been found to have negative impacts on other organisms in the environment (ILSI-CERA 2011b, a). Due the negligible risk posed by these genes and their products, the EPA has exempted both PAT and EPSPS from food tolerance limits from products derived from GE plants containing the *Pat* and *Epsps* traits (US-EPA 2007b, a).

Over the last 20 years, there have been a number of investigations on the soil biota associated with GE glyphosate resistant crops. Most studies report only minor, transient effects on soil biota. Impacts on soil communities due to glyphosate may be limited because glyphosate is rapidly degraded by soil biota. Haney et al. (2002) reported that 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. Likewise, Imparato et al.

[90] Pleiotropic effects: –when one gene influences two or more seemingly unrelated phenotypic traits especially when it is dependent on the context of the DNA insertion site.
[91] EPSPS: 5-enolpyruvylshikimate-3-phosphate synthase.

(2016) reported that glyphosate use may alter the bacterial and protist communities and their interactions through an increase in the availability of organic carbon. Weaver et al. (2007) reported similar findings in that glyphosate was mineralized (degraded) by soil biota, although in these studies no meaningful shifts in microbial communities were observed. Hart et al. (2009) 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 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 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 glyphosate resistant cultivars not treated with glyphosate (Kremer and Means 2009; Kremer 2010). For instance, Kremer and Means (2009) reported that *Fusarium*[92] colonization was higher on glyphosate resistant soybeans treated with glyphosate throughout the growing season, as compared with soybean receiving no herbicide or a non-glyphosate herbicide. A study by Camberato et al. (2011) 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 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. Huber and Haneklaus (2007) have speculated that glyphosate promotes disease in plants by chelating essential metal ions such as Mg^{2+} and Mn^{2+} (Huber and Haneklaus 2007). Others such as Duke et al. (2012) have concluded that (1) 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.

Though not yet deregulated, some GE plants have been developed for resistance to bacterial and fungal pathogens. For instance, GE rice resistant to pathogenic fungi has been developed by inserting a gene encoding a pathogenesis-related protein for chitinase, and potato plants resistant to potato-cyst nematode were developed by inserting a gene encoding a pathogenesis-related protein for cysteine proteinase inhibitor (Turrini et al. 2015).

Findings from studies investigating the potential impact of GE Bt based plants on soil microbiota are somewhat mixed, although no significant adverse effects have been identified (Icoz and Stotzky 2008). 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 et al. 2006; Icoz and Stotzky 2008; Naranjo 2009; Liu et al.

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[92] 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.

2015; Turrini et al. 2015)). An early review of studies conducted by Kowalchuk et al. (2003), 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 et al. 2003). A similar review of the early literature by Motavalli et al. (2004) found no conclusive evidence that cultivation of GE crops resulted in any substantial impacts on soil nutrient cycling. 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 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). More recent reviews suggest that GE crop plants currently cultivated have had no significant adverse effects on soil microbiota (Icoz and Stotzky 2008; Carpenter 2011; Turrini et al. 2015).

One of the more common themes that has emerged from 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 et al. 2007; Naranjo 2009; Kolseth et al. 2015; Turrini et al. 2015). Conflicting results on the potential effects of GE crops on soil microbiota 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.

3.6.6 Biodiversity

Biodiversity refers to the variety and abundance of biota and their functions in ecosystem dynamics. Biodiversity can provide ecosystem services that are important for agriculture. Such species include pollinators (e.g., bees and butterflies), species that control insect pests (e.g., beneficial avian species and predator insects), 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 ecosystem services (Altieri 1999).

Typically, agricultural fields are managed to encourage the growth of the planted crop while controlling 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 mammals. Some birds and mammals may use cropped fields at various times throughout the crop production cycle for feeding and reproduction.

Although some crop production practices, such as planting a single crop type (monoculture), applying pesticides and fertilizers, and harvesting crops, limit habitat and the resulting 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 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). Additionally, 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 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 the 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 2010).

3.7 Human Health

3.7.1 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. Specific consumer health concerns include 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 1.6.1. The Coordinated Framework defines the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: (1) USDA-APHIS, (2) the FDA, and (3) the EPA. Regarding human health, the safety assessment of crop plants derived through biotechnology includes characterization of the modified genetic material (i.e., DNA, RNAi),[93] characterization of the biochemical and functional properties of the gene products, and compositional analysis of the GE plant.

3.7.1.1 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 used for human or animal food purposes may undergo a voluntary consultation process with the FDA prior to release into commerce.[94] 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.[95] 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 (US-FDA 2020). 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, applicants who have wanted to commercialize a GE food product derived from a GE crop typically have completed a consultation with the FDA or were the subject to an evaluation in another more relevant premarket process (see (US-FDA 2020)). APHIS considers the outcome of voluntary consultations with FDA in evaluating the potential impacts of a determination on nonregulated status of GE plants and other GE organisms.

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[93] RNA interference (RNAi) is a biological process where RNA is used to inhibit gene expression or protein function.

[94] Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties: https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/biotechnology-guidance-documents-regulatory-information

[95] 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.

3.7.1.2 EPA: Pesticide Safety

Pesticides used on food crops can present risks to human health based on the specific hazards posed by the pesticide (i.e., toxicity of the active ingredient) and the potential for exposure to such pesticides. The risk of potential adverse health effects from pesticides depends on the toxicity of the ingredients, 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.

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 (FQPA), of 1996, which amended both FIFRA and the 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 and continued use of pesticides on GE and non-GE crops would not be expected.

The EPA, pursuant to the FFDCA and FQPA, establishes pesticide food tolerance limits (40 CFR part 180), 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 2020d). These tolerances include conventional pesticides, such as herbicides and insecticides, as well as gene products that may be introduced through GE processes, such as PIPs (e.g., Bt proteins). If pesticide residues are found above the tolerance limit, the commodity is subject to seizure by the government.

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 2020a). 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 to public health, the EPA conducts pesticide registration reviews. This process 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 2015c). 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.

3.7.1.3 Other Scientific and Regulatory Food Safety Review

In addition to the FDA consultation, foods derived from GE plants typically undergo a safety evaluation among regulatory agencies in other countries 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 2020a)).

Based on over 15 years of peer reviewed research and regulatory review, 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 et al. 2013; Goldstein 2014; Nicolia et al. 2014; WHO 2015), and memorandums by FDA (US-FDA 2020), EFSA (EFSA 2020a), and ANZFS (ANZFS 2020)).

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 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 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, including 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 surrounding 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. Any future GE plant derived foods introduced into the U.S. marketplace would be expected to comply with relevant food safety laws enforced by relevant authorities, described herein, to ensure protection of public health.

A commonly cited risk with GE crops plants is that genetic engineering techniques could have 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 et al. 2014). Similarly, some stakeholders express concern that such unintended 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.[96] As part of the consultation process, the 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.[97]

3.7.2 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 (29 CFR 654). 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

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[96] FDA Issues Guidance to Help Prevent Inadvertent Introduction of Allergens or Toxins into the Food and Feed Supply: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statement-policy-foods-derived-new-plant-varieties

[97] FDA's Regulatory Program for Foods Derived from Genetically Engineered Sources: https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/biotechnology-guidance-documents-regulatory-information

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.

In November 2015, the EPA issued revisions to the WPS regulations to enhance the protections provided to agricultural workers, pesticide handlers, and other persons by strengthening elements such as training, information about pesticide safety and hazard communication, use of personal protective equipment, and provision of supplies for routine washing and emergency decontamination (80 FR 211, November 2, 2015, p. 67495). The EPA expects the revised WPS 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 other persons who may be on or near agricultural establishments, and to mitigate exposures that do occur. Most of the revised WPS requirements became effective during 2017 and early 2018. By the end of FY 2018, the EPA expects to publish a Notice of Proposed Rulemaking to solicit public input on proposed revisions to the WPS requirements for minimum ages, designated representatives, and application exclusion zones (82 FR 60576, December 21, 2017, p. 60576).

In September 2016, the EPA, in conjunction with the Pesticide Educational Resources Collaborative, made available a guide to help users of agricultural pesticides comply with the requirements of the 2015 revised WPS. Agricultural workers and handlers, owners/managers of agricultural establishments, commercial (for-hire) pesticide handling establishments, and crop production consultants are advised to employ this guidance. The updated 2016 WPS "How to Comply" Manual supersedes the 2005 version (US-EPA 2016a).

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.

3.8 Animal Food and Welfare

Animal food refers to food products used as food[98] for animals such as pets and livestock. The composition of animal food derived from non-GE and GE crops is a critical issue for food animals as they are fed tailored diets for optimal health, growth, and product quality. Hence, even a small change 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 final 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,

[98] 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."

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 derived 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, all of which can be derived 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 et al. 2012; Bartholomaeus et al. 2013; Deb et al. 2013; Ricroch 2013; Van Eenennaam 2013; Nicolia et al. 2014; Van Eenennaam and Young 2014)), have not shown any unique risks or adverse effects associated with animal food derived from GE crops.

There have been some studies published outside of peer review, and a few peer-reviewed publications, which suggested animal 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 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 animal food derived from conventional crops (Snell et al. 2012; Van Eenennaam and Young 2014).

As described in detail in Section 3.7.1.1 – FDA: 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. The FDA recommends that developers who intend to commercialize human or animal food from GE plant varieties 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, applicants who have wanted to commercialize a human or animal food product derived from a GE crop typically have completed a consultation with the FDA or the GE product was evaluated in another more relevant premarket process (US-FDA 2020).

Before a pesticide can be used on an 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 animal food processed from that crop.[99] Similar to tolerance values for human food, these EPA tolerance values for animal food are set to

[99] EPA - Setting Tolerances for Pesticide Residues in Foods: https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods

ensure safety of raw or processed commodities for animals and may include conventional pesticides and proteins from GE crop derived food, such as PIPs.

Animal food derived from GE crops is also reviewed by regulatory authorities in other countries such as the EFSA (EFSA 2020b). 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 regulatory authorities in other countries. APHIS expects that developers of GE plant varieties, they intend to commercialize for food and that raise scientific or safety issues, will consult with the FDA about the safety and composition of these GE varieties prior to their introduction into the animal food supply. Developers may also undergo an early food safety evaluation with the FDA (US-FDA 2006).

3.9 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 PEIS, APHIS has conducted a Regulatory Impact Analysis (RIA) and Initial Regulatory Flexibility Analysis of the final rule and Alternatives (USDA-APHIS 2020f), 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.

3.9.1 Affected Entities

The 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 pulp producers that fall into various categories of the North American Industry Classification System. For the purpose of this PEIS 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 2020f). 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.

3.9.2 Domestic Agricultural Commodity Markets

3.9.2.1 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.[100] 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 et al. 2000).

Net benefits derived from a GE crop are a function of a chosen crop and location, output and input prices, farmer abilities and preferences in managing crop production, and unforeseen circumstances such as drought (Fernandez-Cornejo et al. 2014b). 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 3-47) (Fernandez-Cornejo et al. 2014b). 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 those of non-GE crops.

[100] 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).

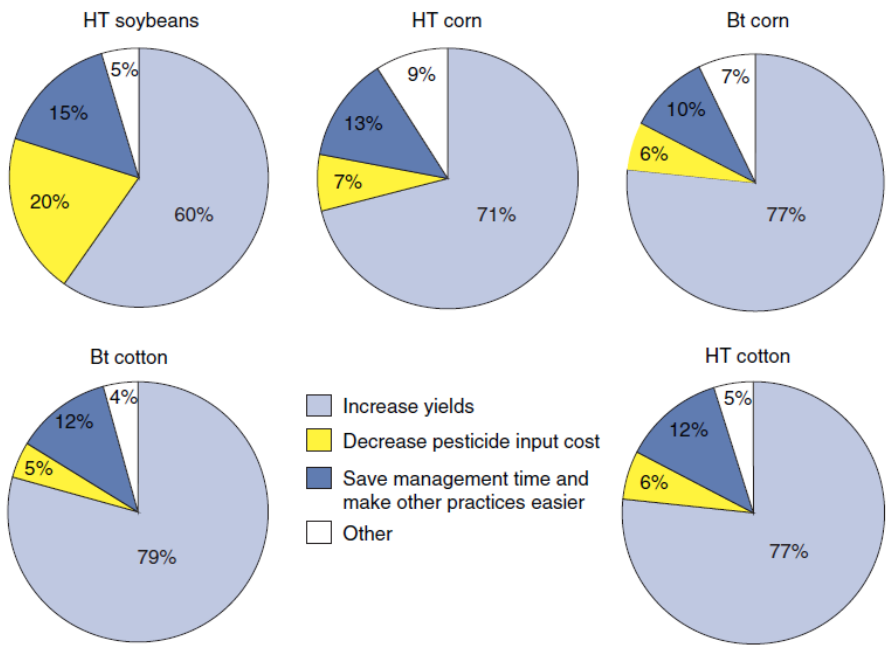

Figure 3-47. Common Reasons Growers Adopt GE Corn Varieties

Sources: (Fernandez-Cornejo et al. 2014b)

3.9.2.2 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 (Fernandez-Cornejo et al. 2014b; Klümper and Qaim 2014; Brookes and Barfoot 2015a; Brookes and Barfoot 2017b). For example, a recent review found that U.S. farmers have realized higher incomes due to their use of GE crops, totaling approximately $72.3 billion in extra income between 1996 and 2015 (Brookes and Barfoot 2017a).

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 et al. 2014b). 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 et al. 2014a). 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.

Yield gains and reductions in pesticide and crop management costs have translated into increased 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 2015a). Over the years 1996-2015, Brookes and Barfoot (2017a) found average farm income benefits of GE IR cotton to be $42/acre, GE IR corn around $33/acre, GE HR soybean $13/acre, GE HR corn around $11/acre, GE HR cotton around $9/acre, GE HR canola $22/acre, and GE HR sugarbeet $47/acre.

The extent to which GE HR crops affect net returns is mixed and relative to weed control and seed costs. 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 et al. 2014a)).

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 et al. 2014a). Adoption rates of stacked-trait varieties have increased in recent years, with stacked-trait corn expanding from < 1% of planted acres in 2000 to 80% in 2018. GE varieties incorporating three or four traits are now common and will likely remain so in the coming years.

Other benefits to growers from the adoption of GE crops have included (Carpenter 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 GE IR crops than for GE HR crops. Yield and farmer profit gains are higher in developing countries than in developed countries.

3.9.2.3 Gene-Flow Among GE, non-GE, and Organic Cropping Systems

Gene flow among conventional, organic, and GE cropping systems can occur as a result of cross-pollination and seed dispersal, and can have economic consequences for farmers, as well as result in repercussions in the marketplace. Consequently, as summarized in Section 3.4.1.1, 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 identity-preserved and organic markets, which are expected 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 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, the maintenance of price premiums in the market, and the 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 2020; USDA-AMS 2020b; USDA 2020b), 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[101] 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 2011) and seed production practices (ASTA 2020).

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[102].

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. From 2011 to 2014, eighty-seven of the more than 12,000 USDA certified organic farms collectively reported losses of approximately $6.1 million due to the presence of GE material in the organic cropping system (Greene et al. 2016). This equates to an average reported 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 2015).[103] From 2006 to 2010, nine of more than 9,000 certified organic farms collectively reported losses of $68,976, at an average reported loss of $7,664 for the nine organic farms that reported losses (USDA-NASS 2015). As

[101] The Association of Official Seed Certifying Agencies (AOSCA) develops, monitors, and coordinates standards for seed purity.
[102] USDA Stakeholder Workshop on Coexistence: Panel Discussion on Economic Perspectives On Coexistence. Comment by Nicholas Kalaitzandonakes. March 12, 2015.
[103] The bulk of reported losses, approximately 3.8 million, were isolated to 3 farms in Texas, which somewhat skews the statistics.

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%.

Depending on supply and market demand, non-GE crops may carry a market price premium. In late 2015, ERS reported non-GE price premiums for food soybean 8–9 percent higher than average food-soybean prices and 12–14 percent higher for non-GE soybean for feed (Greene et al., 2016). As a result, growers in the United States and in other agricultural export regions around the world may decide to meet such demand by avoiding GE seed and growing their crops to meet the required regulatory and market specifications for marketing non-GE crops (NAS 2016b).

U.S. food retailers, restaurants, and food manufacturers are requiring non-GE supplies for "non-GMO" marketing and labeling campaigns (for example, (Schweizer 2015; Strom 2015)). Through contract requirements, growers of organic or non-GE crops may have to supply products that do not exceed a threshold of GE content set by a private company, a strict market (for example, the EU), or a voluntary certifier (for example, the Non-GMO Project, a private voluntary certifier). The grower bears the risk of losing the market premium if the supplied crop is rejected because it does not meet a contractually established standard. However, because contracts between growers and buyers are private, it is difficult to find documented information about how extensively growers are contracting to meet specific non-GE standards or to what extent farmers of organic or non-GE crops are incurring economic losses as a result of being unable to meet contracts because of commingling of GE into non-GE crops.

3.9.2.4 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. Commingling of GE and non-GE plant material can decrease consumer confidence in non-GE agricultural commodities, thereby devaluing these 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 conventionally 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 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. As a result, agricultural commodity traders, marketing organizations, and food processors 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 et al. 2002).

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 2020; USDA-AMS 2020b; USDA 2020b) or through contracts and standards, as relevant. Likewise, ASTA has released guides for co-existence (ASTA 2011) and seed production practices (ASTA 2020). Around 2% of IP cropping systems report rejection of their IP commodity as a result of the unintended presence of GE material[104]. Coexistence and gene flow among conventional, organic, and GE cropping systems, discussed below, is fundamentally an economic issue, not an environmental issue, nor is it unique to GE crops.

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, 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, 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.

[104] USDA Stakeholder Workshop on Coexistence: Panel Discussion on Economic Perspectives On Coexistence. Comment by Nicholas Kalaitzandonakes. March 12, 2015.

3.9.2.5 Herbicide Resistant Weed Costs

Over 90% of U.S. acreage devoted to major crops (e.g., corn, cotton, soybean) is treated with herbicides (Fernandez-Cornejo et al. 2014c). 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 the 1950s 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., GE varieties of 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 summarized in Section 3.4.3.2 –Weed Resistance Management, there are currently 165 unique cases (plant species and site of action) of herbicide resistant weeds in the United States (Heap 2020). The resistance exhibited by these plants includes resistance to pesticides with multiple modes of action (Heap 2020).

The presence of resistant weeds in crop fields increases the cost of production and can reduce net returns (Fernandez-Cornejo et al. 2014b). 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 et al. 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 et al. 2012). 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 et al. 2015). Similarly, Weirich et al. (2011) investigated the effect of grower adoption of glyphosate weed resistance management programs and found weed resistance best management practices (BMPs) initially more costly, but provided yields and net economic returns that offset weed resistance management costs over the long term.

The potential economic impacts from the 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 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 (Owen 2011; Vencill et al. 2012).

3.9.3 International Trade of GE Agricultural Commodities

3.9.3.1 APHIS Regulatory Scope

Because the United States is both an agricultural exporter and importer, it is important to consider the ways exports and imports are different with respect to APHIS regulation, regardless of the Alternatives. The United States does not have regulations or restrictions specifically related to the export of GE organisms or products. The United States and most importing countries have requirements for import of GE organisms or products, discussed below. Imports of regulated GE organisms into the United States 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.

3.9.3.2 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 based on market demand due to increased use of GE crop plants in agricultural production. 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 (Brookes and Barfoot 2010; Brookes and Barfoot 2013b, 2015a; Brookes and Barfoot 2017b). The most recent analysis from Brookes and Barfoot (2017b) found that plant biotechnology has made significant contributions to increasing global production levels of major crops, having added, for example, 180.3 million tons and 357.7 million tons to the global production of soybeans and corn, respectively, since the introduction of the technology in the mid-1990s (Brookes and Barfoot 2017b). Net economic benefits at the farm level over the period 1996–2015 were found to amount to $167.8 billion (Brookes and Barfoot 2017b). 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 2013a; Fernandez-Cornejo et al. 2014b; Brookes and Barfoot 2015a; Brookes and Barfoot 2017b), and yield and farmer profit gains higher in developing countries than in developed countries (Brookes and Barfoot 2017b).

As of 2018, GE crops were grown commercially in 26 countries. Of these, 18 countries planted 120,000 acres or more to GE crops (ISAAA 2018a). The largest producers of GE crops include the United States, Brazil, Argentina, Canada, India, Paraguay, Pakistan, China, South Africa, Bolivia, Uruguay, Australia, Philippines, Myanmar, Sudan, Spain, Mexico, and Colombia (ISAAA 2018a). Four crops account for the vast majority of GE crop production; these are soybean (50%), corn (31%), cotton (13%), and canola (5%) (ISAAA 2018a). In 2016, the direct global farm income benefit from GM crops was $18.2 billion. The cumulative global value of GE crops since 1996 is estimated at $186.1billion (ISAAA 2018a).

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 20 years. Currently, 70 of the world's 195 countries have adopted biotech crops, 26 countries plant biotech crops, and 44 import biotech crop commodities (ISAAA 2018a). 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

3.9.3.3 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 2020a). 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 2020b). 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. agricultural exports were valued at $140 billion in 2018, a 1-percent increase relative to 2017 (USDA-ERS 2020c).

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 are raised on GE crops and crop products. For example, some of the most common GE animal feed ingredients are derived from GE soybean, cotton, corn, canola, sugarbeets, and alfalfa. The majority of corn and soybean crops grown in the United States are used for livestock feed. Because the total demand for animal products in developing countries is expected to more than double by 2030 (FAO 2020b), the demand for animal feed is expected to increase.

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 2020c).

As for developed countries, Canada is currently the primary destination for U.S. agricultural exports. U.S. farm exports to Canada have remained relatively stable while exports to China dropped by over $4 billion in 2015 (USDA-ERS 2020c). The next largest markets are Mexico, the EU, and Japan (USDA-ERS 2020c).

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 et al. 2014b). 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.

3.9.3.4 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 (USDA-ERS 2020d), 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 EU 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 2020; WTO 2020a). 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 (FAO 2020a), WTO Sanitary and Phytosanitary Measures (WTO 2020a), WTO Technical Barriers to Trade (TBT) Agreement (WTO 2020b), and the Cartagena Protocol on Biosafety (CBD 2020).

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 food/feed in some countries, but not others, low level presence (LLP) [105] of GE crop material in internationally traded crop commodities has become a focus of discussion (FAO 2014b). LLP situations occur in the importing country when there is asynchrony between the authorization of the exporting country and that of the importing country; this is an issue described as an "asynchronous authorization." These occurrences can result from natural processes such as the movement of seeds or pollen, or human-mediated processes associated with field testing, plant breeding, or seed production. The issue of asynchronous authorization (AA), and resulting LLP situations, can lead to trade delays, shipment rejection, and costs to traders (FAO 2014b).

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 2020a). 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 imports are 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 bans. 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.

[105] Low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline) in one or more countries that may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined (Codex, 2003)

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 may include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including 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 be potential direct and indirect effects on the human environment. For example, impacts resulting from 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 reduced greenhouse gas emissions that result from fewer insecticide applications on widely planted Bt crops. As discussed in Section 3.9.2, 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 et al. 2014b; Klümper and Qaim 2014; Brookes and Barfoot 2015a). 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 that became widely planted.

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 (See Chapter 4.7).

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 impacts 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 per acre through technological enhancements (Alig 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 impact on these projections as the acreage and area of agricultural land use is primarily determined by market forces (see Section 3.9 – Socioeconomics), and federal and state laws and policy governing land use, which are outside of APHIS authority.[106] USDA projects farmland to remain fairly steady over the next decade for the major crops produced in the United States and with only minor fluctuations in total farmland expected on an annual basis due to domestic and international demands for food, fiber, and fuel.

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 conferring tolerance to herbicides, as pest and weed control 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 issues with a particular type of plant pest or disease occur. 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 resistant)
- 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)

[106] 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.

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 extend the geographic range of a crop, or to meet a consumer 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 or a conventionally bred crop plant will be adopted by farmers. 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.

Under both of the Alternatives considered, there would be variance in the availability of GE crop plants that were not subject to APHIS regulation, and therefore, available for commercial adoption subject to EPA review and approval, and, per customary business practice, after the FDA's voluntary consultation or premarket evaluation, as appropriate. However, APHIS's determinations of the regulatory status of GE crop plants is not considered the driving factor in grower adoption of GE crop plants. Under both 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, determining where and on what types of land that crop can be grown. Neither 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 Alternative 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 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). Therefore, 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 is 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[107] Currently there are no GE forest trees grown commercially 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.

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 reviewing 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 by U.S. government agencies.

4.1.1.4 Pests and Disease

The prevalence and persistence of plant pests and diseases could increase in certain areas of the United States, or a new plant pest or disease could emerge as a result of importation or natural means. GE plants and trees have been and are being developed to mitigate the effects of pests or disease on agricultural and forestry commodity production. These include but are not limited to virus resistant papaya (Gonsalves 2004), plum (Scorza et al. 2013b), squash (Tricoli et al. 1995), cassava, cereals, citrus, maize, cucumber, potato, rice, and sweet potato (Reddy et al. 2009); bacteria resistant citrus and banana (Tripathi 2017); and fungal resistant potato (USDA-APHIS 2015c), tomato, banana (Dale et al. 2017), chestnut (Steiner et al. 2017), soybean (Kawashima et al. 2016), and wheat (Wang et al. 2014; Panwar et al. 2018; Qi et al. 2018). In addition, biocontrol agents are being developed for insect pests such as diamond back moth (Jin et al. 2013) and a gene drive approach has been laboratory tested to control Spotted wing fruit fly, *Drosophila suzukii* (Buchman et al. 2018). 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 in the future. The incidence and prevalence of pests and disease can also determine whether a GE plant resistant to a particular pest or disease is developed, and where and at what scale GE crops resistant to pests or disease are grown. The Insect Allies program[108] is evaluating whether insects may be used as vectors to facilitate the spread of GE plant viruses that can help manage or eradicate certain plant pests as well as stress caused by abiotic factors.

An example of a plant virus being developed to mitigate another plant disease is citrus tristeza virus engineered to protect trees against citrus greening. Citrus greening is a bacterial disease spread by two species of psyllid insects, and is one of the most serious diseases of citrus trees worldwide. It was first detected in the United States in Miami-Dade County, Florida, in 2005, and is known to be present in the United States in Florida, Georgia, California, Puerto Rico, the U.S. Virgin Islands, two parishes in Louisiana and two counties in South Carolina. Other than

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[107] 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.
[108] https://www.darpa.mil/program/insect-allies funded by DARPA

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, citrus tristeza virus engineered with plant defense genes shows promise in mitigating disease symptoms.[109]

4.1.1.5 Impacts from Altered Weather Patterns

Changes in regional weather patterns will likely occur as a result of increasing global temperatures (Hatfield et al. 2014; IPCC 2014). These changes could determine shifts in the type and location of GE plants cultivated for commercial purposes. Such changes in regional weather would affect agricultural land uses for all crops, not just GE-crops. However, where a GE crop provides benefits compared to a non-GE variety, it may be preferred and adopted by growers. Changes in annual mean temperature, precipitation patterns, and the frequency and severity of weather events such as drought have spurred development of plants that are more tolerant of abiotic factors such as drought, heat, salinity, flooding, and freezing. For example, development of drought tolerant corn or soybean might allow these crops to be cultivated in areas with less available water. This may be especially valuable in that it will allow the same crops to be produced in areas that become drier.

Development of GE plants for cultivation in areas that otherwise would be inhospitable to the plants or development of GE plants in response to changes in weather 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 maintaining or extending the areas where crops can be cultivated. Genetic engineering of plants tolerant of drought or other extreme conditions could result in the 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 et al. 2015).

4.1.1.6 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 2019) 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).

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[109] 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

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 such as the removal of a specific type of contaminant such as mercury or arsenic. Whether these types of GE products will emerge as a commercially viable means for bioremediation remains indeterminate, as these products are still in the development stage. However, APHIS expects development of such GE organisms to continue and be refined.

4.1.1.7 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 traits desirable for commercial applications across a range of commercial agricultural and forestry commodities may increase, and could influence where and what type of agricultural commodities may be grown.

4.1.1.8 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 where commercial production of that crop is limited so that large isolation distances can be achieved because of concern of any presence of pharmaceutical and industrial crops in crops used for human or animal food. In some cases, that means growing the crop in areas that are not optimal for their growth. These crops may also be grown indoors. The production of plant made pharmaceuticals using tobacco indoors in highly contained facilities has recently been increasing (Lindbo 2007; Yao et al. 2015; Mardanova et al. 2017). 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 small.

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.[110] 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.

[110] 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

4.1.1.9 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 et al. 2007; Mullet et al. 2014). 7 CFR part 340 does not grant APHIS specific authority over GE bioenergy plants[111] or other organisms used for fuel production, but APHIS could be involved in regulation of these types of GE organisms where there is a plausible plant pest risk.

4.1.1.10 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. In general, socioeconomic forces, discussed later in this chapter (Section 4.6), serve as a primary driver 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 or tree, as well as various federal, state, and local land use requirements. APHIS decisions under the Alternatives are not expected to have direct impacts 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 are not expected to significantly change under either Alternative considered in this PEIS. Consequently, field trials are expected to have negligible impacts on the acreage and areas used for agriculture and forestry in the United States. As summarized in Section 3.3, field trials generally range between 1 and 50 acres, with most field trials being 30 acres or less. For any future regulated 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.

4.1.2 No Action Alternative: Acreage and Area of Agricultural Production

4.1.2.1 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, 2012c). These activities may be authorized in any U.S. state, commonwealth, or territory, as described in Section 3.3.3.

[111] Unlike conventional domesticated crops, bioenergy crops may be selected for their rapid aboveground biomass production, low input requirements, broad climatic suitability, and performance on marginal land.

4.1.2.2 Authorization of Interstate Movement and Importation

APHIS authorized movements and importations of GE organisms are required to adhere to the permit conditions and notification performance standards that ensure confinement of the GE organism during shipping or movement (USDA-APHIS 2011, 2012c). 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 2017, APHIS issued permits or acknowledged notifications for 875 importations and 639 interstate movements. Of the imports, 709 were requested by academic and private research institutions for import of *Drosophila melanogaster* (pomace fly).[112] For both import and interstate movements in 2017, around 1,062 authorizations were requested by universities or public research institutions (~ 70%). The majority of imports and movements are for basic and applied research purposes. 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 permit requirements and notification performance standards 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 impact on the environment. If it occurred, any remedial actions would be transient in nature, and long term impacts 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 of current 7 CFR part 340 regulations will remain the same.

4.1.2.3 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 issued more than 19,500 permits and notifications for field testing of GE organisms (the vast majority of which are plants). In 2017, APHIS issued 143 permits or acknowledged 236 notifications for environmental release in 41 states and Puerto Rico.[113] In contrast to importations and movements, only 136 (36%) of the environmental releases in 2017 were authorized for academic or public research institutions. The majority of authorization requests for field trials are from commercial developers of GE crop plants, trees, ornamental plants, and microbial pesticides.

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[112] *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.

[113] Permit and notification request information for import, movement, and field release is publically available on the USDA APHIS website https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/sa_permits/ct_status

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 comprises ~ 326.5 million acres.[114] 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 species of the GE organisms, the GE trait (e.g., insect or herbicide resistant, etc.), the management practices involved in field testing of the GE organism (e.g., tillage, pesticide use, etc.), and the environment in which the field trial is conducted (e.g., proximity to suburban areas, wildlife refuges, or commercial farms). APHIS requires as part of the permitting request that applicants provide a preliminary critical habitat analysis, which is reviewed by APHIS and used in evaluation of the application. Potential impacts on adjacent lands and land uses would be considered on a case-by-case basis as authorization requests are received by APHIS.

Plants genetically engineered to tolerate stressful climate conditions could result in use of marginal lands to field test such plants, or to increase their geographic range. 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 the 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 under both Alternatives.

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 upon termination of the field trial, and failure to monitor for volunteer GE plants as required by the permit or notification. In all instances remediation was required by APHIS, and in most cases civil penalties issued.

When field testing is conducted pursuant to the present notification and permitting requirements (USDA-APHIS 2011, 2012c) 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

[114] 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. The area includes double cropped acres and unharvested small grains planted as cover crops.

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 had negligible impacts on the acreage or types of land uses in the United States and its territories. No adverse impacts on cropland, rangeland, forestlands, or other land uses has been identified in over 20 years of field testing.

4.1.2.4 Unauthorized Environmental Release

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 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.[115]

Remediation can be required if a violation has occurred and APHIS determines that action must be taken to control or eradicate the GE organism. Although remediation can involve disturbance of land and altered land uses, remedial actions to date have had little to no lasting impacts.

Most of the existing GE crops cannot persist outside of test sites without human intervention. However, APHIS is aware of two situations where regulated GE crops have persisted outside of authorized field test sites. One case involved three different varieties of glyphosate resistant wheat (GRW) that was field tested by Monsanto from 1998-2005 and never deregulated.[116] The other involved glyphosate tolerant creeping bentgrass (GTCB) that was authorized for field testing from 1999-2005.

[115] USDA-APHIS: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_compliance_and_inspections/ct_compliance_history

[116] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/hot_topics/glyphosate_resistant_wheat/wheat_investigation

For reasons that were never determined after an extensive investigation, a small number of GRW plants were detected on a farm in OR in 2013 and a farm in WA in 2016. Neither farm had been used for field testing GRW. In 2014, GRW was detected on a research farm in Montana which had been used for GRW field trials. APHIS imposed restrictions on the field sites that were consistent with normal practices and did not change land use. Unauthorized GE plants were destroyed using a non-glyphosate herbicide. The following season as is customary, a non-glyphosate resistant, non-wheat crop was planted in rotation. In the following season where wheat was planted in rotation, farmers were authorized to plant a Clearfield® (imazamox resistant) wheat variety to eliminate any GRW volunteers during the second season. No further restrictions were placed on the fields for the third year.

In the case of GTCB, although GTCB was devitalized in all field sites, an extreme weather event during September 2003 resulted in regulated GTCB being wind-dispersed into areas outside of the authorized field trial locations in Jefferson County, Oregon. In addition, volunteers of the regulated GTCB have been found in Malheur County, Oregon, and Canyon County, Idaho, all of which constituted unauthorized releases into the environment. One of the original conditions in selecting the field test sites in OR and ID were to localize the test site in an inhospitable environment to limit spread of the GTCB, which need adequate water for establishment. For the most part, the population of GTCB established in the region has been small due to the scarcity of water, however populations have been able to establish along irrigation canals. GTCB has largely been unsuccessful in establishing in irrigated crop fields as the bentgrass is not competitive with the prevalent crops of corn, wheat, and alfalfa and/or is eliminated by normal weed control measures used on those crops. To our knowledge, GTCB has not affected land use in the area. The main impact has been to necessitate a change in management practices controlling weeds growing in irrigation ditches, which can restrict water flow if not controlled. Glyphosate had been the herbicide of choice due to effectiveness, cost, and registration for use near water but is not effective to control GTCB. Recently, Scotts successfully applied for a 24C registration of a glufosinate herbicide use to control weeds in irrigation ditches and this herbicide appears to be providing improved control of bentgrass growing in the ditches (Scotts Company 2018).

In one case known to APHIS, a Kentucky bluegrass seed field was harmed when GTCB growing in the field produced seed that was co-harvested with the Kentucky bluegrass seed. To remedy the situation, Scotts Company purchased the seed from the grower.

Since 2005, Scotts Company has actively managed the unauthorized release of GTCB in Jefferson, Malheur, and Canyon Counties. Although GTCB was deregulated in 2017 (USDA-APHIS 2015b), Scotts Company has committed to a management plan to integrate the management of GTCB into routine weed management programs employed by growers and irrigation managers (USDA-APHIS 2015a). The specific objectives of the plan are to (1) educate and inform growers and irrigation managers on the management of regulated GTCB to prevent its spread, (2) allow growers and irrigation managers to manage regulated GTCB using methods compatible with their existing agricultural practices, (3) minimize the potential for regulated GTCB to be present in commercial seed lots and agricultural products, and (4) provide a response plan in the event of potential regulated GTCB occurrence in new or previously unknown areas (USDA-APHIS 2015a). Scotts Company has also committed to forgo the commercialization of GTCB until 2023, the year their patent on GTCB expires (Scotts Company 2018).

As part of this agreement, Scotts has been educating and informing growers and irrigation managers on the management of GTCB, minimizing the potential for GTCB to be present in commercial seed lots and agricultural products, funding eradication efforts, and managing a hotline and providing assistance to growers encountering problems with GTCB (Scotts Company 2018). During the first two years the management plan was in effect, the detected GTCB population declined by 65% from 2841 plants to 968 plants in part attributable to the new EPA 24C registration allowing in season application of glufosinate on GTCB combined with effective education of growers and irrigation managers (USDA-APHIS 2015a).

4.1.2.5 Environmental Release after Determination of Nonregulated 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 the EPA, FDA, and other federal and state agency requirements. Agriculture will continue to comprise the dominant use of GE plants that APHIS determines are not subject to 7 CFR part 340. However, where GE plants are developed for ecological restoration, various locales outside of the agricultural landscape could see cultivation of GE plants – again, subject to federal and state requirements outside of 7 CFR part 340.

APHIS determinations of nonregulated status under current regulations, which render a GE organism available for commercial production, are not expected to significantly impact 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 deviate from current USDA projections, as described in Section 3.1.

4.1.3 Preferred Alternative: Acreage and Area of Agricultural Production

4.1.3.1 Regulatory Scope

The Preferred Alternative would expand the range of organisms subject to regulation but reduce the number of organisms requiring authorization for movement; remove the notification procedure, require all authorizations for import, interstate movement, or environmental release to 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 plant pest risks.

4.1.3.2 Authorization of Interstate Movement and Importation

Movement and importation of GE organisms within the regulatory authority of 7 CFR part 340 would require an APHIS permit, not a notification. APHIS would use a performance-based approach for shipping of GE organisms within the authority of 7 CFR part 340 and require that they be handled in such a way as to contain the shipment and maintain labeling and identity.[117]

[117] 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."

Movements of GE organisms within the authority of 7 CFR part 340 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 organisms within the authority of 7 CFR part 340 are intended to be received, stored, distributed, or released into the environment would have to be identified within a permit. Locations include but are not limited to greenhouses; laboratories; growth chambers; and field trial, production, propagation, sale, distribution, and manufacturing locations. Unauthorized environmental releases during interstate movement of organisms within the authority of 7 CFR part 340, whether under authorized permit or not, must be reported to APHIS.

Authorized movements or importation of GE organisms, which occur between distinct locations, are not expected to have any impact on the area and acreage of land uses, or land management practices in the United States or its territories.

4.1.3.3 Authorization of Environmental Release

Under the Preferred Alternative, APHIS would be considering a broader range of organisms than under the current regulation. While the scope of organisms subject to review would be broadened, the revisions would focus and limit regulatory oversight to GE organisms that posed a plant pest risk. This will be accomplished by conducting a regulatory status review to identify those GE plants that require permits for interstate movement, importation, and environmental release. The notification process (7 CFR § 340.3) and courtesy permits (§340.4(h) would be eliminated, and all environmental releases of GE organisms within the authority of 7 CFR part 340 would require a permit. APHIS would prescribe permit conditions to limit the unauthorized release of the GE organism from the test site and its persistence in the environment, as well as to 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 final 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).

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 be considered unlikely to pose a plausible plant pest risk. During the comment period for the 2017 proposed rule, some developers expressed the concern that up front risk assessments may slow down their field testing. In response to these concerns, under the final rule APHIS is making available an option by which developers may elect to remain under permit until they identify candidate varieties for commercialization. If so, the number of permits may decline slowly as a function of the assessments that are completed. Eventually, the total acreage for authorized field testing is likely to diminish. However, developers would continue to field test GE organisms determined not to be under APHIS' authority in order to comply with EPA requirements (as applicable), to gather data for consultation with the FDA or otherwise to ensure compliance with food safety requirements enforced by FDA (as applicable), and to improve the quality of their products. The total annual acreage for field testing of GE organisms would likely continue along current trends, perhaps ranging between 400,000 to 500,000 acres. For those GE organisms that APHIS determines are unlikely to pose plant pest 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 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 of GE crops, or land uses in the United States or territories, as compared to the No Action Alternative. Total acreage for field testing of GE 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 GE organisms within the authority of 7 CFR part 340, 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.

4.1.3.4 Unauthorized Environmental Release

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, during regular business hours, 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 permitted by APHIS 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 management program for volunteer GE plants. Records required to be maintained would include all locations and acreage where the GE organism was released 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 GE organism within the authority of 7 CFR part 340 be retained for at least 2 years, and records for environmental releases to be retained for at least 5 years after completion of all obligations required under a relevant permit (including volunteer monitoring) unless a longer retention period is determined to be needed and documented in the supplemental permit conditions. APHIS has increased these time frames because many of APHIS' investigations into instances of noncompliance involve activities that were conducted a number of years before the 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 GE organism (i.e., where a GE organism was planted in area not authorized by APHIS).

Failure to comply with the regulations could result in the following:
denial of future permits
revocation of current permits
destruction, treatment, and removal of organisms permitted by APHIS
issuance of penalties

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).

In cases where regulatory status review of GE organisms is used early in development, APHIS anticipates fewer authorized actions (permits), allowing the Agency to focus oversight more effectively on those releases that represent a plant pest risk. Furthermore, Agency resources will not be expended to enforce measures unrelated to protection against plant pest 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 similar to those described for the No Action Alternative.

4.1.3.5 Environmental Release after a Finding of Unlikely to Pose a Plant Pest Risk

Under the Preferred Alternative, the petition procedure for determination of nonregulated status would be eliminated (7 CFR part 340.6) and APHIS would conduct a risk assessment to inform whether APHIS has authority over a GE plant and therefore is subject to permitting requirements under 7 CFR part 340. Information on all requests for and results of regulatory status reviews will be listed on APHIS' website. If APHIS determined a GE plant was not subject to 7 CFR part 340, and it were later found to present plant pest risks, APHIS would have the authority to re-evaluate its finding and regulate that GE plant under 7 CFR part 340.

Any GE organism that APHIS determined was subject to regulation would not be moved or released into the environment for field testing or commercial purposes unless permitted by APHIS. Any organism that APHIS determined is unlikely to pose a plant pest risk could be moved or released into the environment 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 GE organisms, the Preferred Alternative would differ little from the No Action Alternative. As described for environmental releases under authorization, it is expected that the total number of GE organisms APHIS has authority over under the Preferred Alternative would likely decline; that the list of GE organisms APHIS has authority over would be limited to two categories: (1) those GE organisms that APHIS believes may pose a plant pest risk as determined by a review for plant pest risk, and (2) those GE organisms that are not eligible for a regulatory status review. 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), the EPA (e.g., FIFRA, FFDCA) and regulatory agencies in key markets.

If APHIS' process of reviewing whether a GE organisms is subject to the regulations is efficient, and fewer organisms are subject to APHIS regulation, this process is not expected to impact 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 ordinance). 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. Shifts in the ratio of cultivated GE and conventional plants, however, would not impact the areas or total acreage utilized for commercial crop production.

4.2 Physical Environment

4.2.1 Soils

4.2.1.1 No Action Alternative: Soils

4.2.1.1.1 Authorization of Interstate Movement and Importation

Movements and importations of GE organisms authorized by APHIS 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, 2012c). When conducted pursuant to APHIS requirements, movements and importations under the 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 consequent 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 the release, and limited in scale, making adverse impacts on soils unlikely.

4.2.1.1.2 Authorization of Environmental Release

Agronomic practices such as pesticide and fertilizer inputs, tillage, irrigation, and cover crops used in the field testing of GE plants can potentially impact soil quality and the erosional capacity of soils. Soil erosion can occur through natural processes, and is determined by 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 erosion potential of soils, depending on the practices employed. Soil biota, which are major determinants of soil fertility, are also impacted by agronomic practices. Potential impacts on soil biota are discussed in Section 4.3.1.

Due to the small scale and transient nature of field trials (typically 1 to 3 years) the potential for adverse impacts on soils at field trial sites is rather limited. While field trial activities such as fertilizer and pesticide inputs, and tillage can potentially impact soils, these crop management practices would not be expected to have any lasting adverse impacts on soil quality, or the erosion potential 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, weed, and pest management practices are being investigated.

4.2.1.1.3 Unauthorized Environmental Release

Remediation of noncompliance incidents can adversely impact 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 emerged after termination of the field trial, APHIS could order treatment of the area with a broad spectrum herbicide, compliant with the EPA registration requirements, or mechanical removal to eradicate the GE plants.

The impacts of remediation actions on soils would generally be transient in nature and lasting impacts 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 erosion potential of soils, where remediation actions were taken.

4.2.1.1.4 Environmental Release after a Determination of Nonregulated Status

Agricultural lands are expected to continue to comprise the dominant use of nonregulated GE organisms. For GE crop plants, potential impacts to soils derive from the agronomic practices utilized in the cultivation of the plant. GE trees (e.g., via impacts on evapotranspiration) and GE microorganisms (e.g., effects on microbial communities) may also have the potential to impact soils. Once APHIS determines that a GE crop plant, tree, or microorganism is not subject to 7 CFR part 340, it may be grown anywhere in the United States, subject to applicable oversight by the EPA, FDA recommendations for a voluntary consultation, and state laws and regulations.

GE Crops

Indirect impacts on soils from those GE crop plants that are determined nonregulated derive from grower weed management and tillage choices in cultivation of that GE crop plant. For all cropping systems, GE and non-GE (to include organic), soil erosion has been and will remain a key issue in the central United States (see 3.5.1 – Soils). Excessively eroding cropland soils are concentrated in the Midwest and Northern Plain States, and in the Southern High Plains of Texas. While erosion can occur through natural processes, determined by soil type, local terrain and ecology, and weather; grower practices such as tillage, crop rotation, and cover crop management influence the erosion potential of soils and soil fertility. Conservation tillage systems, including no-till, are highly advised for commercial cropping systems as they contribute to higher soil quality and less erosion, as compared with conventional tillage (see 3.4.2.1 – Tillage).

Further utilization of GE HR, IR, and disease resistant cropping systems is not expected to present any increased risk for soil erosion, as compared to conventional cropping systems. GE HR cropping systems more frequently use conservation tillage than non-GE cropping systems (Fernandez-Cornejo et al. 2012; NAS 2016b). GE IR cropping systems result in reduced insecticide use, which can benefit communities of soil biota and maintain soil quality. To the extent that HR and IR crops facilitate conservation tillage and reduced insecticide use, these cropping systems have beneficial impacts on soils (NAS 2016b).

HR Weeds

The development of HR weeds continues to increase in many areas of the United States (Heap 2020) and are problematic to agricultural soils in that control of resistant populations may necessitate increased tillage (CAST 2012). For example, most corn growing states have from 7 to 26 different species of weeds that are HR (Heap 2020). Where HR weeds are particularly problematic and other strategies are not effective, growers may have to forego conservation tillage and use more aggressive tillage practices to control HR weeds, which can increase soil erosional capacity. This is in fact the case in some areas of the country, such as the Southeast, where growers have returned to more aggressive conventional tillage to control resistant weed populations (Price et al. 2011; Sosnoskie and Culpepper 2014).

The initial increase in glyphosate use with GE HR crops and subsequent development of weed resistance showed that diversified weed management practices are essential for suppression of resistance development. The agronomic practices used in the production of future GE cropping systems will beneficially or adversely impact the quality and erosion potential of soils depending in part on the IWM programs employed. Growers of GE crops, as well as growers of non-GE crops, have to consistently implement sound, recommended IWM practices (3.4.3.2 – Weed Resistance Management) to avoid selection for resistant weed populations and preserve the ability to utilize conservation tillage practices.

It is expected that implementation of recommended IWM programs will further expand in U.S. cropping systems, among both GE and non-GE crops. Where IWM is not practiced and HR weed populations further emerge, adverse impacts to agricultural soils via increased tillage may follow in some areas. For all cropping systems, GE and non-GE alike, growers producing crops on highly erodible land would be required to maintain and implement a soil conservation plan that reduces soil loss – a plan approved by the USDA National Resources Conservation Service (NRCS).[118]

Cover cropping is a practice that has shown benefits for soil health including sustainably controlling weeds and excess nitrates (Flipp et al. 2013; Johnson et al. 2015; Sindelar et al. 2017). Despite the environmental benefits, cover cropping has seen little adoption due to production and economic challenges. Pennycress, has been considered a potential cover crop for corn-soybean rotations in the Midwest because it produces high amounts of oil and grows during the winter season, but it has some serious shortcomings that limits its utility. For example, pennycress produces an inedible oil that limits its value as an oil crop, has weedy characteristics such as dormancy and seed shatter that can contribute to weed control problems during the production of corn and soybean, and may be slow to mature such that it will encroach on the soybean growing season that follows in rotation. Recently, the pennycress genome was sequenced, opening the possibility of using plant breeding innovations to modify pennycress to be a more attractive cover crop by introducing domestication traits that limit seed shatter and dormancy, promote early flowering so as not to detract from the soybean production, increasing

[118] USDA-NRCS: Highly Erodible Land Conservation Compliance Provisions. http://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/alphabetical/camr/?cid=nrcs143_008440

the value of the crop by modifying oils to increase its industrial uses, and eliminating antinutrients so the seed meal can be used for animal feed (Dorn et al. 2015).

Cover crops have traditionally been low input crops. Introducing traits to increase economic value could increase the economic incentive to apply crop protecting chemicals and encourage application during seasons not usually receiving these inputs. For example, CoverCress is a new oilseed crop developed from pennycress by CoverCress Inc. According to CoverCress Inc. CEO, Jerry Steiner, Covercress may be modified to have a non-glyphosate herbicide resistance (Jerry Steiner, personal communication). This trait would allow the crop to be sprayed with an herbicide in the fall to reduce competition from winter annuals and increase net yield. CoverCress is expected to be followed by a spring planting of soybeans. Soybean fields are often sprayed pre-planting however CoverCress shows promise in suppressing spring weed growth so a spring herbicide treatment is not expected to be needed. In this way, total herbicide applications are not expected to be increased by including CoverCress in the corn-soybean rotation and glyphosate reliance should be reduced. Other pesticides such as fungicides and insecticides are not expected to be applied to CoverCress. Preliminary field trials suggest that P and K need not be applied to raise a CoverCress crop. CoverCress is expected to recover about 1/3 of its nitrogen from the preceding corn crop and the remainder of the nitrogen would be applied in the spring when the CoverCress has well developed roots to limit runoff. Thus it is expected that CoverCress can help promote more sustainable farming by improving sustainable herbicide use, promoting nutrient recovery, improving water retention and infiltration, rebuilding soil structure and aggregation, and reducing soil erosion. Under the No Action Alternative, the use of plant breeding innovations to develop new crops that promote sustainable cropping systems is expected to continue.

GE Trees and Microorganisms

Apart from food and fiber crops, GE trees (e.g., faster growing, improved product quality, cold tolerant, and disease resistant) are also being explored as potentially beneficial options for commercial wood and paper production, as well as for ecological restoration purposes. Future GE microorganisms may be designed for release in open environments to enhance nitrogen fixation by plants or for bioremediation at contaminated sites (NAS 2017). The dimensionality of risk assessments may be more complex with GE trees and microbes depending on such variables as areas of use, taxonomic relationships, use of orthogonal genes, environmental conditions within and outside a release site, use of engineered “kill switches” that terminate an organism when the energy or nutritional sources fall below a certain level, or sterility factors (NAS 2017). GE trees and microorganisms subject to 7 CFR part 340 would be reviewed for potential impacts to soils on a case-by-case basis, as with GE crop plants.

4.2.1.2 Preferred Alternative: Soils

4.2.1.2.1 Authorization of Interstate Movement and Importation

As with the No Action Alternative, movements and importations conducted pursuant to APHIS requirements under the Preferred Alternative would have no impact 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 impacts on soils would be highly unlikely.

4.2.1.2.2 Authorization of Environmental Release

As noted in Section 4.1.3.3, while the total annual acreage for APHIS authorized field releases subject to 7 CFR part 340 may decline under the Preferred Alternative, developers would continue to field test GE organisms that were not subject to 7 CFR part 340 as part of standard research and development practices, and total annual acreage for field testing of GE organisms would likely continue along current trends, perhaps increasing due 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 impact the quality and erosional capacity of soils.

GE organisms that APHIS determines do not present potential plant pests 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 these 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 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 needed.

As with the 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 erosion potential of soils at field release sites would be expected to be limited. It is generally the persistent use of crop management practices over an extended period of time at the same location that can adversely impact soils. On a landscape level, field trials present less stress on soils than well-established commercial cropping systems, which due to their far greater scale, may present greater impacts.

4.2.1.2.3 Unauthorized Environmental Release

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 the following:
denial of future permits
revocation of current permits

destruction, treatment, and removal of organisms permitted by APHIS
issuance of penalties
a means to settle civil violations prior to the issuance of an administrative complaint.

To the extent the final revisions help improve the management decisions of permit holders during field testing and transport of GE organisms, and reduce instances of noncompliance, the potential for adverse impacts on soils could be reduced, relative to the No Action Alternative, largely by a reduction of remediation actions.

4.2.1.2.4 Environmental Release After a Finding of Unlikely to Pose a Plant Pest Risk

Potential impacts to soils would be the same as that described for the No Action Alternative. There are no reasonably foreseeable risks presented to soils that would derive from the Preferred Alternative that are above and beyond those described for the No Action Alternative. Where there is adoption of GE HR crops, there is expected to be a sustained implementation of conservation tillage practices. Where GE IR varieties are adopted, there is expected to be a decline in insecticide use. These two trends, which lessen the impacts of crop production on agricultural soils, are expected to continue. However, in the short-term, HR weeds will remain a persistent and increasing problem across the United States, as discussed for the No Action Alternative. It will be incumbent upon the growers and developers of GE cropping systems to consistently implement recommended IWM practices to preclude HR weed development, and preserve the ability to utilize conservation tillage practices. There are likely to be innovations in the development of GE plants and microbes that promote sustainable agriculture. To the extent that the Preferred Alternative facilitates innovation relative to the No Action Alternative, sustainable cropping solutions are likely to occur more rapidly under 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. The potential impacts of pesticides and other NPS pollutants on water resources are regulated by the EPA, state, and local authorities.

Specific water quality issues related to the importation, interstate movement, or environmental release of GE organisms are considered on a case-by-case basis as notifications and permit applications are received. Water quality issues related to petitions for determination of nonregulated status are 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 are mitigated by the way the present regulations provide for the secure shipment of GE organisms. There have been few major noncompliance incidents in the transport of GE organisms under the current regulations (USDA-APHIS 2016); 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, for example 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 experience of over 20 years of interstate 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, involve small quantities of the GE seed, plant, or other material, and remediation measures implemented are expected to be sufficient to prevent significant impacts on water resources.

4.2.2.1.3 Authorization of Environmental Release

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 whether APHIS will acknowledge the notification or issue the permit. Most field tests for GE plants will utilize pesticides and fertilizers. 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 gene products in water bodies could potentially impact aquatic biota and present a concern to some stakeholders. For example, laboratory studies have suggested sub-lethal effects of Bt corn detritus on some aquatic insects. However, field results have not substantiated these effects on a landscape level (Chambers 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, 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, and determined that they do not pose unreasonable risk to human health or the environment when used according to the EPA requirements (US-EPA 2020a). Any unregistered pesticide would require EPA consultation and approval prior to use during field testing. In registering PIPs, the EPA conducts risk assessments for freshwater, estuarine, and marine biota (US-EPA 2020a). Any future field tested PIP would be subject to EPA review and requirements, and EPA Experimental Use Permits (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 require consideration individually for permit applications or notifications on a case-by-case basis. Where potential impacts are a 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 exposure 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 has 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. Typically, 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 area 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 (USDA-APHIS 2017a).

There is current interest in developing GE drought and saline tolerant crops. These traits are also being explored in conventionally bred plants. There have been over a hundred requests for APHIS authorizations of permits or notifications for drought tolerance alone (USDA-APHIS 2020a). 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 requirements 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.

The risk to water resources from field testing of GE organisms conducted according to current APHIS notification and permit requirements for confinement are considered minimal. While potential adverse impacts on aquatic species such as daphnia and aquatic insects have been observed in response to exposure to Bt crop residues (Rosi-Marshall et al. 2007; Chambers 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, that may be field tested in the future, would require review as to their potential impacts on aquatic environments.

4.2.2.1.4 Unauthorized Environmental Release

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 (average size of around 20 acres, generally 1 year in duration), these types of impacts would be transient in nature, and likely result in no lasting impacts on ecosystem dynamics, water quality, or aquatic biota.

4.2.2.1.5 Environmental Release After a Determination of Nonregulated Status

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; water consumption; competing demands for water resources; and water quality through the inputs of sediments, nutrients, pesticides, or/and GE-trait material. APHIS expects that the majority of future GE organisms it will be reviewing pursuant to 7 CFR part 340 will be GE crop plants. APHIS expects GE trees and ornamental plants will also be reviewed, and to a lesser extent bacteria, fungi, insects, nematodes, and similar organisms.

All agricultural production, GE and non-GE alike, can result in impacts on water resources as summarized in Section 3.5.2. GE cropping systems, like all non-GE cropping systems, can adversely impact water quality through the use of pesticides, fertilizers, and tillage practices, and associated run-off into nearby water bodies. As discussed in Section 3.4.2- Agronomic Practices and Inputs, conservation tillage is widely practiced in production of GE HR crops. Under the No Action Alternative this trend would be expected to continue. To the extent that GE crops facilitate use of conservation tillage practices, including no-till (NAS 2016b), water quality in the areas of GE HR crops would be expected to be sustained through reductions in soil, pesticide, and nutrient runoff. The use of GE IR crops can help diminish impacts on water quality through reductions in the quantity of insecticides used. To the extent that GE IR crops reduce insecticide use, commensurate improvements in water quality in nearby water bodies and those downstream would be expected.

Some GE crops in the pipeline could have a beneficial impact on water quality. These include crops that utilize nutrients such as nitrogen and phosphorus more effectively (Achary et al. 2017; Gilbert 2018; ISAAA 2018b; Pandeya et al. 2018; Rehm 2018) or produce their own nitrogen (Science 2.0 2013) thereby decreasing agricultural runoff of polluting nutrients. As mentioned in Section 4.2.1, GE cover crops are being developed that could increase the value of cover crops to farmers, thereby increasing the adoption rate of cover cropping in row crop systems. Winter cover cropping is an effective means of reducing leaching of nutrients that reduce water quality. Plants with higher water use efficiency are also being developed, which would be expected to improve water quantity. (Głowacka et al. 2018).

As discussed in 3.4.2.2 – Pest and Weed Management, herbicide use during the last 10 years (lbs a.i,/acre, lbs a.i./year) has increased in some GE crops, and declined in others. The singular, widespread use of glyphosate on GE HR crops is one among a variety of factors that have driven increases in lbs a.i,/acre and lbs a.i./year herbicide applied. GE HR crops influence the types of herbicides used, application rates (lbs a.i./acre), and consequently, changes in herbicide quantities. Other factors affecting overall herbicide use trends since 1980 (as measured in lbs a.i./year and lbs a.i./acre) have been: (1) changes in crop acreage, which is influenced by economic and policy factors, (2) the replacement or discontinuance of older pesticides (MOAs) with newer ones (changes in per-acre application rates), which is influenced by pesticide regulation, and contributes to changes in pesticide quantities,[119] and (3) emergence of weed populations resistant to various herbicide MOAs over the last several decades (discussed below in Section 3.4.3 – Pest and Weed Resistance). Relative to the latter, development of HR weed populations can increase herbicide use and necessitate increased tillage (Owen 2010; Owen 2011; Mortensen et al. 2012). Any increases in the quantity and variety of herbicides used to manage resistant weeds could have potentially adverse impacts on aquatic ecosystems, determined by the toxicity of the herbicide.

The increased use of glyphosate on GE HR crops, along with increased crop acreage, has contributed to increases in quantity of herbicide utilized from 2002 to 2012 (Osteen and Fernandez-Cornejo 2016). While herbicide a.i. application rates have increased in some GE crops (as well as non-GE crops, e.g., wheat), it is not an increase in quantity of a.i. that necessarily increases risk; of primary concern is the inherent toxicity of the a.i. to aquatic biota. For example, the use of GE glyphosate-resistant crops has resulted in an increase in herbicide use as evaluated via lbs a.i./year. However, relative to other available herbicides glyphosate has relatively low toxicity to aquatic organisms (an LD50 lower than more than 90% of herbicides on the market).

The potential impacts of agricultural run-off on water resources will remain a pressing problem in the United States in both GE and non-GE crop production systems. GE crops that eventually reduce pesticide use (e.g., insect and disease resistant crops) can benefit water resources and aquatic biota, while those that result in increased use of more toxic pesticides increase risks to

[119] Higher application rates indicate lower potency of the herbicide; more potent herbicides require a lower rate to achieve the desired degree of weed control. For example, metolachlor was supplanted by the lower-rate S-metolachlor, and cyanazine was phased out by the U.S. EPA (in cooperation with DuPont) by 2002.

aquatic biota. Under the No Action Alternative it is expected there will be more GE glyphosate-resistant crops stacked with resistance to other herbicide active ingredients such as dicamba, glufosinate, and 2,4-D, as well stacked-trait varieties utilizing these and other herbicide active ingredients (e.g., isoxaflutole, sulfonylureas). Some of the newer stacked-trait varieties may increase herbicide use as additional chemistries are used to manage HR weeds. Under the No Action Alternative, increased tillage to manage HR weeds will likely occur in some areas, which can lead to increased soil erosion and decreases in water quality from run-off of sediments, pesticides, and fertilizers.

When APHIS approves petitions for nonregulated status, it allows for the GE plant that is the subject of the petition to be planted, but it does not allow for new uses of pesticides associated with management of the GE plant. The use of pesticides on GE crops and other GE plants, and their potential impacts on water quality and aquatic biota, are and would continue to be regulated by the EPA under FIFRA. For both drinking water and aquatic exposure assessments and for water quality assessments, the EPA typically relies on field monitoring data as well as mathematical models to generate exposure estimates.

4.2.2.2 Preferred Alternative: Water Resources

The Preferred Alternative would differ little from that of the No Action Alternative in regard to water resources.

4.2.2.2.1 Authorization of Interstate Movement and Importation

Movement and importation of GE organisms within the authority of 7 CFR part 340 would be conducted only under APHIS permit, however as authorized interstate movement and importation poses little risk to water resources, the protection of water resources conferred under the Preferred Alternative would be marginal, relative to the No Action Alternative.

4.2.2.2.2 Authorization of Environmental Release

Environmental releases/field tests of GE organisms under the authority of 7 CFR part 340 would be conducted solely under APHIS authorized permits with protective conditions prescribed as necessary.

As field tests are of limited area, they are unlikely to harm water resources. The Preferred Alternative is unlikely to be more protective of water resources than the No Action Alternative.

4.2.2.2.3 Unauthorized Environmental Release

As the Preferred Alternative is expected to strengthen prevention of the unauthorized release and dissemination of GE organisms during field testing, and the remedial measures available to APHIS in the event an unauthorized release occurs, the Preferred Alternative could provide better protection of water resources relative to the No Action Alternative. However, as noted in Section 4.2.2.1.3, field releases present little risk to water resources and noticeable differences to water resources are not expected under either Alternative.

4.2.2.2.4 Environmental Release After a Finding of Unlikely to Pose a Plant Pest Risk

Trends in weed management, tillage practices, agronomic inputs, and sustainable practices are likely to be similar under both Alternatives. To the extent that the scope of the regulation would be broader and more risk based under the Preferred Alternative, the Agency would be better positioned to oversee GE organisms that could adversely impact water resources under the Preferred Alternative. For example, under the current regulations, during the course of evaluating a petition for nonregulated status, the agency evaluated the impact of Freeze Tolerant Eucalyptus on local water resources through a study with the USDA Forest Service (USDA-APHIS 2017a). If Freeze Tolerant Eucalyptus was created without the use of a plant pest sequence, this GE organism could avoid regulatory oversight under the No Action Alternative whereas under the Preferred Alternative, this organism would still fall under the scope of 7 CFR part 340 based on the plausible risk hypothesis that Freeze Tolerant Eucalyptus could adversely impact local water resources. After more information was supplied addressing the risk hypothesis, for example a study evaluating the impact of Freeze Tolerant Eucalyptus on local water resources, APHIS could complete the regulatory status review. As under the No Action Alternative, agricultural NPS pollutants and their potential impacts on water resources would continue to be monitored and regulated by the EPA, states, and local authorities.

4.2.3 Air Quality

4.2.3.1 No Action: Air Quality

4.2.3.1.1 <u>Regulatory Scope</u>

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, 2012c). These activities may be authorized in any of the U.S. states, commonwealth, or territories.

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. States enforce NAAQS through the creation of state implementation plans (SIPs), which are designed to achieve the EPA established NAAQS.

4.2.3.1.2 <u>Authorization of Interstate Movement and Importation</u>

APHIS authorized importations and interstate movements have negligible adverse impacts on air quality. GE organisms are securely transported in sealed containers between defined locations via trucks, vans, ships, airplanes, and similar transport vehicles. To the extent that authorized shipments utilize nonrenewable fossil fuels, there will be emissions of NAAQS air pollutants.

4.2.3.1.3 <u>Authorization of Environmental Release</u>

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 procedures conducted by industry, academia, and government have taken place throughout the United States and its territories. To date, APHIS has issued more than 19,500 permits and notifications for field testing of GE organisms; the vast majority of these were GE plants.

Authorized field trials can adversely impact 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 planting, tillage, pesticide application, and harvest (CO_2, NOx, SOx); and soil nitrous oxide (N_2O) emissions from the use of fertilizers (Aneja et al. 2009; US-EPA 2013b). Drift and volatilization of pesticides from soil and plant surfaces can adversely impact air quality via introduction of various chemicals (active and inert ingredients) into the atmosphere.

Pesticide volatilization and drift would adversely impact 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., < 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 limited, commensurate with the scale of the trial, which range from .001 to 100,000 acres, and average around 20 acres.

4.2.3.1.4 Unauthorized Environmental Release

APHIS works with state and other federal agencies, including the FDA, EPA, and 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 2017, APHIS conducted 763 inspections. APHIS compliance inspection and enforcement activities would result in emissions of NAAQS via travel 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 the EPA NAAQS.

4.2.3.1.5 Environmental Release After a Determination of Nonregulated 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 the EPA, and other federal and state agency requirements. The vast majority of nonregulated GE organisms are GE crop plants utilized for commercial agriculture. As described in Section 3.5.3, commercial crop production can result in emissions of air pollutants that can adversely impact the environment and human health, and challenge regional NAAQS.[120] Agricultural emission sources include smoke from agricultural burning (PM), soil particulates

[120] See EPA - Agricultural and Air Quality: https://www3.epa.gov/airquality/agriculture/

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 impacts 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 and international demand, and the inherent effects of crop production on air quality at commercial scales. The potential impacts on air quality are similar 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, due to crop management practices employed by the grower.

Given the well-recognized emission sources associated with commercial crop production, the EPA and USDA-NRCS have developed guidance to assist growers in implementing conservation measures that can reduce air emissions (USDA-EPA 2012a). 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 the EPA recommended reasonably available control measures and best available control measures 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, fire management, manure management, integrated pest management, nutrient management, chemigation and fertigation (inclusion of pesticides and fertilizers in irrigation systems), and conservation irrigation (USDA-NRCS 2006d, c).

The EPA's Office of Pesticide Programs, which regulates the use of pesticides, 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 that reduce pesticide drift. The 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 2020c)). In October of 2012, the EPA and USDA published guidance that further provides options for improving air quality on agricultural lands (USDA-NRCS 2012a).

GE cropping systems can reduce or increase air emissions due to the crop management practices employed by growers. To the extent that 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. Adoption of conservation tillage is likely to continue to increase where HR crop varieties are adopted. Where IR GE crop varieties are used, there may be 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 also 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.

While beneficial impacts on air quality can derive from cultivation of certain GE crops, adverse impacts can also occur. Conventional tillage is often used to combat HR weed populations, and where practiced, would increase soil borne PM and vehicular NAAQS emissions. To the extent that there is an increase in HR 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. Some herbicide formulations are more volatile than others. For example, dicamba drift associated with dicamba resistant (Xtend® trait) crops has been particularly problematic (Bradley 2018). According to this report, "many growers in the area have adopted the Xtend® trait so they don't experience injury on their soybean crop three years in a row" (Bradley 2018). Whereas soybean, cotton, and corn growers can mitigate the impacts of dicamba drift by purchasing seeds with the Xtend® trait, many fruit and vegetable producers have little recourse. In 2018, most crop injury from dicamba drift has occurred on specialty crops, vegetables, ornamental fruit, and shade trees (University of Missouri IPM 2018). After the 2017 growing season, the EPA worked with states, USDA cooperative extension agents, and the pesticide manufacturers to develop tangible solutions to address the underlying causes of dicamba related crop damage incidents in 2017 (US-EPA 2018b). The manufacturers voluntarily agreed to label changes that impose additional requirements for over the top use of these products in 2018 (US-EPA 2018b). The EPA has monitored the success of these changes to help inform their decision whether to allow the continued over-the-top use of dicamba beyond the 2018 growing season. In 2018, EPA extended the registration for two years for over-the-top use (i.e. use on growing plants) of dicamba to control weeds in fields for cotton and soybean plants genetically engineered to resist dicamba. This decision was informed by extensive collaboration between EPA, the pesticide manufacturers, farmers, state regulators, and other stakeholders. The registration includes label updates that add protective measures to further minimize the potential for off-site damage. The registration will automatically expire on December 20, 2020, unless EPA further extends the registration. (US-EPA 2018b).

4.2.3.2 Preferred Alternative: Air Quality

4.2.3.2.1 Authorization of Interstate Movement and Importation

APHIS anticipates fewer GE organisms will be within the authority of 7 CFR part 340 under the Preferred Alternative. Therefore, the air emissions as a result of permitted interstate movements and importations are expected to decline relative to the No Action Alternative. Air emissions from movement of GE organisms not within the authority of 7 CFR part 340 may increase so overall there is not expected to be a meaningful difference from the Preferred Alternative on air emissions resulting from importation and interstate movement.

4.2.3.2.2 Authorization of Environmental Release

As with importations and interstate movement, the total annual acreage for APHIS authorized field releases would likely decline because APHIS expects that fewer GE organisms would require permits under the Preferred Alternative. However, considering both those GE organisms within the authority of 7 CFR part 340 (final revisions), and those not within APHIS authority, the overall annual acreage utilized for field testing of GE organisms is expected to remain similar. An increase in field testing of GE organisms is possible if the reduced regulatory burden spurs innovation in the agricultural biotechnology sector. Under the Preferred Alternative, developers may use genetic engineering more extensively in breeding such that there may be an increase in field tests of GE organisms not under APHIS authority, and a decrease in the field testing of organisms that have not been genetically engineered. Overall, NAAQS emissions from field testing is expected to remain similar to the No Action Alternative because the amount of field testing is not expected to change under the two Alternatives. Rather, a greater proportion of GE organisms would be expected to be field tested relative to non-GE organisms under the Preferred Alternative.

4.2.3.2.3 Unauthorized Environmental Release

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, as described under the No Action Alternative (USDA-EPA 2012a).

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 incident, 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 the EPA NAAQS and SIPs. APHIS expects that the number of inspections will be similar under the No Action and Preferred Alternatives. In the latter case, the proportion of permitted field trials that are inspected would increase since fewer field trials will require permits. As a result, there are expected to be fewer noncompliance incidents under the Preferred Alternative and therefore PM and NAAQS emissions from remediation of noncompliance incidents are expected to be less under the Preferred Alternative.

4.2.3.2.4 Environmental Release After a Finding of Unlikely to Pose a Plant Pest Risk

The acreage used for the cultivation of GE crops not within APHIS authority, which determines the magnitude of emissions, under 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 subject to the regulation under the Preferred Alternative would likely decline. Under the Preferred Alternative, research and development efforts are expected to be less costly. This regulatory relief is expected to spur innovation leading to more rapid development of GE organisms for agriculture. However, under the Preferred Alternative, GE organisms would still be subject to EPA and/or FDA and regulations in other countries so introduction into commercial production and markets is not expected to increase relative to the No Action Alternative. Areas and acreage of lands used for cultivation of commercial crops or forestry are not expected to change under the Preferred Alternative as acreage used for commercial agriculture and tree plantations is determined by market demand. Under both the No Action and Preferred Alternatives, certain GE crop plants may supplant conventionally bred crop plants where grower or consumer demand for the crop drives the cultivation of the GE plant variety.

The Preferred Alternative is expected to differ little from the No Action Alternative in regard to the relationship between commercial crop production and impacts on air quality. Air quality would continue to be impacted by GE and non-GE cropping systems due to the agronomic practices utilized in commercial crop production. The potential beneficial and adverse impacts on air quality that may derive from the 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 2012a). The USDA and EPA recommended management practices are applicable to all growers, whether producing a GE or non-GE crop. The EPA would continue to provide the Drift Reduction Technology program, which was developed to encourage the manufacture, marketing, and use of spray technologies that can reduce pesticide drift (e.g., see (US-EPA 2020c).

4.3 Biological Environment

4.3.1 Soil Biota

4.3.1.1 No Action Alternative: Soil Biota

4.3.1.1.1 Authorization of Interstate Movement and Importation

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 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). Therefore, 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 standards 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 it occurred would result in remediation actions at the site of the 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, due to innovation in the development of GE organisms both in the United States and abroad.

4.3.1.1.2 Authorization of Environmental Release

The 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 have positive or negative impacts on soil biota, 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, maintain nutrient availability and soil structure, transmit and prevent plant diseases, and degrade pesticides (Garbeva et al. 2004; Gupta et al. 2007; Parikh and James 2012). The healthier the populations of soil biota, the healthier the 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 et al. 2007). About 80 - 90% of soil biological activity is carried out by bacteria and fungi (Gupta 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 (USDA-NRCS 2018). 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 (Bierman and Rosen 2005).

The effect of extreme changes in the soil environment on small organisms is typically less than for larger organisms, possibly due to the sheer numbers of these organisms in soils and their fast generation time (Gupta et al. 2007). Communities of larger organisms such as arthropods and earthworms are expected to be more sensitive to change than communities of bacteria and fungi. Macroscopic soil organisms aerate and mix soil, regulate the populations of other soil organisms, and help produce soil organic matter.

The primary sources of potential impacts on soil biota due to field testing of GE plants are expected to be pesticides (Locke and Zablotowicz 2004; Jänsch et al. 2006; Gupta et al. 2007) and tillage (Gupta et al. 2007; Roger-Estrade et al. 2010). When they are applied at recommended rates, pesticides typically have only minor, transient impacts on populations of particular species in the soil community (Locke and Zablotowicz 2004). Pesticide use on GE plants during field trials is regulated by the EPA, and its use must adhere to the 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 et al. 2007; Roger-Estrade et al. 2010). In no-till systems soil organic matter is higher, fungi (including beneficial fungi) are more prolific, populations of (beneficial) nematodes, protozoa, and macro fauna are more abundant, and residue decomposition and nutrient mineralization are slower than in systems utilizing tillage (Gupta et al. 2007; Horowitz et al. 2010; Roger-Estrade et al. 2010). Under conventional tillage, bacterial and viral populations increase, fungal populations decline, residue decomposition and nutrient mineralization is more rapid, soil organic matter decreases, and beneficial nematode populations significantly decrease (Gupta et al. 2007; Horowitz et al. 2010; Roger-Estrade et al. 2010).

In addition to pesticide inputs, the potential impact of GE plants themselves on soil microbial communities has also been noted (e.g., see (e.g., see Locke and Zablotowicz 2004; Lynch et al. 2004; Naranjo 2009; Turrini et al. 2015)). There have been some reports in the scientific literature that GE glyphosate resistant plants modify soil 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 et al. 2015). Other reports have not observed such effects (Powell et al. 2009; Duke et al. 2012). 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 et al. 2012; Hannula et al. 2014; Turrini et al. 2015).

There has been 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 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 commercially produced. The insecticidal properties of Bt 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 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.[121] 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 has raised concerns among the public and some scientists about their environmental impacts (Naranjo 2009; Turrini 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 et al. 2008; Carpenter 2011; Turrini et al. 2015)). In several papers, which spanned from molecular based laboratory studies to field studies, there have been reports that Bt plants may affect soil communities, for example by altering fungal populations and shifting microbial community composition. However, adverse impacts are not consistently observed, and differences have been attributed to variation in geography, temperature, plant variety, soil type (nutrients), soil community composition, and the difference between field and laboratory studies (Icoz and Stotzky 2008; Wolfenbarger et al. 2008; Carpenter 2011; Turrini et al. 2015). There have been some differences observed in the composition and structure of soil microbial communities between Bt and non-Bt crops, although

[121] 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

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 adverse impacts 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 et al. 2008; Koch et al. 2015)).

In general, a considerable number of studies have been conducted investigating the potential adverse impacts of GE Bt plants on soil biota. Scientific evidence has not demonstrated that GE Bt plants have substantively different effects on soil biota as compared to controls or conventionally bred crop plants, or affect soil communities to a greater extent than natural variation (Icoz and Stotzky 2008; Lancaster et al. 2010; Carpenter 2011; Turrini 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 remains ongoing (Icoz and Stotzky 2008; Turrini et al. 2015).

APHIS currently oversees field trials of GE plants producing PIPs. When test sites exceed 10 acres, the EPA also regulates and issues EUPs for the field testing of PIPs.[122] The regulations at 40 CFR part 172.4 contain the requirements for applications for EUPs. The 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.

4.3.1.1.3 Unauthorized Environmental Release

Remediation of noncompliance incidents can potentially adversely impact 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 emerged 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 impacts of these types of remediation actions on soil biota would generally be transient in nature, and lasting impacts on soil communities once remediation was completed are considered unlikely. Any such remediation activities would be done so in compliance with applicable federal and state laws and regulations.

4.3.1.1.4 Environmental Release After a Determination of Nonregulated 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

[122] Current and previously registered plant-incorporated protectant registrations: https://www.epa.gov/ingredients-used-pesticide-products/current-previously-registered-section-3-plant-incorporated

compliance with the EPA, and other federal, state, and county requirements. For GE organisms that APHIS determines to be not subject to regulation, the potential impacts on soil biota would be the similar to those described above under environmental releases, namely from pesticide use, tillage, exudates, and decomposition of PIPs. As mentioned above, adverse direct impacts of Bt crops on soil biota have not been clearly established. Indirectly, they are associated with reduced pesticide applications which may have a beneficial impact on soil biota. HR crops may also benefit soil biota in cases where they promote the use of conservation tillage.

4.3.1.2 Preferred Alternative: Soil Biota

4.3.1.2.1 Authorization of Interstate Movement and Importation

Conducted pursuant to APHIS requirements under the Preferred Alternative, movements and importations of GE organisms 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 impacted by APHIS authorized importation or interstate movement.

4.3.1.2.2 Authorization of Environmental Release

Potential impacts to soil biota as a result of APHIS authorized field trials under the Preferred Alternative are expected to be the same as that described for the No Action Alternative in that any potential adverse impacts would largely derive from use of chemical pesticides, PIPs, and GE microbial pesticides. As described in the No Action Alternative, PIPs may have beneficial impacts on soil biota by reducing pesticide applications and HR crops may have beneficial impacts when they encourage the use of conservation tillage.

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.

4.3.1.2.3 Unauthorized Environmental Release

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, would be unlikely to inflict long-term adverse impacts on soil biota. Use of pesticides for remediation would follow EPA and local requirements.

4.3.1.2.4 Environmental Release After a Finding of Unlikely to Pose a Plant Pest Risk

For those GE organisms found not to be within the authority of 7 CFR part 340, the potential impacts on soil biota (both beneficial and adverse, as described throughout this section) from unrestricted release in the environment are not expected to differ from those described for the No Action Alternative.

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 impacts on invertebrate community structures, in general.

4.3.2.1 No Action Alternative: Invertebrate Organisms

The majority of species in the animal kingdom, over 90%, are invertebrates. Terrestrial invertebrate organisms include ants, bees, wasps, grasshoppers, crickets, stick insects, butterflies and moths, cicadas, aphids, millipedes, snails, slugs, spiders, beetles, true flies, true bugs, and worms. 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, including any living stage of insect, mite, nematode, slug, snail, protozoan, bacterium, fungus, oomycete, or other invertebrate animals, or any organism 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.

4.3.2.1.1 Authorization of Interstate Movement and Importation

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 authorized to move or import GE organisms adhere to current notification performance standards and permit requirements, the potential for inadvertent release of GE organisms is limited to instances of container failure or human error. Accidental release while possible would be limited to instances of accidents, unforeseen and severe weather events, or human error and if they occurred would result in remedial actions at the site of release. These types of incidents would generally have no lasting impact on the area of release. If a noncompliance incidence occurred, any remediation actions would be transient in nature, and long term impacts on invertebrate communities from such an incident are unlikely.

4.3.2.1.2 Authorization of Environmental Release

As part of the permit and notification applications, APHIS requires that 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 an invertebrate species listed as threatened or endangered under the ESA which may require special management considerations or protection.

Field trials are commonly conducted for GE plants engineered to produce PIPs, which confer GE plant resistance to a target group of invertebrate pests. For example, the most commonly used PIPs are those derived from naturally occurring soil bacteria *Bacillus thuringiensis* (Bt), which synthesize Cry and Cyt proteins, also known as δ-endotoxins (Bravo et al. 2007). Once ingested, the Cry and Cyt proteins are solubilized in the midgut thereby releasing protoxins, which are cleaved by proteases that release the active toxin (Bravo et al. 2007; Pardo-López et al. 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 et al. 2007; Pardo-López et al. 2013). In addition to Bt based PIPs, GE microbial pesticides, such as bacteria, fungi, or viruses, and RNAi based PIPs, are increasingly explored and field tested as mechanisms to protect plants from insects and disease (Sherman et al. 2015).

The Bt-derived PIPs approved for commercial release to date are highly specific for their hosts (Bravo 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 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 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 plant tissues such as pollen, leaf, root, or nectar/sap; plant detritus; and absorption. Invertebrate exposure in aquatic environments may occur as a result of pollen drift to these areas, and potentially through movement of plant material from cultivated fields into lakes, streams, ponds, or estuaries. Exposure to GE microbial pesticides may occur through absorption.

The EPA regulates most PIPs and GE microbial pesticides under FIFRA, and publishes information on registered PIPs on its website.[123] 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.[124] In these rules, the Agency has determined that, in regulating PIPs, the EPA regulates the new protein and its genetic material; the plant itself is not regulated. The EPA also regulates GE microbial pesticides. These are bacteria, fungi, viruses, protozoa, or algae which in their native state or after modification produce pesticidal compounds. To date, the 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.[125] Because GE microbial products are subject to extensive regulation by the EPA, APHIS entered into a memorandum of understanding (MOU) with the EPA stating that APHIS will not exercise duplicative regulatory oversight of GE microbial products (USDA-EPA 2012b).

The EPA requires an 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, including GE PIPs and GE microbial pesticides, can be used commercially, there must be sufficient data demonstrating that

[123] 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
[124] EPA - Overview of Plant Incorporated Protectants: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants
[125] EPA - Biopesticide Active Ingredients: https://www.epa.gov/ingredients-used-pesticide-products/biopesticide-active-ingredients

it will not pose unreasonable risks to human health or the 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 (US-EPA 2020a).

The 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 Section 4.3.4 – Plant Pests and Disease. If APHIS determines that an environmental assessment or environmental impact statement must be prepared for a field release, APHIS may request additional information from applicants on the potential impacts 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 impacts, including impacts on invertebrate populations.

4.3.2.1.3 Unauthorized Environmental Release

Remediation can be required if a noncompliance incident occurs and APHIS determines that action must be taken to control or eradicate the GE organism. Remediation actions such as pesticide use (e.g., potential toxicity) or tillage (e.g., disturbance of habitat) could potentially impact invertebrate populations, although any adverse impacts would be temporally and spatially limited. No significant long-term impacts would be expected due to such activities.

4.3.2.1.4 Environmental Release After a Determination of Nonregulated Status

Individuals that petition APHIS for determinations of nonregulated 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 the EPA and FDA evaluations of the GE organism in regard to deregulation.

As described for environmental releases above, all GE plants engineered to produce PIPs and all GE microbial pesticides, are regulated by the EPA under FIFRA, as are the pesticides that may be used on GE plants used for commercial or experimental purposes. Some GE organisms are also regulated by the EPA under TSCA. PIPs and similar genes/gene products are also evaluated by the OECD, EU, Australia, and other countries and international authorities in other countries. For example, the European Food Safety Authority (EFSA) assesses potential risks of GE organisms to human and animal health, and the environment, inclusive of potential adverse effects on invertebrate populations.[126] 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 also considers these risk assessments where potentially harmful impacts 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

[126] Regulating GM crops: EU countries' rights: http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32001L0018

adopted. Pesticides are used on both commercial GE and conventional cropping systems. As described throughout this PEIS, 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 resistant weeds (see 3.4.3) can potentially lead to greater use of herbicides in some situations. Pesticide spray drift is a well-recognized concern associated with the application of certain pesticides with high volatility. The EPA has several initiatives to help minimize pesticide drift, including the voluntary Pesticide Drift Reduction Technology program that encourages the manufacture, marketing, and use of spray technologies and equipment scientifically verified to reduce pesticide drift.[127]

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, whether GE or non-GE. 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 2017. The most commonly grown plant varieties containing one or both of the IR or HR traits were soybean (where 78% of world soybean production is biotech), cotton (76%), corn (30%), and canola (29%) (ISAAA 2018a). A few other PIPs, such as virus resistant papaya and fungal resistant potato, are cultivated on a relatively small number of acres worldwide.

To date, significant adverse impacts 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 planted to GE crops, worldwide. Over this time, no adverse 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 et al. 2008; 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 impacts 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.

Similarly, a review on the potential impacts of the currently commercialized GE Bt crop plants on honey bees concluded that Bt pollen and nectar from these varieties are not harmful to honey bees (Johnson 2015). Beneficial outcomes have also been associated with the use of Bt crop varieties; planting of GE Bt crop varieties tends to result in higher insect biodiversity than planting of similar varieties without the Bt trait that must then be treated with synthetic insecticides (NAS 2016b). In relation to the potential impacts of GE crop plants on non-target

[127] EPA, What EPA is Doing to Reduce Pesticide Drift: https://www.epa.gov/reducing-pesticide-drift/what-epa-doing-reduce-pesticide-drift

invertebrate species, interest and debate among scientists and stakeholders will continue as new GE crops are developed and cultivated, both in the United States, and abroad (NAS 2016b).

There has been debate on the potential impacts of herbicides (primarily glyphosate) on milkweed and monarch butterfly populations as discussed in Section 3.6.4. In general, there is as yet no consensus among researchers that increased glyphosate use is associated with decreased monarch populations. Most studies on monarch butterfly migratory dynamics have not shown that suppression of milkweed by glyphosate is the cause of monarch decline (NAS 2016b). More recent findings indicate that other factors, such as habitat fragmentation and the availability of late season nectar plants, are likely responsible for the observed decline in migratory monarch populations (Agrawal 2017). Findings by Agrawal (2017) also suggest that planting milkweed is not going to increase populations or save monarch populations from demise (Maeckle 2016).

Due to the population decline, the Natural Resources Conservation Service (NRCS) and others – including the USFWS – have developed a collaborative landscape level partnership to benefit the monarch butterfly (*Danaus plexippus plexippus*).[128] The primary focus of the partnership is the design and application of selected NRCS conservation practice standards and enhancements to benefit the monarch butterfly. These conservation practice standards and enhancements are applied by NRCS when providing technical and financial assistance to eligible landowners using its Farm Bill authorities. Other actions implemented by the NRCS include the conversion of suitable monarch butterfly habitat types to other land uses, including crop production; and implementation of certain conservation practice standards and enhancements as part of the application of pesticides to benefit the monarch butterfly, including but not limited to Integrated Pest Management and Herbaceous Weed Control.

Based on extant data (e.g., (Naranjo et al. 2005; Carpenter 2011; NAS 2016b), and others), the current process and criteria for APHIS determinations of nonregulated status presents a very low risk to invertebrate populations. As part of its PPRAs for new GE crops, APHIS evaluates the potential impacts of the GE organisms on non-target invertebrate organisms beneficial to agriculture.

4.3.2.2 Preferred Alternative: Invertebrate Organisms

4.3.2.2.1 Authorization of Interstate Movement and Importation

Conducted pursuant to APHIS requirements under the Preferred Alternative, movements and importations of GE organisms would present little risk to invertebrate populations. When entities authorized to move or import GE organisms adhere 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 had impacts to 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

[128] Monarch Butterfly: Conference Report, NRCS and USFWS: https://www.fws.gov/savethemonarch/pdfs/MonarchConferenceReport2016.pdf

nature; localized to the site of release; and based on APHIS' history in regulating movements and imports, highly unlikely to impart long-term adverse impacts.

4.3.2.2.2 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 impacts of Bt-based PIPs on non-target species (e.g., beneficial insects and pollinators), and the impacts of chemical insecticides and herbicides used in conjunction with GE IR and HR crop plants on non-target species.

Similar to the No Action Alternative, the field trials anticipated under the Preferred Alternative are expected to be relatively small in scale and transient in nature. The potential for field releases to significantly alter invertebrate communities is therefore expected to be 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.

4.3.2.2.3 Unauthorized Environmental Release

The potential for compliance, enforcement, and remediation actions to cause adverse impacts on invertebrate communities is expected to be low under the Preferred Alternative, similar to the No Action Alternative.

4.3.2.2.4 Environmental Release After a Finding of Unlikely to Pose a Plant Pest Risk

With regards to environmental releases of GE organism not under APHIS authority, the sources of potential impacts on non-target invertebrate species would be similar to the No Action Alternative in that the potential for any adverse impacts 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 the No Action Alternative, pesticides, including GE PIPs and GE microbial pesticides, would be regulated by the EPA.

In regards to potential benefits; GE Bt crop varieties are well-recognized to reduce the use of synthetic insecticides in those fields where they are cultivated and in some cases the use of Bt crop varieties has also been associated with a reduction in the use of insecticides in nearby non-Bt crop varieties due to a regional reduction in insect-pest populations (NAS 2016b). Where insect resistant GE crop varieties were adopted, there could be a decline in insecticide use, reducing the exposure of invertebrates to such chemicals. 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 then treated with synthetic insecticides (NAS 2016b).

As described for environmental releases, there may be certain GE organism-trait-MOA combinations subject to the regulation under the Preferred Alternative that would otherwise escape regulatory oversight under the current 7 CFR part 340 framework because the scope of regulatory capture under the Preferred Alternative is greater. This could provide for reduction of risk to invertebrate organisms, if such risk were to be identified by APHIS. If no concern was identified, the impacts to invertebrate species from releases under the Preferred Alternative is expected to be very similar to the No Action Alternative.

4.3.3 Vertebrate Animals

4.3.3.1 No Action Alternative: Animal Communities

4.3.3.1.1 Authorization of Interstate Movement and Importation

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 are designed so that no interaction with the environment will occur. While 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 would be required in order to minimize potential adverse impacts of unauthorized releases. Very few of APHIS authorized movements have resulted in incidents of noncompliance, such as shipment without proper identification. None have resulted in adverse impacts to vertebrate animals.

4.3.3.1.2 Authorization of Environmental Release

Under the No Action Alternative, APHIS authorizes environmental releases under permit or notification. For notifications, the responsible person 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. Some GE organisms, such as GE plants developed to produce a pharmaceutical or industrial product, present unique environmental risks, which may include risks to vertebrate animals. For these organisms, APHIS requires additional information, standard operational procedure (SOPs), and personnel training (68 FR 11337-11340). The responsible person must comply with permit conditions and any supplemental conditions required by APHIS.

The potential impacts of GE plants on vertebrate animals during field trials depends on the trait and gene product(s) expressed and the animals that are consuming the regulated GE plant. It is possible that a GE trait can be harmful to vertebrates, however this is rarely the case.

Locations used for field trials can host a variety of animal species. Vertebrate animals include mammals (especially rodents and deer), birds, reptiles, and amphibians all of which may use field tested plants and surrounding vegetation for food and habitat. Generally, highly managed environments such as crop fields are low in biodiversity and support limited populations of vertebrate animals while field trials of forest trees and perennial grasses will host relatively more vertebrates. 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 ESA (see Chapter 6).

The type of pesticides that may be used in the cultivation of a plant authorized for release 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.[129] Once registered, developers are required by law to use pesticides pursuant to the EPA label requirements and other EPA use requirements, such as those issued under an EPA 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. When individuals comply with current APHIS notification and permit requirements, the 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. There are no known adverse impacts on animal communities that have resulted from authorized field trials under the current regulatory review and authorization process, and the current authorization procedures are considered protective of wildlife.

4.3.3.1.3 Unauthorized Environmental Release

Remediation can be required if an unauthorized environmental release 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 and the location of transportation or shipping routes, the impacts of remediation activities on wildlife would likely be limited in geographic scope, transient in nature, and have no lasting impact on animal communities once remediation actions were complete. Under current regulations, APHIS expects compliance, enforcement, and remediation actions will continue to have 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.

4.3.3.1.4 Environmental Release After a Determination of Nonregulated Status

As part of the risk assessment conducted in conjunction with a determination of nonregulated status, APHIS evaluates the potential impacts of the GE organism on vertebrate animal communities.

All commercial crop production, GE and non-GE alike, can potentially affect terrestrial and aquatic 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 pesticides, sediments, and fertilizers can be damaging to the 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 on the pesticide label.[130]

[129] EPA - Data Requirements for Pesticide Registration: https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration

[130] EPA - Factsheet on Ecological Risk Assessment for Pesticides: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/factsheet-ecological-risk-assessment-pesticides

Vertebrate wildlife are generally undesirable in cropping systems, as they may cause significant losses in yield, on the order of hundreds of millions of dollars per year (USDA-APHIS 2012a). The USDA Wildlife Services works directly with crop producers, providing technical and management assistance to resolve wildlife conflicts that can threaten the Nation's agricultural resources. Many states, have wildlife damage management programs that likewise provide assistance in controlling nuisance wildlife through Cooperative Extension Services.[131] 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 grown for human consumption. As described in that rule, FDA encourages the co-management of food safety, conservation, and environmental protection.[132] It is reasonably foreseeable that GE traits will be developed that are unpalatable to vertebrates such as rabbits, deer, and feral hogs to discourage feeding that results in crop damage.

After over 20 years of cultivation, there are no adverse impacts on vertebrate wildlife that have derived from commercial cultivation of GE crops *per se*. A recent review of the scientific literature by the National Academy of Sciences found little evidence to connect GE crops with adverse agronomic or environmental problems (NAS 2016b).

The EPA regulates the registration, sale, and distribution of pesticides used in association with GE plants, including regulation of PIPs and GE microbial pesticides under FIFRA. The FDA oversees the safety of human and animal food under the FFDCA. 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, including mammalian toxicity testing of trait proteins or gene products, comparison of trait proteins or 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 vary somewhat between GE and non-GE cropping systems, and these differences may impact terrestrial and aquatic species directly or indirectly. The adoption of conservation tillage and no-till practices associated with the use of HR crops is generally considered to benefit wildlife through improvements in water quality, availability of crop residues, and increased populations of invertebrates. 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 for 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 counterparts, and reduce insecticide inputs, both of which can be of benefit to vertebrate wildlife.

[131] For example, see Purdue Extension: https://www.extension.purdue.edu/extmedia/FNR/FNR-265-W.pdf

[132] FDA - FSMA Final Rule on Produce Safety: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

The continued emergence of HR weeds can indirectly impact vertebrate populations through the management practices used to control such weeds. GE glyphosate resistant crops contributed to this problem, and glyphosate resistant weeds will continue to be a problem. Herbicide use may increase in some areas, even where IWM is implemented, to control the spread of HR weed populations. Some areas may see the adoption of conventional tillage practices where resistant weed populations are particularly 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, impacting water quality, and vertebrate wildlife dependent on those waters. Management of weed resistance by developers and producers of GE crops is discussed in Section 4.3.5.

4.3.3.2 Preferred Alternative: Vertebrate Animals

4.3.3.2.1 Authorization of Interstate Movement and Importation

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 likely to present little to no 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 impacts.

4.3.3.2.2 Authorized Environmental Release

Any potential impacts on vertebrate animals would be similar to those described for the No Action Alternative. However, in the event an unusual risk was presented by a particular GE organism-trait-MOA combination, the Preferred Alternative may be more protective of vertebrate animals than the No Action Alternative as a result of the broader range of GE organism-trait-MOA combinations that could be assessed under 7 CFR part 340, the refinement of the permitting procedure to provide for assigning protective measures, and the more clearly defined compliance, enforcement, and remediation authority, as well as reporting requirements.

4.3.3.2.3 Unauthorized Environmental Release

The harm to vertebrate animals from unauthorized releases are expected to be minimal under both the No Action and Preferred Alternatives.

4.3.3.2.4 Environmental Release After a Finding of Unlikely to Pose a Plant Pest Risk

As with the No Action Alternative, potential adverse impacts on vertebrate animals would largely result from altered habitat in agricultural fields, use of pesticides, and degradation of water quality through run-off of agricultural inputs, sources of potential impact common to both GE and non-GE commercial cropping systems. Similar to the No Action Alternative, the impacts to vertebrates from the Preferred Alternative are expected to be low.

Under the Preferred Alternative just like the No Action Alternative, EPA oversight of pesticides, including GE PIPs and GE microbial pesticides would remain the same, as would FDA oversight of foods derived from GE plants. Under the final revisions to 7 CFR part 340, PIP-containing GE plants would not be subject to the regulation unless they presented a plant pest risk. As the EPA usually issues EUPs 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.

4.3.4 Plant Pests and Disease

4.3.4.1 No Action Alternative: Plant Pests and Disease

4.3.4.1.1 Authorization of Interstate Movement and Importation

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. Most authorized importation and interstate movements involve seeds of GE plants, disarmed agrobacterium which does not cause disease symptoms, or courtesy permits of GE *Drosophila melanogaster*. As irregularities in shipments are rare and the GE organisms being shipped are unlikely to cause plant disease, APHIS authorizations of the movement or importation of GE organisms under current regulations have not had, nor are they expected to have, any adverse impacts on plant pests and diseases in the United States.

4.3.4.1.2 Authorization of Environmental Release

APHIS has authorized more than 19,500 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.

Environmental considerations for field testing of GE pest and disease resistant plants include whether the PIPs affect non-target organisms; whether the plants are more likely to harbor disease; or, particularly in the case of viral resistant plants, whether they can through recombination lead to the more rapid evolution of new plant viruses. The EPA considers whether pest organisms will also develop resistance to the PIP. To date, APHIS is unaware of any GE plant that unreasonably harmed non-target organisms, caused the spread of plant disease, or led to the creation of a more harmful plant virus through recombination. As discussed in Section 3.6.5, reports that GR crops are more susceptible to disease (Huber and Haneklaus 2007; Fernandez et al. 2009) have not been substantiated by other labs (Duke et al. 2012). Based on these considerations, it is expected that the risk of wide spread disease susceptibility originating in GE plants is low under the No Action Alternative.

4.3.4.1.3 Unauthorized Environmental Release

APHIS compliance and enforcement activities help ensure that regulated GE organisms developed for pest and disease resistance are confined to the areas authorized for import, movement, or field testing. 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 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. These measures help to ensure the confinement of plant pests and diseases in the United States.

4.3.4.1.4 Environmental Release After a Determination of Nonregulated Status

Under the No Action Alternative, APHIS conducts a PPRA in response to petitions for determinations of nonregulated 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; result in the introduction, spread, and/or creation of a new disease; and/or 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 considers the potential impacts of the GE organism on plant pests and diseases, and the potential impact of a PIP on non-target organisms.

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 which pests and diseases are present or emerging. There are several insecticidal proteins derived from Bt, Cry and Cyt, each of which is toxic to different orders of insect (Palma 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.

While 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 selection pressure 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; it is inherent to virtually any substance to which a target population is exposed. 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 in the crop species, or a gene introduced by recombinant DNA techniques or other technologies (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 as that of related conventional biopesticides such as microbial Bt sprays (McGaughey and Whalon 1992; Webber 1995). Consequently, the development of and selection for 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. Therefore, 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 crops for insect control, which began 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 inhibit the development of resistant populations.[133] Currently, these primarily involve implementation of recommended insect resistance management practices (US-EPA 2015b). The EPA requires companies supplying GE Bt seed to implement an Insect Resistance Management (IRM) program for corn rootworm management, and work with growers to implement Integrated Pest Management programs. IPM practices 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 the EPA registered PIPs as part of an IRM plan. 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, 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.[134]

A Center for Science in the Public Interest 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 (CSPI 2009). Corn rootworm refuge distance compliance percentages fell from 82% percent to 63% over the same time frame (CSPI 2009). Compliance has since improved[135] but remains an ongoing concern. Compliance programs are important to assist growers to comply with the EPA IRM and industry stewardship requirements (Tabashnik et al. 2013). Groups like the National Corn Growers Association promote 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

[133] EPA - Framework to Delay Corn Rootworm Resistance: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/framework-delay-corn-rootworm-resistance
[134] Insect Resistance Management Plans - The Farmers' Perspective: http://www.agbioforum.org/v10n1/v10n1a04-alexander.htm
[135] NCGA: http://www.ncga.com/news-and-resources/news-stories/article/2015/02/refuge-compliance-report-shows-increased-compliance-in-2014

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).

Disease Resistance

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 diseases in a given area.

For example, the availability of GE plants that can resist bacterial and fungal pathogens may lead to a reduction in pesticide use for the control of these pathogens, and prevent or delay development of antibiotic resistance. Currently, Citrus Greening caused by the bacteria, *Candidatus liberibacter* and spread by the Asian citrus psyllid is devastating Florida citrus groves. APHIS has approved field trials where a GE *Citrus tristeza virus* was used to inoculate young trees that have so far resisted infection by *C. liberibacter*. Based on the promising pilot studies, a statewide release is being planned (USDA-APHIS 2020b). Treatment with the GE virus can potentially reduce the large quantities of insecticide that are being sprayed to control the psyllid insect vector and the large quantities of fertilizer that are being applied to encourage growth in the diseased trees (USDA-APHIS 2020b).

A potato resistant to late blight (*Phytophthora infestans*) was determined by APHIS to have nonregulated status and is being grown on limited acreage for fresh market use in the United States. According to the company website, if all Russet Burbank potatoes in the United States had this GE trait, potato waste (in field, during storage, packing, retail and foodservice for fresh potatoes) would be estimated to be reduced by 986 million pounds. In addition, CO_2 emissions could be reduced by 146 million pounds, water usage reduced by 17 billion gallons, and a total of 495,000 fewer acres would require fungicide applications (Simplot 2018).

It is expected that disease resistant GE crop plants could reduce the amount of antibiotics and other pesticides that are applied to control certain microbial diseases in plants as well as improve the overall sustainability of agriculture.

Potential Impacts on Non-target Species

The Cry and Cyt proteins (δ-endotoxins) produced by *B. thuringiensis* 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. These proteins have also been expressed in Bt crop plants. Bt 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 impacts of Bt crops on invertebrate organisms (Naranjo 2009). Note that the findings from these studies are also discussed in Section 4.3.2 – Invertebrates, and 4.3.1 – Soil Biota, and 4.3.7 – Biodiversity.

In general, the GE Bt plants cultivated so far appear to have little adverse impacts on soil biota such as earthworms and soil microflora (Saxena and Stotzky 2001; Baumgarte and Tebbe 2005; Icoz and Stotzky 2008; Zeilinger et al. 2010; Carpenter 2011; Turrini 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 impacts of GE Bt plants released to date on non-target populations appear to be minimal, if any impacts were observed (Wolfenbarger et al. 2008; Naranjo 2009; Carpenter 2011). There have been some effects of Cry and Cyt proteins on non-target organisms, namely soil microbes, reported in the literature, although effects are not consistently observed and differences in effects attributed to variances in geography, temperature, plant variety, and soil type (Wolfenbarger 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 the short-term, GE Bt crop plants have no adverse effects on arthropod biota of agricultural landscapes (Szenasi 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 et al. 2008).

There was some concern that Bt crops were adversely impacting monarch butterfly (*Danaus plexippus*) populations. Pollen from Bt corn plants was shown to be toxic to monarch larvae in laboratory studies (Losey et al. 1999). Follow up experiments and a risk assessment concluded that it was unlikely that monarch butterflies would be exposed to much Bt pollen and that the impact of Bt corn pollen from current commercial hybrids on monarch butterfly populations is negligible (Sears et al. 2001; USDA-ARS 2015).

There has also been some concern that the widespread planting of GE crop plants could harm honeybee populations. A meta-analysis of 25 studies investigating the potential effects of Bt Cry proteins on honeybee 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 honeybee larvae or adults in laboratory settings (Duan et al. 2008; Hendriksma et al. 2013).

Indirect impacts on specialized natural predators, parasites, and pathogens of target insects such as European corn borer, could theoretically occur, as populations of predators, parasites, and pathogens of target insects would decline as their host populations decline. However, 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 2010). 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, a marked increase in populations of three types of generalist predators (ladybirds, lacewings and spiders) and a decrease in aphid pests was observed 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 2010; Lu et al. 2012). Lu et al. (2012) also suggest that the higher populations of generalist predators in Bt cropping systems relative to the non-GE systems may provide biocontrol services to neighboring crops (e.g., corn, peanut, and soybean).

In general, scientific evidence supports the conclusion that Cry and Cyt proteins released to date are highly selective for insect pests of 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.

There has been some concern among stakeholders regarding the use of newer RNAi-based products to protect plants from insects and disease, and the potential impacts of such PIPs on human and environmental health (Sherman 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 et al. 2015). The current framework for the risk assessment of RNAi PIPs is found in the EPA's white paper on use of RNAi technology as a pesticide (US-EPA 2013a, 2014a). The EPA convened a Scientific Advisory Panel Meeting[136] in 2014 (US-EPA 2014a) 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 PIPs, as well as those exogenous RNAi products. The Panel recommended an exposure model to reduce the uncertainties in the ecological risk assessment of RNAi PIPs and RNAi 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 2014a). One GE crop, a corn modified to produce a double stranded RNA (DvSnf7) that confers resistance to corn rootworm, has completed reviews through the USDA, FDA, and EPA. The trait is known as CRW III and is expected to be stacked with other herbicide and insect resistance traits in a corn known as SmartStax Pro® and released sometime in 2020 (Batty 2016). To evaluate the potential exposure of non-targets in the environment, the environmental fate of DvSnf7 dsRNA was measured (Dubelman et al. 2014). Results from the study indicate that DvSnf7 RNA is degraded to a biologically inactive state within 2 days of application to the soil, regardless of texture, pH, clay content and other soil differences (Dubelman et al. 2014). Hence DvSnf7 RNA is unlikely to persist or accumulate in the environment.

While the science indicates that current PIP-containing GE crop plants present minimal risk to non-target populations, the potential for future PIP-containing crops to have adverse impacts 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, as PIPs are incorporated into plants as stacked-traits (or pyramided), and as PIPs are expressed at different levels. Likewise, regulatory processes and procedures to ensure sufficient evaluation of the human and ecological risks of such PIPs will continue to evolve (US-EPA 2013a, 2014a; Sherman et al. 2015).

[136] The FIFRA Scientific Advisory Panel 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.

Environmental Benefits

While the potential for adverse impacts on non-target species exists, insect and disease resistant GE cropping systems are, for the most part, considered more environmentally benign than cropping systems utilizing conventional insecticides, bactericides, and fungicides, (Gatehouse et al. 2011; Brookes and Barfoot 2013a) and highly effective in controlling target plant pests and diseases. Based on data from1995 through 2014, there has been a pronounced reduction in pesticides used on GE Bt-crops; by one estimate the reduction is approximately 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 plant pest populations on the landscape scale, which benefits surrounding crops and reduces the need for insecticide use in nearby fields, including non-GE cropping systems (Carpenter 2011). While the environmental benefits conferred by such reductions in pesticide use are obvious, such reductions likewise reduce exposure of farmworkers to pesticides and consequent risk 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. Fungal infections are more pronounced in grains that have been damaged by insect feeding. Mycotoxins, namely fumonisin and aflatoxin, can be significant contaminants of food (Wu 2006) and are known to have adverse health effects in animals, and likewise a human health risk (Abbas et al. 2006; Wild and Gong 2010).

4.3.4.2 Preferred Alternative: Plant Pests and Disease

4.3.4.2.1 Authorization of Interstate Movement and Importation

Conducted pursuant to APHIS requirements under the Preferred Alternative, movements and importations of GE organisms would not present increased plant pest or disease risk as compared to the No Action Alternative. Irregularities in shipments are rare and the GE organisms being shipped are unlikely to cause plant disease. APHIS authorizations of the movement or importation of GE organisms to date have not had, nor are they expected to have, any adverse impacts on plant pests and diseases in the United States under both the No Action and Preferred Alternatives.

4.3.4.2.2 Authorization of Environmental Release

The environmental concerns in field testing of insect and disease resistant GE plants, and microbial pesticides in regard to potential impacts on non-target species, are the possibility that the GE plants could spread disease, and the potential for new viruses to emerge by recombination with viral sequences in the GE plant. These potential impacts would be the same as described under the No Action Alternative.

The purpose of many of the GE organisms field tested is protection against plant pests and disease. The GE organisms field tested to date have and are expected to continue to present negligible plant pest risks. Issues of development of resistance to PIPs has 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.

4.3.4.2.3 Environmental Release After a Finding of Unlikely to Pose a Plant Pest Risk

When a GE organism does not fall within the authority of 7 CFR part 340, that organism may be introduced into any environment in the United States or its territories, subject to compliance with the EPA, and other federal and local agency requirements, without APHIS authorization. The EPA would continue to regulate organisms that contain PIPs or are microbial pesticides, as described under the No Action Alternative and throughout this PEIS.

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 was effective utilization of insect and disease-resistant GE crop plants, a reduction in pest and disease populations in the areas where these crops are cultivated by virtue of suppression of target insect pests and pathogens could be seen. This would indirectly benefit neighboring cropping systems, GE and non-GE alike. These benefits would take the form of reduced crop damage, which can increase product quality and yield, a reduction in the overall use of synthetic pesticides for control of plant pests and disease, and improved return on investment.

The Preferred Alternative is considered more supportive and protective of agricultural plants than the No Action Alternative, as it broadens the scope of organisms considered for plant pest risks while reducing oversight of GE organisms that present no such risks.

4.3.5 Agricultural Weeds and HR Weed Management

This section describes potential impacts on weed management of common agricultural weeds, the development of herbicide resistant weed populations, and management of noxious weeds.

4.3.5.1 No Action Alternative: Agricultural Weeds and Herbicide Resistant Weeds

4.3.5.1.1 Authorization of Interstate Movement and Importation

When APHIS notification and permit requirements are followed, there is a very low likelihood of release of GE organisms and therefore a very low potential for GE organisms to pose weed risks.

Unauthorized release of GE organisms could occur if there is accidental spillage of seed, intact plant, or other material, as a 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 are unauthorized releases. 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 Section 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 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 pose a weed problem, all of these conditions in 1) or 2) would have to be met. Therefore, there is low probability that a GE organism would pose a weed risk 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, mitigation would entail removal of seeds or plants from the environment. In the rarer cases where plants have established, GE plants could 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 the EPA requirements, and negligible risks that HR weeds would be selected for from repeated herbicide exposure.

In the unlikely event there is a noncompliance incident associated with importations and interstate movements, APHIS assesses the event and takes 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.

4.3.5.1.2 Authorization of Environmental Release

Agricultural weeds are common in and around field test sites. Weed management during field trials is the same as in commercial crop production and could involve the use of herbicides, tillage, crop rotation, cover crops, etc. It is well recognized that the repeated long-term use of a particular herbicide or herbicide class can promote the development of HR weeds. This is not unique to GE plants; herbicide resistance has routinely developed in non-GE cropping systems since the introduction of herbicides in the1950s.

Use of herbicides during field trials may select for weed species that have innate resistance to the herbicide (shift in weed community) or select for resistant individuals in a sensitive population (development of resistant populations). While the potential exists wherever herbicides are used, the likelihood of altering weed communities or selecting for HR weed populations during field trials is quite low due to the spatial and temporal constraints place on field trials, and the intensity with which weeds are generally managed during field trials.

In order to reduce the potential for development of resistant populations, developers that field test GE plants must implement an 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 HR weed populations as part of authorization for the field testing of GE plants.[137] Herbicides used during field trials are regulated by the EPA and must be registered with the EPA prior to use. Developers are required by law to use herbicides pursuant to the 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) BMPs for weed resistance management.[138] The EPA may also require a weed resistance management plan as part of

[137] 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

[138] 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/

authorization of use. It is expected that herbicides will be judiciously used during field trials per APHIS and WSSA recommendations, and the EPA requirements.

To the extent individuals comply with current APHIS notification and permit requirements, the EPA requirements for herbicide use, and well recognized industry standards for management of development of HR weeds (e.g., WSSA), the development of resistant weed populations as a result of field trials is expected to be limited. Field trials are generally short in duration and small in area, typically occurring for 1 year, and generally comprising around 5 to 50 acres. This limits the potential for selection of HR 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 selection of HR 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 and with the WSSA to develop strategic approaches to the management of weeds and weed resistance to herbicides. In the event that a resistant line of weeds was discovered in a regulated field trial, company personnel and the EPA would be notified of the occurrence and a remediation plan would be enacted to minimize the spread of that weed population.

4.3.5.1.3 Environmental Release After a Determination of Nonregulated Status

When APHIS approves petitions for nonregulated status, it allows for the GE plant subject of the petition to be planted. The use of herbicides on GE crops and other GE plants are and would continue to be regulated by the EPA under FIFRA. While APHIS does not regulate pesticide use, crop production, or weed management practices, APHIS regulatory decisions under 7 CFR part 340 on GE HR, IR, and disease resistant crops can indirectly contribute to influencing pesticide use patterns. Major factors affecting overall herbicide use trends (as measured in lbs a.i./year and lbs a.i./acre) have been: (1) changes in crop acreage, which is influenced by economic and policy factors, (2) the replacement or discontinuance of older pesticides (MOAs) with newer ones (changes in per-acre application rates), contributing to changes in overall pesticide quantities, (3) the introduction and adoption of GE crops by growers, and (4) the emergence of weed populations resistant to various herbicide MOAs over the last several decades.

As discussed in 3.4.3.2 – Weed Resistance Management, management of HR weeds has been addressed in part by the introduction of stacked-trait varieties of GE crop plants. Because these varieties allow use of multiple herbicides with varying modes of action, the herbicide regimes used in these cropping systems can reduce selection pressure for resistant weed biotypes. GE crop varieties incorporating two or more HR traits are now common (see petition table on APHIS website for some examples (USDA-APHIS 2020e)). The preference for these varieties is due in part to the emergence of glyphosate resistant weeds and a need for their management.

There is disagreement in the weed-science research community about the benefit of stacking multiple HR traits and spraying multiple herbicides for resistance management (NAS 2016b). Some agronomists and weed scientists have expressed concern regarding the potential impact of GE HR cropping systems on sustainable weed control. Critics of GE crops assert that the use of herbicides on HR crop plants facilitates overuse and perpetuation of weed management systems. Critics of stacked-trait GE HR varieties, in particular, assert that these cropping systems are likely to (1) increase the severity of resistant weeds (e.g., resistance to multiple herbicide MOAs), (2) facilitate a significant increase in herbicide use, with potential negative consequences for environmental quality, and (3) deter further research into integrated weed management (Mortensen et al. 2012). This position derives in part from the repeated and singular use of glyphosate on GE glyphosate resistant crops, which led to wide-scale selection for weeds with resistance to glyphosate.

Proponents of GE HR varieties assert that herbicide resistance is a problem for all crops on which herbicides are applied, not just GE crop plants (see Section 3.4.3.2), that herbicides represent an extremely valuable tool for weed management, and that, with proper practices, selection of HR weed populations can be minimized. Scientists supporting the benefit of stacked-trait GE HR varieties in particular assert they provide growers a broader range of options in using multiple MOAs and rotation of herbicide MOAs.

A number of new stacked-trait GE HR varieties are currently under development and may provide growers with broader weed management options when fully commercialized, but the sustainability of those new GE varieties in weed management will be determined by how the traits are managed (Owen 2011; Duke 2015). If they are managed like early glyphosate-resistant crops, the same problems of selection of HR weed populations and weed shifts will occur. To prevent selection of HR weeds, current and future GE HR crop varieties will have to be utilized in an efficient IWM program incorporating herbicide rotation, crop rotation, cultural and mechanical control practices, and sanitation and harvesting practices that minimize selection of HR weeds. These practices will need to be supported through collaborative efforts among federal and state government agencies, private-sector technology developers, university extension services, and farmer organizations to develop crop-specific cost-effective resistance-management programs and practices that preserve effective weed control in HR crops (Owen 2011; Mortensen et al. 2012; Shaner and Beckie 2014; Duke 2015). Lastly, effective management of HR weed populations requires widespread implementation of IWM/WRM among neighboring farms.

Where IWM practices are not implemented with GE HR crops and resistant populations emerge, there will likely be further increases in herbicide use. For example, in 2013, almost two-thirds of glyphosate resistant soybean crops received an additional herbicide treatment, compared to 14% in 2006 (USDA-APHIS 2014d). Where HR weeds are a significant problem there will likely be a loss of conservation tillage practices, with commensurate impacts on soil erosion and declining water quality in some areas.

When IWM practices are implemented, there is evidence that HR weed populations can be controlled and diminished over time. For instance, it has been shown that weed population densities can be lowered in continuous glyphosate resistant corn cropping systems incorporating IWM strategies over a period of 2 to 6 years (Gibson et al. 2015).

There are collaborative efforts underway to expand grower implementation of recommended IWM practices to control weeds and reduce development of resistant populations. These include efforts by university extension and the WSSA to educate growers, and greater oversight of herbicide management by the EPA through the inclusion of stewardship requirements on herbicide registrations (US-EPA 2017c). However, grower management of herbicides may not align with recommendations for optimal management of resistant weed populations (Owen 2011). As discussed in Section 3.4.3.2, there is some uncertainty as to exactly how many, and to what extent growers will implement recommended IWM practices (Shaner and Beckie 2014).

Growers may not adopt recommendations they perceive as being too expensive, time consuming, or complicated (Shaner and Beckie 2014). Because of the inherent economic risks in farming, it may be difficult for some growers to manage for long-term benefits when those practices conflict with short-term economic returns (Shaner and Beckie 2014). Moreover, growers who rent or lease land may have less incentive for land stewardship, including adoption of IWM practices, than growers that own the land (Shaner and Beckie 2014).

All things considered, it is in the best interest of the crop producer to avoid practices that select for HR weed populations, because HR weeds reduce yield, increase costs, and require greater effort to control. 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. On the other hand, because only a handful of companies provide herbicides, critics of herbicide providers assert that there may be no cost to a company overall, and thus little monetary incentive to take significant actions to prevent development of HR weeds. Some critics further argue that HR weeds present a market opportunity for sale of expensive new GE HR seeds and increased sales of the additional herbicides used with them. However, this argument is considered untenable. While there will always be incentive to sell herbicide and capture market share, due to the lack of new herbicide MOA chemistries over the last several decades, the herbicide industry is realizing that it is mutually beneficial to themselves, their dealers, and growers to maximize the effective lifetime of their products by promoting reasonable frequency-use intervals within cropping systems (Shaner and Beckie 2014). For example, BASF recommends use of an acetolactate synthase (ALS)-inhibiting herbicide no more than twice within a 4 year period in a field.[139]

Under the No Action Alternative, management of extant HR weeds, and their development, will remain a fundamental concern in commercial agriculture for the foreseeable future. This applies equally to GE and conventional cropping systems. For example, there are a broad array of HR weeds in non-GE wheat, rice, and barley. If APHIS approves petitions for nonregulated status of single and stacked-trait GE HR varieties, and growers adopt these varieties without implementing effective IWM programs, it is highly likely that the effectiveness and value of the trait will decrease. Effective, long-term weed management will require implementation of IWM programs that effectively integrate chemical, physical, biological, and cultural methods to control weeds and reduce selection for resistant populations. Reliance solely upon herbicides for weed management will result in further selection of resistant weed populations, including populations resistant to multiple herbicide MOAs. Fundamentally, sustainable weed management will only be achieved if there is diversity in both the agroecosystem and in the herbicide and non-herbicide tools employed for weed control (Shaner and Beckie 2014).

The adoption of HR crops and their associated agronomic practices may facilitate the achievement of effective weed management and overcome increasing HR weed problems as well as other environmental issues associated with the intensification of agriculture (Lamichhane et al. 2017). However, the management of HR crops must integrate sustainable practices and measures. Although such sustainable practices may be more costly for growers to implement in

[139] BASF – The Clearfield Commitment to Stewardship (2013). Available online: http://agproducts.basf.us/products/research-library/clearfield-lentils-stewardship-guildelines.pdf

the short-term, they will be beneficial in the longer term, especially if appropriate policies and incentives are put in place (Lamichhane et al. 2017).

Under the No Action Alternative, increased herbicide use can be expected as growers adopt stacked-trait varieties to manage HR weeds. With additional herbicide use there could be an increase in harmful impacts to humans, plants, and wildlife (see Section 3.4.2.2 – Pest and Weed Management).

4.3.5.2 Preferred Alternative: Agricultural Weeds and Herbicide Resistant Weeds

4.3.5.2.1 Authorization of Interstate Movement and Importation

Under the Preferred Alternative, the weed risks from the interstate movement and importation of GE organisms would be similar to the No Action Alternative. To the extent that the regulation would apply to a broader scope of organisms, the Preferred Alternative is considered to be more protective of agriculture and the environment than the No Action Alternative.

4.3.5.2.2 Authorization of Environmental Release

Under the Preferred Alternative, environmental releases 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; release of GE 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 of GE organisms.

The Potential for selection of herbicide resistant weeds under the Preferred Alternative is expected to be the same as under the No Action Alternative. APHIS would recommend the same BMPs for management of herbicide resistant weed populations as described under the No Action Alternative.[140] 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 HR weed populations would be the same under both the Preferred Alternative and No Action Alternative.

4.3.5.2.3 Unauthorized Environmental Release

By changing the regulatory trigger under 7 CFR part 340, APHIS would be able to assess a broader range of GE organisms for authority. Consequently, the Agency would have a stronger position, under the Preferred Alternative compared to the No Action Alternative, to prevent and mitigate the unauthorized release of GE organisms that has a plausible pathway to increased plant pest risk. Under both the No Action and Preferred Alternative, GE plants that posed weed risks would be regulated pursuant to our statutory authority and the regulations issued under that authority.

[140] 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

4.3.5.2.4 Environmental Release after a Finding of Unlikely to Pose a Plant Pest Risk

In regard to the management of agricultural weeds and development of herbicide resistant weeds, the potential beneficial and adverse consequences of APHIS deregulation of GE organisms are not expected to significantly differ from that discussed under deregulation for the No Action Alternative. The pesticide stewardship and IWM/IPM strategies recommended by weed and pest management scientists, and implemented by developers and growers of commercial crops, would remain the same. Adoption of the regulatory framework under the Preferred Alternative would have little effect on implementation of extant weed management strategies or current efforts to manage and reduce development of herbicide resistant weeds (see 3.4.3.2 - Weed Resistance Management). Hence, the outcome of regulatory status decisions on weed management under the Preferred Alternative would be expected to be the same as or similar to the No Action Alternative, in terms of effects on agricultural weed management.

If a GE organism which was determined to be outside APHIS' authority was later found to have a plausible pathway to increased plant pest risk, APHIS has the authority to reverse its finding and subject that organism to its regulation under 7 CFR part 340.

4.3.6 Gene Flow and Weediness

This section describes the potential for gene flow from GE to non-GE organisms, and the weediness of GE plants. Weediness in this section 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 Authorization of Interstate Movement and Importation

Unauthorized and unintended releases during movement and importation can occur, however, such unintended releases would be limited to rare instances of container failure and human error. Major incidences of noncompliance, such as shipping without proper identification, have been of low incidence and when they have occurred, remedial actions have been 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.

4.3.6.1.2 Authorization of Environmental Release

Potential Risks of Gene Flow during Environmental Release

Where sexually compatible species grow in proximity to GE plants, gene flow from the GE plants to the sexually compatible plant species are possible. For plants, the particular species of

GE plant and occurrence and proximity of sexually compatible species is the primary factor in reviewing the risk of gene flow, as discussed in Section 3.4.1.1. For example, corn soybean and alfalfa do not have wild relatives of concern in the United States. Cotton lacks relatives, except in Hawaii, Florida, Puerto Rico, and the US Virgin Islands (Mendelsohn et al. 2003). Sugarbeet lacks relatives except in CA. Other crops such as wheat, rice, sorghum, rapeseed/canola, sunflower, squash, eucalyptus, and creeping bentgrass have relatives distributed throughout the United States. In cases where gene flow to persistent populations of sexually compatible relatives is a possibility, permit conditions may require the responsible party to prevent flowering of the GE plant and/or scouting and removing sexually compatible species from adjacent areas. If flowering is necessary for the field trial and the GE plant can persist or has sexually compatible relatives that can persist in the environment without human intervention, an EA is typically completed to inform the decision making about the permit request.

Microorganisms 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 important exceptions exist. The reproduction of fungi and oomycetes is both sexual and asexual, although the majority 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 for applications for product registration. 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 the EPA, APHIS entered into a memorandum of understanding (MOU) with the EPA stating that APHIS will not exercise duplicative regulatory oversight of the products (USDA-EPA 2012b).

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. For most GE crop plants, their potential for evolving as an invasive or weedy plant is considered quite limited, as discussed in Section 3.4.1.1. For certain GE grasses and trees, and to some extent ornamentals, the risks are higher. These risks are summarized in the following paragraphs.

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 crop 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, most domesticated plants stay domesticated. While domesticated crop plants have the capacity to occur as feral populations, they rarely establish and become invasive (Warwick and Stewart 2005; Ellstrand et al. 2010). As summarized in Section 3.4.1.1, there are few examples of domesticated crop plants directly evolving into competitive weedy or invasive plants. One study examining domesticated plants that have been cultivated for at least 1000 years found only 13 examples of weedy plants that descended from crop progenitors (Ellstrand et al. 2010). As further detailed in Section 3.4.1.1, the domesticated nature of most crop plants limits the likelihood of crop species colonizing outside areas of cultivation, and subsequent evolution into weeds.

GE crop plants are comprised of the same domesticated genome as their non-GE counterparts with the exception of the introduced trait gene(s).[141] Consequently, a GE crop plant is inherently 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 selection favored the GE plant or GE plant/wild-relative hybrid. Abiotic stress tolerance could enhance fitness when it increased reproductive and vegetative growth, or 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 et al. 2013).

The potential weediness and invasiveness of GE trees require considerations beyond those of annual crop plants because they are long lived perennials, and the potential range of pollen distribution can be substantial. 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 trees occur, deflowering of trees, removal of the GE tree before flowering, and application of biocontainment/sterility techniques. Grasses likewise are perennials that frequently have sexually compatible wild relatives, and GE varieties require considerations beyond those of crop plants when authorization of field testing is requested.

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 and abiotic environment including such factors as the particular role or function of the plant species in ecosystem dynamic, the fecundity and overall vigor of the particular GE plant species or hybrid progeny, the particular selection pressures

[141] 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.

present such as herbicide use, insects pests, pathogens, herbivory, or 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 the GE plant or hybrids derived from it could in theory 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 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 crosses between crops and their wild relatives, and fitness and fertility of potential hybrids (i.e., (Stewart et al. 2009; Warwick et al. 2009; Ellstrand 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 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 are applied to permits depending on the type and nature of the GE organisms being field tested (USDA-APHIS 2011, 2012c).

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 imposes 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 likelihood 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, the likelihood that the GE organism or its progeny can persist in the environment, reproduce, and establish without human assistance. Other risk factors that are considered include the availability of suitable hosts or habitats for the GE organism, the abundance of sexually compatible species with which the GE organism can breed, and the likelihood that the modified organism itself 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 these possibilities. Fundamentally, the key to minimize gene flow and potential establishment of GE plants as weeds/invasive plants during authorized field testing is confinement. Mitigation measures must be in place to remedy instances where accidental release of a t 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 factors such as seed dormancy and ability to persist as volunteers, special conditions may be prescribed as required to prevent gene flow between GE and non-GE plants.

Notifications, discussed in Section 2.1, 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 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:

- spatial 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 releases 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.

Site inspections are critical to ensuring that field tested GE plants do not persist beyond the conditions of permit or notification. 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. For perennial plants, site inspections may be different than that of annual plants depending on the biology of the species.

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 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. The potential impacts and remediation requirements of an unauthorized release are assessed on a case-by-case basis, in the event such occurs.

Notification and permit authorization procedures under the current regulations have been effective, as discussed above. However, 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. OIG suggested that APHIS revise the regulations to minimize the risk of inadvertent dissemination of regulated articles from a test field. Among other things, OIG recommended that we include in the regulations provisions that would require developers to provide written protocols prior to approval of the field trial and require that a biotechnologist review the protocols to ensure they are sufficient to meet performance standards for a notification of a GE organism. In addition, OIG recommended APHIS develop and implement science-based protocols and criteria for approving permits and notifications. 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 APHIS provide more explicit guidance regarding how to terminate a field test and document this termination. Hence, APHIS has finalized revisions to regulations, discussed subsequently under the Preferred Alternative.

While gene flow will always be a factor to consider 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 that are 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.

4.3.6.1.3 Unauthorized Environmental Release

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. In addition, the responsible person for an environmental release is required to orally notify APHIS 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 is initiated and remedial measures are applied as necessary. The consequences of an unauthorized release are likely to be local, limited to the area where the unauthorized release occurred, and 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 destroying of wild plants through the use of herbicides or plowing, and disturbance of habitat for various species. These disturbances would be local and temporary.

To the extent individuals comply with current APHIS notification and permit requirements, the likelihood 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, the EPA, the DOJ, 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' 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).

4.3.6.1.4 Environmental Release after a Determination of Nonregulated Status

Under the No Action Alternative, APHIS conducts a PPRA in response to petitions for determinations of nonregulated 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 2020e)).

As part of the decision-making process regarding a GE organism's regulatory status, APHIS conducts the relevant environmental analyses in accordance with NEPA and the ESA to provide the Agency with 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 nonregulated status for a GE organism.

As with the potential impacts described for environmental releases, one of the principle concerns among some stakeholders regarding commercial use of nonregulated GE plants (e.g., agricultural or forestry products) is gene flow. As part of the PPRA, APHIS evaluates the potential for gene flow, crossing 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 organism is unlikely to pose a plant pest risk, APHIS will determine the organism is not subject to regulation.

Under current regulations APHIS also provides 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.[142] 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, or environmental release of the organisms. That organism may still be subject to other APHIS regulations pursuant to our statutory authority and the regulations issued under that authority (USDA-APHIS 2014b, a).

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

[142] USDA-APHIS: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

GE plant, including regulation of PIPs and GE microbial pesticides. The FDA, under the FFDCA, oversees the food safety of GE plant products used for human or animal food.

The vast majority of GE organisms that have been deregulated by APHIS have been crop plants. Many, but not all, are commercially produced in the United States (see Section 3.3). It is expected that the majority of future GE organisms APHIS will be reviewing 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 insects and 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.

Gene Flow and Deregulated GE Plants

Minimizing the potential adverse impacts of gene flow lays, in part, in the regulation of GE organisms during research and development and, in part, in the collective reviews among APHIS, the EPA, and other applicable federal agencies prior to commercial use based on scientific 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 in 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 organism is unlikely to pose a plant pest risk, and that gene flow to wild relative species is also unlikely to result in plant pest risks, APHIS will deregulate a GE organism under 7 CFR 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 were implemented to minimize the likelihood of gene flow. Producers of GE and non-GE crops may use practices prescribed by the USDA National Organic Program (USDA-AMS 2020b), ASTA (ASTA 2011, 2020), and AOSCA (AOSCA 2020) 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.

4.3.6.2 Preferred Alternative: Gene Flow and Weediness

4.3.6.2.1 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.[143] Movements of GE organisms would have to meet the

[143] 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.

containment requirements defined within the new regulations and be 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 organisms under permit 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; and production, propagation, sale, distribution, and manufacturing locations.

Under the Preferred Alternative, APHIS' regulation of interstate movement and importation would encompass oversight of the movement of a broader range of GE organism-trait-MOA combinations. Movement of GE organisms would be conducted by authorized permit only, which would allow for issuance of specific confinement requirements where there were particular concerns in regard to gene flow or weediness.

4.3.6.2.2 Authorization of Environmental Release

As with movement and importation, environmental releases 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 site and its persistence in the environment on conclusion of the authorized release.

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 GE organisms within the authority of 7 CFR part 340, 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 GE organism in the environment, including but not limited to a description of how the phenotype of the GE 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.

As a result of the broader range of GE organisms assessed for authority under regulations and the elimination of the notification option, the Preferred Alternative could provide more protections than the No Action Alternative. Permit conditions would allow confinement requirements tailored 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 GE organisms.

4.3.6.2.3 Unauthorized Environmental Release

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 nonregulated organisms; and failure to monitor for volunteer GE plants in the year following a field test. In all instances, APHIS required remediation actions, and in many instances, civil penalties issued.

Considering the final 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 of an unauthorized release. With extended oversight of GE organisms that may have a plausible pathway to increased plant pest risk, APHIS can devote its resources to provide better oversight

4.3.6.2.4 Environmental Release after a Finding of Unlikely to Pose a Plant Pest Risk

Under the Preferred Alternative, it will be possible for GE organisms to undergo a regulatory status review prior to field testing. For those situations where the Agency finds it has no regulatory authority, GE organisms may be field tested without being subject to APHIS permits. A subset of these organisms may be subject to EPA regulation. Any of these organisms used for food and feed will be subject to the food safety requirements enforced by FDA and APHIS anticipates that they generally would go through FDA's voluntary food safety pre-market consultations. The potential for gene flow during field testing of GE plants not under APHIS authority is unlikely to differ between the No Action and Preferred Alternatives, based on the factors discussed below.

Currently the vast majority of the field tests are conducted by a few large developers in the industry (Monsanto merged with Bayer, Dow/DuPont merged to form Corteva, Syngenta merged with ChemChina, BASF acquired some Bayer assets that Bayer needed to divest after merging with Monsanto). From preliminary discussions held after the withdrawal of the 2017 rule and prior to the submission of the proposed 2019 rule, there are indications that the larger developers in industry would continue to conduct most of their field testing under permit. At least initially, it seems that the large developers would continue to operate in a manner similar to the No Action Alternative. However even if this assumption is not borne out and the large developers seek findings of unlikely to pose a plant pest risk prior to field testing, it is expected that industry will continue to impose measures on these field trials to restrict gene flow. Among the drivers in the industry are the need to protect intellectual property, to minimize legal exposure from selling seed that might have traits from competing seed companies, and to avoid risks related to potential trade disruptions. Consequently, genetic testing is routinely employed during the breeding process to ensure unwanted traits are not inadvertently maintained in the breeding program. In addition, the large companies have implemented stewardship programs, quality management systems, and use 3rd party audits to verify these systems. They participate in programs such as Excellence Through Stewardship[144] and/or the APHIS biotechnology quality

[144] https://www.excellencethroughstewardship.org/page/About

management support program.[145] For these reasons, APHIS does not expect an increase in gene flow from nonregulated GE field trials under the Preferred Alternative compared to gene flow from regulated GE field trials under the No Action Alternative, at least stemming from the major developers who conduct the vast majority of the field trials.

It is expected that small companies and academics are more likely than the big developers to take advantage of the regulatory relief offered in the final rule. It is expected that this group would increase their field testing relative to the No Action Alternative and these tests would predominantly involve plants that were outright exempted from the regulations or were not subject to 7 CFR part 340 based on an APHIS finding of unlikely to pose a plant pest risk. In either case, gene flow would not be expected to harm plants. Potentially, there could be socioeconomic impacts if the traits entered commerce but were still subject to regulation by another authority. There are several reasons why the risk of socioeconomic impacts from gene flow from these field trials would be low:

1) Many of the small developers have taken BQMS, employ quality management systems and have institutional biosafety committees that provide oversight,

2) The field trials conducted by the small developers are expected to be small in size and therefore limited in exposure to croplands and seed nurseries, and

3) The traits employed are likely to be very similar to those inherent in conventional breeding programs and therefore as safe and indistinguishable from conventional traits.

Management of gene flow in the commercial production of nonregulated GE crop plants would be the same as described for the No Action Alternative. Strategies for management of gene flow in agriculture are well-established and where implemented minimize the likelihood of gene flow. Producers of GE and non-GE crops may use practices prescribed by the USDA National Organic Program (USDA-AMS 2020b), ASTA (ASTA 2011, 2020), and AOSCA (AOSCA 2020) to minimize unintended presence and meet market standards for IP and certification as applicable. 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.

4.3.7 Biodiversity

4.3.7.1 No Action Alternative: Biodiversity

In general, species abundance and variety will be lower 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.

4.3.7.1.1 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

[145] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/bqms

organism during shipping or movement (USDA-APHIS 2011, 2012c). Conducted pursuant to APHIS requirements, movements and importations under current regulations have no impact 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 such spillage occurred, any remediation actions would be transient in nature, localized to the site of release, and adverse impacts on biodiversity would be highly unlikely. These types of incidents would generally have no lasting impacts on wildlife, wildlife habitat, or ecosystem dynamics in the area of release and remediation.

4.3.7.1.2 Authorization of Environmental Release

To control and minimize the occurrence of a GE plant or other organisms beyond the area where it is intended to be tested, notification performance standards and permit conditions are designed to confine regulated GE organisms to the field site and preclude persistence of the GE organism beyond termination of the field trial.

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 impacts on biodiversity is rather limited.

Certain GE organisms may present unique issues that warrant special restrictions during field release. 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 the development of any stress tolerant plant and possible expansion or shifting of the region in which it may be field tested. Development of plants for stress tolerance or for adaptation to marginal lands is likely to continue (with or without the use of plant biotechnology). These types of plants could see field testing in areas where crop 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 ESA,[146] EPA regulations protecting air and water quality (discussed throughout this PEIS), 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).

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 impacts 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 impacts on wilderness areas, forestlands, or critical habitat has been identified in over 20 years of field testing.

4.3.7.1.3 Unauthorized Environmental Release

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. 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 a volunteer plant population was present, APHIS could order treatment of the area with a broad spectrum herbicide or mechanical removal to eradicate the GE plants. The impacts 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 impacts on the affected area once remediation actions were completed. However, some areas may require long term monitoring and in extenuating circumstances, eradication of GE plants or other organisms could require months to years to complete. 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.

4.3.7.1.4 Environmental Release after a Determination of Nonregulated 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 the EPA and other federal and state agency requirements. Agricultural lands will continue to comprise the dominant use of nonregulated GE organisms. Therefore, potential impacts on biodiversity would be largely limited to these and surrounding areas.

While agricultural practices can contribute to conserving and promoting biodiversity, some practices can also serve as a major driver of biodiversity loss. Agronomic practices associated

[146] By example, see http://www.fws.gov/endangered/laws-policies/regulations-and-policies.html, and https://www.fws.gov/permits/ltr/ltr.html

with the cultivation of GE plants, such as pesticide application, fertilizer applications, tillage, and crop rotation (all of which are part of IPM and IWM practices) can all impact animal and plant populations and their habitats. Likewise, utilization of GE microbial pesticides can impact 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. A shift in weed species can impact 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 no different for non-GE agricultural systems, save for variance 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, which may consequently contribute to sustaining 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 HR weeds, and an increase in herbicide use and conventional tillage to manage resistant weed populations, neither of which serve to promote biodiversity. 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 2010; 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 studies have generally identified negative impacts 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 impacts 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 impacts of Bt crops have been observed; a greater number of adverse impacts have been identified in laboratory studies than have been observed in the field. This may be explained partially by the facts that protein exposures in laboratory studies were more controlled and often at higher levels than in field concentrations and 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 et al. 2004; Naranjo 2009).

A meta-analysis of 42 field experiments, which are more apt to provide data relevant to the potential adverse impacts 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 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 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 in conjunction may enable reductions in tillage, which is beneficial to water quality and 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 a.i. used; a 29.9% reduction (Naranjo 2009). In 2011, the global insecticide reductions from using GE IR corn and cotton were estimated 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).

While the potential impact of GE crops on biodiversity has been a topic of general interest, a 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 agriculture (Carpenter 2011). Sustainment of biodiversity will depend on the GE plant variety cultivated and agronomic practices employed, which will determine 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 benefit crop production and are 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).[147] 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."

[147] USDA - NAL, Sustainable Agriculture: https://www.nal.usda.gov/afsic/sustainable-agriculture-information-access-tools

The USDA recognizes that conservation by farmers, ranchers, and forest owners is required for sustaining agriculture for the future; therefore the Department provides various programs that support biodiversity and sustainability, such as landscape-scale conservation initiatives and CRP.[148] 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;[149] 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, species abundance and variety will be lower in intensively managed agro-ecosystems relative to any undisturbed ecosystem. However, practices such as those summarized above can foster 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, and use of more environmentally benign pesticides.

4.3.7.2 Preferred Alternative: Biodiversity

4.3.7.2.1 Authorization of Interstate Movement and Importation

As with the No Action Alternative, movements and importations conducted pursuant to APHIS requirements under the Preferred Alternative are not expected to impact 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 considered highly unlikely to adversely impact species abundance and diversity. These types of incidents may have transient impacts on individuals of animal or plant populations, but would generally have no lasting impact on animal or plant communities, or ecosystem dynamics in the area of release and remediation.

4.3.7.2.2 Authorization of Environmental Release

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.

Those GE organisms that APHIS determines do not present potential plant pest risks and which are therefore not subject to regulation may be field tested anywhere in the United States or its territories without APHIS oversight. 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

[148] USDA- Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation
[149] SARE- Sustainable Agriculture Grants: http://www.sare.org/Grants

threatened and endangered species under the ESA,[150] EPA regulations protecting air and water quality (discussed throughout this PEIS), 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, and are expected to be 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 finalized and factors discussed above, regulation of environmental releases under the Preferred Alternative are expected to 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. This trend would be expected to continue.

4.3.7.2.3 Unauthorized Environmental Releases

Because the Preferred Alternative involves evaluation 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-MOA combinations than under the No Action Alternative. This is not to imply that novel GE organism-trait-MOA combinations will present risk, only that if any risk of plant pest 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 finalized revisions help improve the management decisions of permit holders during field testing and transport and reduce instances of noncompliance, potential impacts on biota could be reduced, largely in the way of reduction of remediation actions.

4.3.7.2.4 Environmental Release after a Finding of Unlikely to Pose a Plant Pest Risk

Potential beneficial and adverse impacts on biodiversity of GE organisms not within the authority of 7 CFR part 340 after an APHIS' finding of unlikely to pose a plant pest risk under the Preferred Alternative would differ little from the No Action Alternative. When APHIS finds that it has no regulatory authority over a GE organism under 7 CFR part 340, that organism could still be subject to compliance with the EPA, and other federal and state agency requirements. As with the No Action Alternative, agricultural lands would continue to comprise the dominant use of GE organisms; therefore, potential impacts on biodiversity would be largely 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 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 CRP,[151] and the USDA funded SARE program.[152] As described under the No Action Alternative, current scientific evidence suggests that commercial GE crops can reduce the impacts of agriculture on biodiversity through facilitating adoption of conservation tillage practices,

[150] By example, see http://www.fws.gov/endangered/laws-policies/regulations-and-policies.html, and https://www.fws.gov/permits/ltr/ltr.html
[151] USDA - Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation
[152] http://www.sare.org/

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, they 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, they would not be expected to present any greater risk to loss of biodiversity than conventionally bred plants produced under conventional cropping systems.

4.4 Human Health

4.4.1 No Action Alternative: Human Health

As discussed in Section 3.7 – Human Health, under the No Action Alternative, GE organisms would continue to be evaluated for food safety by the FDA. Pesticides used on GE crops would continue to be regulated and evaluated for human health risks by the EPA. APHIS would consider potential impacts to human health under NEPA reviews, where appropriate, associated with APHIS decisions made under 7 CFR part 340 (USDA-APHIS 2020e).

4.4.1.1 Authorization of Interstate Movements and Imports

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, 2012c). Conducted pursuant to APHIS requirements, movements and importations under current regulations have no impact on human health. 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 such spillage occurred, any remediation actions would be transient in nature, localized to the site of release, and adverse impacts on human would be highly unlikely.

A small number of GE plants are modified to produce pharmaceutical or industrial compounds. Conceivably, these plants could present a risk to humans in cases where the PMPI are toxic and human error leads to inadvertent release. However, the risk of exposure during shipment is considered negligible because shipments are in secured containers designed to preclude accidental release and handled in a closed loop system that minimizes human error.

4.4.1.2 Authorization of Environmental Releases

APHIS currently uses notifications and permits to authorize environmental releases of regulated GE organisms. Permit and notification requirements limit the regulated GE organism to the field test site and are designed to preclude persistence of the GE organism beyond the termination of the field test. 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 nonregulated materials.

As with authorization for imports and movements, it is considered highly unlikely that any risk to human health would be 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 probability of unintended release of GE organism during field testing would be low. APHIS is not aware of any adverse impacts on human health that have derived from field trials authorized under notification or permitting procedures.

There is, however, one class of GE plants that is of potential concern in regard to food safety: plants that have been genetically engineered for non-food uses such as the production of pharmaceutical and industrial compounds. Under the No Action Alternative, PMPI-producing plants engineered using plant pests would continue to be regulated under 7 CFR part 340. PMPI-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. In 2003, APHIS implemented additional safeguards for PMPI-producing plant field trials that exceeded those previously in effect. These added safeguards, which were implemented as permitting conditions, included requiring location coordinates, authorizing release only in low-production geographies for the particular crop at issue, requiring dedicated equipment, and providing for frequent inspections of each trial site (USDA-APHIS 2003).

Although the number of permits issued by APHIS for PMPI-producing plants varies somewhat from year to year, in the past 5 years, the number of permits for this type of outdoor planting has been 5 or so per year with an aggregate total average acreage of 44 acres/year. These outdoor plantings are subject to significant oversight, typically with seven inspections of each planting per year, from planting through post-harvest.

4.4.1.3 Unauthorized Environmental Releases

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). When low levels of regulated GE plant materials occur in commercial seeds or grain that may be used for human or animal food, the material might be safe and non-actionable, but 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 FFDCA.

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 responsibilities to the regulated community.

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. 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 an incident of noncompliance has proven to be a violation of APHIS requirements, APHIS may take enforcement actions. While APHIS enforcement actions are legal remedies that would have no direct impact 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 of GE organisms that pose a risk to human health are 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.

Remediation can be required if a violation of APHIS notification or permit requirements has occurred. Public health could be impacted if an unauthorized release ended up in the food supply. In such a case APHIS would issue an emergency action notification (EAN) to stop the further distribution and planting of the material while FDA evaluated its food safety. This was done in the case of LibertyLink rice 601 an unapproved event detected in the commercial rice variety Cheniere. APHIS initially issued an EAN that prevented the further distribution and planting of Cheniere rice. Based on the available data and information, FDA concluded that the presence of this bioengineered rice variety in the food and feed supply poses no food or feed safety concerns (USDA-APHIS 2006). In response to FDA’s conclusion about the food safety of the rice, APHIS lifted the EAN and the rice was available for domestic consumption. Because foreign markets still rejected rice containing any detectable LLRice601, and rice exports accounted for about 50% of the U.S. rice production, the U.S. rice Federation made a concerted effort to test and remove all rice seeds containing any LLRice 601 and LLRICE 604, another similar unauthorized GE rice event found at low levels in the commercial rice line CL131. These unauthorized releases had substantial socioeconomic impacts as described in Section 4.6.3.

Unauthorized releases of PMPI have also occurred prior to APHIS’s implementing additional safeguards for PMPI field trials in 2003 (USDA-APHIS 2003). Plants producing pharmaceutical or industrial products are not intended for food use because they could cause harm to humans and animals if ingested. If material from a PMPI-producing plant commingled with the food or feed supply such an event would likely incur socioeconomic impacts because commingled food/feed would be unmarketable. As an example, in 2002 APHIS inspectors found flowering volunteer corn from the previous year's PMPI test site growing in a soybean field. APHIS required the company to remove all the volunteer corn to prevent its harvesting, along with the soybeans. Despite APHIS notification of appropriate volunteer corn removal, about 500 bushels of soybeans from the field was harvested with the volunteer corn plants standing in the field. The soybeans were sent to a grain elevator where they were mixed with 500,000 bushels of soybeans.[153] The PMPI protein produced by the crop was avidin, a protein commonly found in the food supply (egg whites) which tightly binds to vitamin B7 (biotin). Exposure to high amounts of avidin such as the consumption of large amounts of raw egg could lead to biotin deficiency. Common symptoms of biotin deficiency are hair loss and red scaly rashes.[154]

In the case of the unauthorized release of volunteer corn in the soybean crop, the volunteer corn was diluted more than 1 million fold with soybean in the grain elevator. Nevertheless APHIS and the company stopped movement of all the soybeans at the elevator. The USDA destroyed the 500,000 bushels of soybeans and fined the company $250,000 for the compliance infraction and nearly $3 million compensation for the quarantine and destruction of the crop (Pollack 2002).

The example provided above illustrates that there can be substantial socioeconomic impacts from commingling of PMPI with the food supply. As a result, in 2003 APHIS implemented additional safeguards for PMPI-producing plant field trials that exceeded those previously in effect. These safeguards, which were implemented as permitting conditions, included requiring location coordinates, authorizing release only in low-production geographies for the particular crop at issue, requiring dedicated equipment, and providing for frequent inspections of each trial site.

4.4.1.4 Environmental Release after a Determination of Nonregulated Status

APHIS makes a determination of nonregulated status for GE organisms under current 7 CFR part 340 regulations based on the likelihood of the GE organism causing a plant pest risk. APHIS evaluates potential human health impacts under NEPA, as in this PEIS, and considers the FDA and the EPA evaluations in the NEPA document. However, the decision on whether to deregulate a GE organism is based solely on plant pest risk.

For those GE plants that are intended for food purposes and which APHIS has found to not be subject to 7 CFR part 340, developers routinely consult, and are expected to continue to do so, with the FDA on the safety and composition of the food product as part of their voluntary consultation process. For GE plants issued determinations of nonregulated 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 2020a) and Australia and New Zealand Food Standards Agency (ANZFS 2020), 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 have had, to some degree, beneficial impacts on the health of agricultural workers and the general public through

[153] USDA_APHIS - Noncompliance History: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_compliance_and_inspections/ct_compliance_history
[154] NIH – Biotin: https://ods.od.nih.gov/factsheets/Biotin-HealthProfessional/

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 3.7 – Human Health). In general, after over 20 years of cultivation and a cumulative total of 2 billion acres planted, no adverse human health impacts 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 et al. 2013; Goldstein 2014; Nicolia et al. 2014; WHO 2015)).

To the extent GE crops can maintain or increase agricultural productivity to supply 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 altered weather patterns 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 et al. 2013; Ammann 2014). Current and emerging plant biotechnologies may help address such challenges, particularly where GE crops are produced using sustainable agricultural practices.

In terms of the 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 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 triggering 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.

Under the No Action Alternative, future determinations of nonregulated status for a GE organism would be based on current regulations and processed on a case-by-case basis. The potential adverse health impacts 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 7 CFR part 340 and intended for use as human or animal food would likely be submitted to the FDA for consultation, and regulatory authorities in other countries where imported as human or animal food (e.g., (ANZFS 2020; EFSA 2020a)). Any pesticide used on a GE crop would be regulated under the authority of the EPA.

4.4.2 Preferred Alternative: Human Health

Federal oversight of GE plants and other organisms that may be used for food purposes would largely remain unchanged under the Preferred Alternative. Under the Coordinated Framework, GE organisms would continue to be evaluated for food safety by the FDA, as they currently are. Pesticides used on GE crops would continue to be regulated and evaluated for human health risks by the EPA. Both the FDA and USDA would continue to monitor foods for pesticide residues to enforce EPA established tolerance limits to ensure protection of human health. For all GE plants that did not qualify for an exemption, APHIS would conduct an initial review and a more substantial Plant Pest Risk Analysis where a plausible pathway to greater plant pest risk is identified. NEPA reviews would be conducted in conjunction with the PPRA where appropriate.

4.4.2.1 Authorization of Interstate Movement and Importation

The risk to human health as a result of importation or movement of GE organism would be negligible. The final revisions to 7 CFR part 340 would update the requirements for shipping. Shipping containers or means of conveyance would have to meet the standards listed under APHIS' definition of secure shipment, i.e., would have to be of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation. These requirements would make the performance standard more explicit in the regulations than it is now, while at the same time making the requirements less prescriptive, thus eliminating the need for a request process for variances.

APHIS would also retain a provision from the current regulations, currently a footnote to § 340.8, that specifies that all organisms shipped under permit must be shipped in accordance with the regulations in 49 CFR part 178. Those regulations, which are administered by the Department of Transportation (DOT), provide packaging requirements for materials, including organisms that DOT has designated as hazardous materials.

Shipping containers would have to be accompanied by a document that included the names and contact details for both the sender and the recipient. These details are essential for purposes of enforcement. Following the completion of the shipment, all packing material, shipping containers, and any other material accompanying the organism would have to be treated or disposed of in such a manner so as to prevent the unauthorized dissemination and establishment of the organism. This requirement is currently a general permitting condition, but could more accurately be described as a shipping requirement.

4.4.2.2 Authorization of Environmental Release

Under the Preferred Alternative, PMPI producing plants would not be eligible for an RSR. The scope of the regulation would be expanded relative to the No Action Alternative in that, all GE PMPI producing plants would require a permit for movement even if they were created without the use of a plant pest. GE PMPI producing plants would be regulated similar to how they are regulated under the No Action Alternative using the additional safeguards for PMPI field trials established in 2003 (USDA-APHIS 2003).

4.4.2.3 Unauthorized Environmental Release

APHIS would continue similar inspection, compliance, and enforcement activities discussed under the No Action Alternative. Furthermore the Preferred Alternative proposes to strengthen provisions in 7 CFR part 340 in order to manage compliance with the regulations more efficiently. APHIS would augment the approaches currently used to prevent or remediate plant pest risks, and to utilize appropriate enforcement strategies. These final regulatory changes reflect provisions of the 2008 Farm Bill and align with recommendations of the 2005 and 2015 OIG audits.

4.4.2.4 Environmental Release after a Finding of Unlikely to Pose a Plant Pest Risk

The Preferred Alternative could have positive effects to public health to the extent that innovation in the agricultural biotechnology industry is promoted by the regulatory framework described under the Preferred Alternative. There could be benefits to public health, through facilitating the availability of crops with traits that improve nutritional content of foods, decrease food allergens, or lead to increased consumption of fruits and vegetables (for example by making them easier to eat or more available).

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 and all other applicable laws and regulations governing the safety of human and animal food. For this reason, this section is abbreviated to avoid redundancy.

4.5.1 No Action Alternative: Animal Food

Animal food is evaluated for food safety by the FDA, as described in Section 3.8 – Animal Food and Welfare. Pesticides used on human or animal food crops must comply with the EPA tolerance limits described under Section 408 of the FFDCA and Section 405 of FQPA (US-EPA 2020d). Similar to tolerance values for human food, the 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). As part of its NEPA analysis, APHIS considers the FDA and EPA decisions, and evaluates potential impacts on animal food under NEPA, as in this PEIS.

GE plants determined by APHIS to have nonregulated status that are used for animal food are still evaluated for food safety by FDA per customary business practice prior to commercialization, and the effects of pesticides including PIPs on animal health are still reviewed by the EPA. Those GE crops authorized 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 2020a), and Australia and New Zealand Food Standards Agency (ANZFS 2020).

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 some instances there may be improvements conferred to animal food and the animal food industry, directly or indirectly, that have beneficial impacts on animal welfare. For example, Roundup Ready® Alfalfa fields have better weed control than conventional alfalfa, so livestock fed the GE alfalfa are less exposed to toxic and thorny weeds (Green and Legleiter 2018). Another example includes GE canola with a modified fatty acid profile in the seed. Canola has been genetically engineered to produce long chain omega-3 polyunsaturated fatty acids (LC-PUFAs), which are recognized as important dietary nutrients for both human and animal health. The most common dietary source of omega-3 LC-PUFAs is marine algae and fish. GE canola oil and whole seed, enriched in omega-3 LC-PUFAs, may be used in the production of animal food for use in the aquaculture industry. Considering that the majority of fisheries, globally, operate at maximum withdraws per annum to supply fish for human consumption, as well as for industrial fish farms and fish oil for supplements (FAO 2016), it is possible that plant based sources of omega-3 LC-PUFAs, such as GE canola, could help address a growing global demand for omega-3 and omega-6 LC-PUFAs, and relieve, to some degree, pressure on wild fish stocks, as well as farmed fish sources.

4.5.2 Preferred Alternative: Animal Food

As with the No Action Alternative, there are no foreseeable adverse impacts to animal food and animal welfare that could derive from the Preferred Alternative. Similar to the No Action Alternative, plant breeding innovations are expected to lead to improvements in feed that will benefit animal welfare. Animal food would continue to be evaluated for food safety by the FDA, as described in Section 3.8 – Animal Food and Welfare.

4.6 Socioeconomic Impacts

In addition to this PEIS, APHIS has conducted a Regulatory Impact Analysis (RIA) & Initial Regulatory Flexibility Analysis of the final rule and Alternatives, and the reader is referred to this document for a more thorough analysis on potential economic impacts (USDA-APHIS 2020f). 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.

In this discussion, unintended presence refers to the occurrence of GE plant material in harvested crops where it is not wanted or expected. This can occur via cross-pollination or commingling. Unintended presence of crops approved domestically may result in market impacts in crops intended for a GMO sensitive domestic market or in foreign markets where the GE crop has not been approved. APHIS currently has oversight of regulated GE organisms during interstate movement, field trials, and importation. However, once a GE plant has been deregulated, APHIS does not have the authority to take any compliance action if the GE plant material is found in harvested crops in any amount. If a GE crop had been approved in another country and was being imported into the United States without having gone through the applicable required or recommended procedures of USDA-APHIS, EPA, and FDA, the United States would treat it the same way as if it had been developed in the United States and had not gone through these procedures.

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 risk assessments; review of submitted notifications, permit requests, and petitions; NEPA analyses including preparing 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 final rule are estimated to total about $3.5 million. This estimate is based on activities in 2017, when APHIS processed 196 importation and interstate movement permits and 139 environmental release or release and movement permits; conducted 761 inspections; and acknowledged 116 import notifications, 306 interstate notifications, 240 release notifications or combined interstate and release notifications. Inspections cost roughly $800/inspection. Over the last three years, APHIS has conducted an average of 44 site inspections for PMPI-producing plants. 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 inspections of field trials for PMPI-producing plants have cost roughly $35,000 in total annually.

4.6.2.1.2 Biotechnology Industry

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 (2011) 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 $147.2 million (2016 dollars). In the Phillips-McDougal study, the costs of meeting all regulatory requirements, including those incurred as a result all federal regulation of GE organisms, amounts to around $38 million (2016 dollars), or 25.8 percent of total costs (Phillips-McDougall 2011). 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. In the Kalaitzandonakes et al. (2007) study, the estimated costs for development of a biotechnology product, including regulatory costs, were highly variable ranging from about $8.3 million to $18.6 million in 2016 dollars for insect resistant corn, and from about $7.2 million to $17 million in 2016 dollars for herbicide resistant corn (Table 4-1). These estimates are roughly one-half of the total regulatory costs estimated by Phillips-

McDougall (2011).[155] In research supported by the National Institute of Food and Agriculture (NIFA), Kalaitzandonakes also found that for the period 2009-2014, regulatory compliance costs had roughly doubled, potentially in line with Phillips-McDougall (2011) although the size and structure of those compliance costs have not yet been published (Kalaitzandonakes 2014).

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 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 et al. 2016). For example, recent analyses found 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 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.

[155] APHIS does not have access to enough detailed information to account for this discrepancy.

Table 4-1. Developer Costs for Herbicide-Resistant Corn and Insect-Resistant Corn, 2016 dollars	
Cost Categories	**Range of Costs Incurred ($)[(1)]**
General Costs	
Preparation for hand-off into regulatory process	23,400 - 58,500
Molecular Characterization	351.000 - 1,404,000
Compositional Assessment	877,500 - 1,755,000
Animal Performance and safety studies	351,000 - 988,650
Protein production and characterization	189,540 - 2,018,250
Protein safety assessment	228,150 - 1,000,350
Agronomic and phenotypic assessment	152,100 - 538,200
Production of tissues	795,600 - 2,574,000
ELISA development, validation and expression analysis	485,550 - 713,700
EU specific import (detection method, fees)	269,100 - 473,850
Canada specific costs	46,800 - 228,150
Stewardship	193,050 - 1,170,000
Toxicology (90 day rat — when done)[(2)]	292,500 - 351,000
Facility and Management overhead costs	655,200 - 5,265,000
Costs Specific to Inspect Resistant Corn	
Non-target organism studies	117,000 - 702,000
EPA expenses for Plant-incorporated protectants (PIP) (e.g., Experimental use permit tolerances)	175,500 - 836,550
Environmental fate studies	37,440 - 936,000
Total Insect-resistant Corn	8,260,200 - 18,064,800[(3)]
Costs Specific to Herbicide Resistant Corn	
Herbicide residue study	122,850 - 643,500
Total Herbicide Tolerant Corn	7,230,600 - 16,976,700[(3)]

Source: (Kalaitzandonakes et al. 2007)

The costs of withdrawn events are not included in the figures. To preserve the confidentiality of firm-level data used, the means of the individual cost categories and total costs were not presented.
(1) Adjusted to 2016 dollars.
(2) These tests have not been conducted to date (FDA personal communication) and are therefore not included in the estimates in Tables 4-2 and 4-3.
(3) Because an individual firm could have costs anywhere within the range of each cost category, the totals do not sum from the individual cost category figures shown.
Where the estimated cost for a general cost category differed between insect-resistant and herbicide-tolerant corn, we included the entire range.

Under the Coordinated Framework, GE organisms are regulated by the 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 the FDA would have regulatory oversight. For a crop that was not used for food but contained a PIP, the crop would be regulated by both USDA and the 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 a different flower color. Therefore, APHIS considered two regulatory oversight scenarios: USDA either has sole regulatory authority or shares oversight with the 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 $2.4 million to $13 million for a given GE trait. When the EPA and/or FDA have regulatory oversight in addition to USDA, compliance costs are estimated to range from $4.4 million to $18 million for an herbicide resistant trait, and $4.6 million to $20 million for an insect resistant trait.

Table 4-2. Estimated Current Regulatory Compliance Costs under Two Oversight Scenarios for Herbicide-Resistant Corn and Insect-resistant Corn, per trait, 2016 dollars

Activity	APHIS	APHIS & EPA and/or FDA
	($1,000)	
Preparation for hand-off into regulatory process	23-58	23-58
Molecular characterization	351-1,404	351-1,404
Compositional assessment	N/A	878-1,755
Animal performance and safety studies	N/A	351-989
Protein production and characterization	190-2,018	190-2,018
Protein safety assessment	N/A	228-1,000
Agronomic and phenotypic assessments	152-538	152-538
Production of tissues	796-2,574	796-2,574
ELISA development, validation and expression analysis	N/A	486-714
Stewardship	193-1,170	193-1,170
Facility and Management overhead costs	655-5,265	655-5,265
Subtotal[(1)]	**2,360-13,028**	**4,302-17,485**
Herbicide residue study	N/A	123-644
Total for Herbicide resistance	N/A	**4,425-18,129**
Non target organism study	N/A	117-702
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	176-837
Environmental fate studies	N/A	37-936
Total for Insect resistance	N/A	**4,632-19,960**

Source: (USDA-APHIS 2020f)

[(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 a 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 for ornamental plants. 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 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 nonregulated 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 2015a). 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 2015a). Potential economic benefits to producers of GE crops are expected to continue if not improve.

GE corn, soybean, cotton, canola, and sugarbeet 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 et al. 2016). As for potentially emerging GE crops, APHIS has recently 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 are the second most popular fresh fruit (after bananas) in America (Greene et al. 2016). Considering the market demand for these commodities, adoption of GE potato and apple may reduce the cost of production and provide the same or superior product quality.

Consumers

Under the No Action Alternative, potential beneficial impacts to consumers of commodities derived from GE crops and commercial markets is expected to continue as described in Section 3.9. Agricultural commodities derived from GE crops are recognized as economically beneficial to domestic markets and are expected to remain so (Fernandez-Cornejo et al. 2014b; Brookes and Barfoot 2015a; 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 2014f).[156] Organic food sales in the United States approached an estimated $45.2 billion in 2017. Total organic sales in 2017 were $49.4 billion–which includes sales of organic personal care products, linens, and other non-food products (OTA 2018). The Organic Trade Association estimates that organic food purchases now account for nearly 5.5% of total U.S. food sales (OTA 2018).

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 5 million acres in 2016–latest survey data), compared to the approximately 47% of GE and 52% of conventional crop acreage (Greene et al. 2016). While the industry is on a continued upward trajectory (6.4% percent growth from 2016 to 2017), 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 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% higher 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 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 reported losses of approximately $6.1 million due to the presence of GE material in the organic cropping system (USDA-NASS 2015).[157] This equates to an average reported loss of $70,099 for each of the eighty-seven organic farms for removal of the GE

[156] USDA Organic Standards state 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 that organic standards are followed. Farms that follow the USDA 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. For more information, see USDA-AMS, Organic Labeling at https://www.ams.usda.gov/rules-regulations/organic/labeling.

[157] The bulk of reported losses, approximately $3.8 million, were isolated to 3 farms in Texas, which somewhat skews the statistics.

material, remediation, lost sales, or lost price premiums. 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 reported a collective loss of about $68,900, at an average loss of $7,664 per farm (USDA-NASS 2015). 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 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 frequently 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 by this route. 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 sugarbeets, 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, oats, and rye. Other crops such as hops could also be affected, in the event such GE varieties are evaluated by U.S. regulatory agencies and then commercially produced.

As acreage devoted to GE 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, Association of Official Seed Certifying Agencies (AOSCA 2020; USDA-AMS 2020b; USDA 2020b), ASTA (ASTA 2020), or through contracts, as applicable. These are fundamentally based on temporal and spatial isolation, use of dedicated equipment, storage, and/or clean out procedures.

Bearing these factors in mind, GE, non-GE conventional, and organic crop production systems are expected to 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 improved environmental performance. In order to receive the price premiums that can be obtained for organic and non-GE agricultural commodities, producers will need to 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 et al. 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 to 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. 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 is 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.[158] 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). However, the EPA did not establish a tolerance limit of the Bt protein, Cry9C, in 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.

Based on the few estimates available, this incident resulted in $298 to $964 million in lost revenue for producers in market year 2000/2001 (Lin et al. 2003). A separate study estimated that the presence of StarLink corn in the food supply caused a 6.8% drop in the price of corn, lasting for one year. In total, nearly 300 human food products were taken off the market (Lin et al. 2003). Product removals did not necessarily occur 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.

[158] 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. FDA is responsible for the enforcement of pesticide tolerances. This enforcement authority is derived from section 402(a)(2)(B) of the FFDCA.

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 et al. 2003).

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, and Aventis agreed 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 Cry9C 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.

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 the 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).

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

Current annual APHIS personnel costs of conducting activities under current 7 CFR part 340 regulations that would be affected by the final rule total about $3.4 million. These include compliance activities, inspection activities, AIR process activities, notification activities, permit activities, and petition activities. Under the final rule, APHIS' overall annual personnel costs of regulating GE organisms are not expected to change. While the volume of specific activities will change, the overall volume of regulatory activities, the general nature of those activities and the level the skills necessary to perform those activities will not change. Costs to APHIS of implementing the final 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 $77,000. Requests for regulatory status and response letters under the final rule could be handled in a manner similar to the current 'Am I Regulated' process outside the electronic permitting system without incurring new costs.

There would be no notification, petition, or courtesy permit processes. NEPA/ESA activities are estimated to range from 50 percent to double the current level. The final rule would provide for a new regulatory status review process, which would replace the petition process in our current regulations and provide functions similar to the AIR process. The final rule would eliminate the current notification procedure but still require permits with specific conditions for movement (importation, interstate movement, or release into the environment), of all GE organisms that are subject to the regulations. Developers of GE plants that have not previously been reviewed for plant pest risks would be given the option of requesting a regulatory status review to determine the regulatory status of their product. A developer who makes a self-determination would have the option to request written confirmation from APHIS that the self-determination is valid. A confirmation letter would provide a clear and succinct statement about the regulatory applicability of the organism and the nexus to plant health. The current courtesy permit and accompanying Letter of Unlikely to Pose a Plant Pest Risk, 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.

APHIS would likely incur modest additional costs in conducting outreach activities for the final 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.

4.6.2.2.2 Biotechnology Industry

Direct regulatory costs to biotechnology developers would be reduced under the Preferred Alternative. Petitions for nonregulated status, and the petition costs incurred, would be eliminated. Under the Preferred Alternative, permitting would only be required for those GE organisms that APHIS found had a plausible pathway to increased plant pest risk. No APHIS regulatory oversight would be needed once APHIS has concluded, via a regulatory status review, that a GE plant is unlikely to present a plant pest 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 the regulatory process
2. Protein production and characterization
3. Agronomic and phenotypic assessments
4. Production of tissues

The first activity involves the administrative work preparing samples in the research and development department and transferring those samples to the regulatory group within the company or to a third party contractor. The second activity aims to extract protein from the GE plant or from a bacterial or insect expression system to measure properties of the protein. The third activity consists of field studies to collect data on the GE plants growing in greenhouses or the field. The fourth study consists of growing large amounts of tissue for measuring the composition of the plant and other characterization assays.

Under the final rule when APHIS is the only agency with oversight, GE plants that are exempt from the regulation or are not regulated based on a regulatory status review would not necessitate activities 1-4 and their associated costs.

Currently, APHIS typically receives data based on each of these activities, although the information gained from the third activity is the primary way APHIS evaluates whether a plant is unlikely to pose a plant pest risk in accordance with its oversight authority. Based on the risk assessments APHIS has performed in accordance with the petition process over 30 years, we have determined that, in many cases, we would have been able to evaluate the plant pest risks associated with a GE organism without field-test data. Accordingly, APHIS considers information from field tests to be unnecessary, in most cases, for a determination of regulatory status under the final regulations and, therefore, would not require the submission of such data under a regulatory status review.

Under the final rule, if EPA and/or FDA also have regulatory oversight, but a permit from APHIS is not required, agronomic and phenotypic assessments (third activity) would not be necessary as these data are not relevant to assessing food or environmental safety, the purpose of FDA and EPA oversight. The EPA and FDA would still rely on or make use of activities 1, 2, and 4 and the associated costs would be realized under the final rule in cases where these agencies also have regulatory oversight. The EPA and FDA evaluate data obtained from toxicity testing, feeding studies, and compositional analyses performed on tissue samples.

Furthermore, costs of preparing APHIS dossiers and permits (included within facility and management overhead costs) would be reduced when APHIS permits are no longer necessary. These cost savings would come mainly from a reduction in time spent managing the process. We estimate that the reduction in management and administrative costs would be about $385,000 per trait, as shown by the difference in facility and management overhead costs in Table 4-3 and Table 4-4. This estimate is based on the assumption that two mid-level and one upper-level management employees work full-time conducting these processes for each trait.

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 APHIS dossiers and permits (included within facility and management overhead costs) would be reduced in all scenarios.

APHIS assumes that even in cases where APHIS 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.[159] Table 4-3 describes the estimated regulatory compliance costs under the final rule for the oversight scenarios evaluated.

[159] 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, and to avoid risks related to potential trade disruptions.

Table 4-3. Estimated Regulatory Costs Under the Rule: Two Oversight Scenarios, per GE Plant Not Regulated by APHIS, 2016 Dollars

Activity	APHIS	APHIS & EPA and/or FDA
	($1,000)	
Preparation for hand-off into regulatory process	0	23-58
Molecular characterization	351-1,404	351-1,404
Compositional assessment	N/A	878-1,755
Animal performance and safety studies	N/A	351-989
Protein production and characterization	0	190-2,018
Protein safety assessment	N/A	228-1,000
Agronomic and phenotypic assessments	0	0
Production of tissues	0	796-2,574
ELISA development, validation and expression analysis	N/A	486-714
Stewardship	193-1,170	193-1,170
Facility & management overhead costs	270-4,880	270-4,880
Subtotal[(1)]	**814-7,454**	**3,765-16,562**
Herbicide residue study	N/A	123-644
Total for Herbicide resistance	N/A	**3,887-17,206**
non target organism study	N/A	117-702
EPA expenses for PIPs (e.g., EUPs, tolerances)	N/A	176-837
Environmental fate studies	N/A	37-936
Total for Insect resistance	N/A	**4,094-19,037**

[(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

There would be some new costs borne by regulated entities under the final rule including rule familiarization and recordkeeping. Recordkeeping costs 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 $1,070,000. There have been about 1,250 unique entities who have applied for permits or notifications under 7 CFR part 340, and APHIS estimates that each of those entities would spend a total of about 24 hours becoming familiar with the provisions of this rule at a total cost of about $1,468,000 (USDA-APHIS 2020f) or about $1,174 per entity. The regulatory compliance costs that are associated with this rule occur only in conjunction with activities that occur under permit. This rule provides ways, such as through exemptions and the RSR process, that APHIS permits will not be necessary for the development of certain GE plants. Small entities, including small-scale biotechnology developers as well as land-grant and other public university researchers, are most likely to develop GE plants that do not require APHIS permits, and thus will face lower regulatory compliance costs under this rule.

In terms of net reductions in costs to developers, APHIS estimates that biotechnology developers could save from $551,000 to $937,000 per GE trait when the EPA and/or FDA also have regulatory oversight, and from about $1.6 million to $5.6 million per GE trait when APHIS is the only regulatory agency (Table 4-4). 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 plants developed annually will increase over time. For the purposes of economic analysis, APHIS assumes, on an annual basis, a range of newly developed GE plants from 5 (the current annual average of processed petitions) to 10 (twice this average). APHIS further assumes that about 20 percent of those new GE plants are solely within the purview of APHIS oversight, and that the remaining 80 percent will also be under the purview of FDA and/or EPA oversight. If 5 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 4 still with EPA and/or FDA evaluation), the annual savings would be $6.5 million. If 10 new GE plants are developed annually without APHIS permits (all with no USDA permit, but 8 still with EPA and/or FDA evaluation), the annual savings would be $13.0 million.

Because the regulatory cost savings for GE crops that require only APHIS approval are expected to be much larger, the final rule may provide added impetus to the development of new horticultural varieties. Very few such crops have been developed, presumably because the regulatory costs have been too high in relation to a relatively small market.

Table 4-4. Estimated Regulatory Cost Savings Under The Rule: per Trait not Regulated by USDA, Two Oversight Scenarios, 2016 dollars

Activity	APHIS	APHIS/EPA/FDA
	($1,000)	
Preparation for hand-off of events into regulatory	23-58	0
Protein production and characterization	190-2,018	0
Agronomic and phenotypic assessments	152-538	152-538
Production of tissues	796-2,574	0
Facility & management overhead costs	386	386
Required recordkeeping & reporting costs(1)	13	13
Total	**1,559-5,588**	**551-937**

(1)APHIS permits. Estimated average hourly wage of $33.28 multiplied by 1.4706 to capture employee benefits ($48.94). U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational Employment and Wages in the United States.. Permitting procedure requires 20 hours per response (20 hours x $48.94 = $978.80). Permit recordkeeping requires 10 hours per response and 25 responses (25 responses x 10 hours = 250 hours. 250 hours x $48.94 = $12,235). $978.80 + $12,235 = $13,123.80. Source: (USDA-APHIS 2020f).

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 has described several exemptions under the Preferred Alternative that may lead to additional cost savings to the regulated community and 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 APHIS is the only agency with oversight, the approval time is expected to decrease for GE organisms that are unlikely to pose plant pest risks, due to a more efficient regulatory review process (described in Section 2.2). This could be a significant time savings. While the final rule would shorten the regulatory process for APHIS, it is not expected to affect the time needed by the FDA or EPA.

APHIS' experience over the past 20 years is that most of the GE organisms that have been reviewed by the Agency are unlikely to pose a plant pest risk and have not merited regulatory oversight. APHIS has determined many of these organisms are not subject to the PPA or APHIS regulation.

Some plants that would not have been regulated under previous 340 regulations because there was not a plant pest used in their development will now be under the purview of APHIS oversight. This change in scope was made because plants engineered without a plant pest can still pose plant pest risks. If such plants become widely distributed, they potentially could lead to increased management costs for farmers. APHIS believes that the number of plants that fit in this category is likely very small, less than 1 per year based on historical activity. For those few instances where an APHIS permit is required, developers could incur new costs associated with permitting from about $13,000 to $671,000 depending on the necessary additional recordkeeping, reporting, stewardship and testing.

For GE plants that will require an APHIS permit, compliance costs for the developer will include permitting, reporting, and recordkeeping. Fewer than 1 in 10 concepts are ever tested in the field. And of these, fewer than 1 in 100 demonstrate sufficient commercial viability to warrant further data collection necessary to address questions raised in the RSR process (McDougall 2011; Prado et al. 2014). If we nonetheless assume that one plant per year fits this category of expanded APHIS purview and goes under permit, the additional recordkeeping and reporting costs could be about $13,000 annually for a field trial that requires 25 reports per year.[160] Because few plants tested in the field are likely to demonstrate commercial viability, we expect that those plants would be tested on a limited number of sites. If a developer incurs additional stewardship costs under regulation for that plant, those costs could range from about $20,000 to $120,000.[161] Most developers are, however, already incurring stewardship costs in order to

[160] Estimated average hourly wage of $33.28 multiplied by 1.4706 to capture employee benefits ($48.94). U.S. Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook, 2019 Report - Occupational Employment and Wages in the United States.. Permitting procedure requires 20 hours per response (20 hours x $48.94 = $978.80). Permit recordkeeping requires 10 hours per response and 25 responses (25 responses x 10 hours = 250 hours. 250 hours x $ = $12,235). $978.80 + $12,235 = $13,123.80.

[161] A detailed study of component regulatory compliance cost categories included stewardship costs throughout the development and petition process of between $4,000 and $24,000 per site year. For most products this would be a maximum of 5 site years (5 x $4,000 = $20,000, 5 x $24,000 = $120,000) (Kalaitzandonakes et al. 2007).

protect their intellectual property, to prevent commingling to maintain varietal purity, and to avoid risks related to potential trade disruptions. In the rare case that a plant demonstrates commercial viability and therefore warrants further data collection necessary to address questions raised in the RSR process, the developer could incur additional testing costs. Under the current regulations, testing costs are estimated at between about $152,000 and $538,000.[162] Since the data required under the RSR process are more targeted than under the current process, those costs are expected to be closer to the lower bound.

The cost savings under this rule are expected to more than outweigh the new costs associated with this rule. Developers who are not required to have permits under this rule will realize cost savings in comparison to the current regulatory process. Overall, there would be both direct and indirect economic benefits of not subjecting GE organisms to current regulatory requirements, and instead reviewing and regulating such organisms under the regulatory framework described under the Preferred Alternative (USDA-APHIS 2020f). First, direct regulatory costs to biotechnology developers would be reduced for those organisms that are considered unlikely to pose a plant pest risk. 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 regulatory approvals internationally, 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 2015a). 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. In comparison to the No Action Alternative, the final revisions to APHIS' regulation of GE organisms may more readily help sustain or even improve farm-level profitability.

[162] Agronomic and phenotypic assessments are the primary means by which APHIS evaluates whether a plant is unlikely to pose a plant pest risk in accordance with its oversight authority under the permit and petition process. Costs are estimated based on(Kalaitzandonakes et al. (2007). Because these plants are likely to also fall under the regulatory oversight of FDA and/or EPA, other regulatory costs are likely to be incurred by developers regardless of whether they are also under the oversight of APHIS.

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 et al. 2014b; Klümper and Qaim 2014; Brookes and Barfoot 2015a).

The final 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. In that case, 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 or commingling 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%) reported a total $506,552 in losses. In 2014, the total value of sales of certified and exempt organic field crops was $5.5 billion (USDA-NASS 2015). The total value of sales from certified and exempt organic crops in 2014 was $3.3 billion.[163] 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 reported 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 reported 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 incidents of unintended presence of GE crop material in non-GE crops or crop products. This would primarily be due to the possibility that there would be more crop types in production that would be targeted for specific markets and need segregation. 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

[163] This includes nursery and greenhouse crops, which skews the total sales data when evaluating food crops.

chains. The pace of commercialization of GE products commercialized is not expected to significantly change from current levels. Similarly, the developer's control over the development process is not expected to change. However, 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 impacted. 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 impacted 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 varieties on the market. These are crops where the seed is the valued part of the plant and are 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 a reduction in the potential economic impacts of unauthorized releases under the Preferred Alternative. In contrast to commingling of nonregulated GE plant material in non-GE crops or crop products, which can impact 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 have a plausible pathway to increased plant pest risk. 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 impacts of such unauthorized releases.

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 as well as a food safety assessment before either confined or unconfined environmental release (i.e., field testing, commercial cultivation) of such organisms is allowed (OECD 2013). 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 that 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" authorization (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) of GE plant material that has been approved in an exporting country, but not approved in a particular importing country.

The number and variety of GE crop commodities being developed, cultivated, and traded worldwide is increasing annually. Consequently, this requires consideration of the increased possibility of AAs and the potential for trade disruptions that could result from LLP among trading countries. LLP and the potential for GE plant material that has not received approval in any country to be found in internationally traded crops are leading concerns among both the private and public sectors (FAO 2014a) 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 2014a), and management of the risk to trade arising from LLP is and will continue to be of vital importance to the free flow of trade. LLP impacts importing and exporting countries alike and global food security in general.

As an example, China refused entry of corn with trace amounts of a GE corn variety (MIR-162) that it had not approved. The embargo, from November 2013 until China ultimately approved the use of MIR-162 on December 16, 2014, affected corn sales and prompted extensive litigation, including class action lawsuits, where U.S. corn producers and U.S. grain merchants sued Syngenta (now owned by ChemChina) (Chaney et al. 2015)). In 2017, a $1.51 billion settlement was reached with Syngenta to resolve the complaints of more than 100,000 U.S. farmers. The settlement does not include Canadian lawsuits (Smethie and Heilshorn 2019). Archer Daniels Midland Co. reached a confidential settlement with Syngenta in 2018 (Begemann, 2018).

A grain and feed industry study of the MIR 162-induced trade disruptions on the U.S. corn, distillers dried grains with solubles, and soybean sectors of the U.S. grain industry claimed estimated losses of up to $3 billion during the 2013/14 marketing year (Fisher 2014). Disruptions in international trade can be minimized, albeit at substantial cost (as noted below), by delaying commercialization of new GE traits until regulatory approval has been secured in all major markets. Some biotechnology firms have self-regulated toward that end by not releasing new GE traits until they have been approved for use in major import markets (CLI 2020b). Both regulatory and development costs can be significant for plant biotechnology developers, as described under the domestic economic 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 impact U.S. farmers’ access to entire market segments (Lipson 2011). As described in Section 3.9.3, 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 approach 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[164] 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 or the International Seed Testing Association, 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, 2020), FAO (FAO 2014b), and WTO (WTO 2020a, b). As part of the current U.S. agricultural production system, the concept and practice of coexistence has evolved to facilitate achieving

[164] 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.

agreed upon market standards. For instance, ASTA has released guides for co-existence (ASTA 2011) and seed production practices (ASTA 2020).

A 2013 survey related to GE crops conducted by the FAO,[165] which included 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%. In total, 35% reported that they had faced LLP incidents in the last 10 years, and 50% said they had not (FAO 2014a). Most incidences were reported from the United States, 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 asynchronous authorizations or importation of GE organisms authorized in another country but not in the United States.

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, as 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 plants, APHIS will take appropriate remedial steps using its authority under the PPA. In cases in which APHIS determines that remedial action is not necessary to mitigate unintended presence of regulated GE plant material to protect plants, APHIS is not precluded from taking enforcement action against a company or individual for violations of APHIS regulations.

[165] The survey was sent to national government organizations through FAO Representations (FAORs), Codex contact points, and individual contacts in early 2013.

4.6.3.2 Preferred Alternative: International

4.6.3.2.1 APHIS Costs

The APHIS costs under the Preferred Alternative would be the 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 will be shortened for GE organisms solely under the authority 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 impacted by this Alternative and are expected to be similar to the No Action Alternative.

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. For food and feed commodities, 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 Alternative because the review and approval process for the EPA is not anticipated to substantially differ, nor is the FDA's recommended consultation process. One unknown factor is whether the approval process in other countries will change if USDA codifies the Preferred Alternative.

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.

4.6.3.2.4 Unauthorized Releases

The potential impacts on trade are expected to be the same as or similar to those described for the No Action Alternative. However, the final revisions for compliance and enforcement activities and the permitting process are expected to translate to reductions in unauthorized releases, which could potentially 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 risks, outside of a petition or request to do so, and making findings of regulatory authority. APHIS anticipates this will result in a larger number of certain types of GE organisms over which APHIS has authority. APHIS anticipates that those GE organisms determined to be subject to regulation will be those that have a plausible pathway to increased plant pest risk. Therefore, 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, that GE plant might still need EPA approval and would still likely go through the FDA voluntary consultation process before being released for commerce. If this process is more efficient under the Preferred Alternative, the number of GE crop plants in commerce could increase. There would then need to be authorizations of such GE crop plants in foreign countries prior to export, to preclude instances of LLP. If more regulatory authorizations and commercial production of new GE crop plants in the United States occurs and these new GE crop plants have not been reviewed and authorized by foreign countries, then there is potential increased risk of LLP for certain commodities, such as corn and soybean.

4.7 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 analyses 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.

For both the No Action and the Preferred Alternatives, APHIS would complete the appropriate NEPA analysis (e.g., categorical exclusion, EA, or EIS) prior to making decisions about issuing permits. In most cases permits are categorically excluded from the need to prepare an EA or EIS (7 CFR part 372). In cases where an EA or EIS is prepared, 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 public comment period, and would have the option to extend the public comment period as requested or needed. This process is described in APHIS NEPA implementing regulations at 7 CFR part 372. The 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. In the past APHIS has prepared EAs for permits where field trials might not be confined, such as for flowering trees and grasses, or insects, as well as some PMPI-producing plants (USDA-APHIS 2020c).

APHIS recently amended 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].[166] APHIS will prepare a record of categorical exclusion (7 CFR part 372) for certain permits for the importation, interstate movement, or environmental releases of GE organisms, provided that permit conditions, such as isolation distances from sexually compatible relatives, control of flowering, or physical barriers ensure confinement of the regulated article. Under the No Action Alternative, APHIS also prepares records of categorical exclusion for extensions of nonregulated status under 7 CFR part 340 to organisms similar to those already deregulated. To qualify for the extension, the subject of the extension request must be similar to an organism that has already been deregulated and for which an EA or EIS has been previously prepared. Consequently, APHIS expects no difference with respect to the impacts on the biological or physical environment between the two organisms. If there were any extraordinary circumstances, APHIS would not prepare a categorical exclusion, and would instead prepare an EA or EIS, depending on the degree of potential environmental impacts.

APHIS currently evaluates the regulatory status of GE organisms when it receives a petition for a determination of nonregulated status for a GE organism (see Section 2.2). 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 appropriate.

Under the Preferred Alternative, there will be actions outside of the Agency's purview that will not be subject to NEPA. These actions include developer self-determinations that a plant-trait-MOA combination meets one of the exemptions (see Section 2.2 of this PEIS) or that the plant-trait-MOA combination is similar to one that has been previously reviewed by APHIS and found to not be subject to regulation under 7 CFR part 340. Letters written to applicants confirming that their self-determination meets the exemption criteria also would not be subject to NEPA.

Under the Preferred Alternative in final § 340.4(b)(1), upon receiving a request for a regulatory status review of a GE plant, APHIS would conduct an initial review of the potential plant pest risk posed by the GE plant and any sexually compatible relatives that could acquire the engineered trait, based on following factors:

- The biology of the progenitor plant and its sexually compatible relatives;
- The trait and mechanism-of-action of the modification(s); and
- The effect of the trait and mechanism-of-action on:
    - The distribution, density, or development of the plant and its sexually compatible relatives;
    - The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;
    - Harm to non-target organisms beneficial to agriculture; and
    - The weedy impacts of the plant and its sexually compatible relatives.

[166] See 81 *Federal Register*, No. 139, Wednesday, July 20, 2016, p.47051.

Because the screen is objective, rapid, and based on transparent predetermined criteria, it has functional similarity to the current Am-I-Regulated process. In both, the outcome is a finding that such a GE organism is not subject to the regulations at 7 CFR 340. APHIS will maintain on our website a list, with CBI deleted, of all GE plant-trait-MOA combinations that have been reviewed. The list will include the inquiry, and the agency finding.

When the Agency identifies a plausible pathway to increased plant pest risk, APHIS would conduct a plant pest risk assessment, a more robust analysis than the initial review, to evaluate the factor(s) of concern and to determine the likelihood and consequences of the potential plant pest risks identified in the initial review. In some cases, the Agency may be able to reach a finding that the plant-trait-MOA combination is not subject to the regulations based on the outcome of the plant pest risk assessment. In other cases, the Agency may determine that additional information is needed to evaluate the potential plant pest risks and field trials or greenhouse studies may be necessary to collect additional information to inform the risk assessment.

In either case, under § 340.4(b)(3), APHIS would make available information, with CBI deleted, on the results of both the initial review and the subsequent plant pest risk assessment in a notice in the Federal *Register*, accompanied by any associated NEPA analysis, and take public comments. After reviewing the comments, APHIS would make a final determination of regulatory status and notify the public via a second *Federal Register* notice.

APHIS would maintain on its website information on all requests for and results of regulatory status reviews and would update the website to provide that information in a timely manner. We would also note that APHIS would protect CBI associated with individual regulatory status reviews on the website.

4.8 Federal, Tribal, and State Governance

4.8.1 Federal Oversight

The Coordinated Framework, discussed in Section 1.6.1, 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 final 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 is unlikely to present a plant pest risk.

The final revisions to 7 CFR part 340 under the Preferred Alternative would update the regulations by revising terms and definitions to broaden the scope of GE organisms that could be reviewed and potentially regulated under 7 CFR part 340. While the scope of GE organisms that APHIS would review for plant pest risk would be broadened, the revisions would focus and limit ultimate regulatory oversight to GE organisms that APHIS found had a plausible pathway to increased plant pest risk, as identified in a science-based risk assessment, or were not eligible for a regulatory status review. The final revisions are expected to promote process efficiency by allowing APHIS to focus its resources on oversight of GE organisms that have potential plant pest risks, and eliminating oversight of GE organisms that are unlikely to pose such risks. Noxious weed risks would be considered pursuant to our statutory authority and the regulations issued under that authority. 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 (final rule), APHIS would no longer require permitting for field testing of GE organisms prior to determination of their plant pest risks. Rather, developers would first be able to assess whether their modified plant qualified for an exemption or was similar to an organism that was previously reviewed. If not, APHIS would conduct an initial review and/or a plant pest risk assessment first, and only require permits for field testing of GE plants that APHIS found had a plausible pathway to increased plant pest risk. For those GE plants that are determined unlikely to pose a plant pest risk, biotech developers will be able to field test without APHIS authorization. Developers concerned about a bottleneck in regulatory status reviews in the early years could elect to be regulated under permits and could request a regulatory status review at a later date. In effect, it is expected that APHIS would be regulating fewer GE plants, eliminating unnecessary regulation, but regulating a broader range of GE organisms that presented plant pest risks. 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 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 the following 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 procedures required for successful commercialization of their product, as occurs 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 APHIS 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.

Companies providing GE seed are motivated to adhere to strict stewardship requirements to maintain the integrity of their crops and reduce legal exposure. Best management practices include (Loberg 2010):

- 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
- 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

While the aforementioned measures represent the best practices followed by the sugarbeet seed industry, similar stewardship measures are followed in other instances such as the production of GE alfalfa seed and Enogen® corn, where the latter case as little as 1 seed in 10,000 can affect the characteristics of processed corn (NAFA 2008; Syngenta 2020). 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% or more of the alfalfa seed acres choose production of GE or non-GE seed (NAFA 2014). 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 (NAFA 2020).

Second, while under the Preferred Alternative research, development, and innovation in the agricultural biotechnology sector is expected to increase, the pace of commercialization of GE crop plants is not 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 will be required to comply with these laws and implementing regulations, as under the No Action Alternative.

Lastly, reputational considerations among domestic and international markets and among domestic and foreign 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 oversight of field trials is in developers' best interests. 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 is unlikely to pose a plant pest risk.

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 risks that a GE organism may pose. Accordingly, for those GE organisms that APHIS will not be regulating under the Preferred Alternative, the EPA and/or FDA may continue to exercise oversight. However, APHIS acknowledges that the final revisions to 7 CFR part 340 could have direct or indirect impacts on the manner in which the FDA and EPA exercise their roles within the Coordinated Framework; these potential impacts are discussed below.

Plant Made Pharmaceutical and Industrial Compounds

As previously discussed in 4.4 – Human Health, APHIS has exercised oversight of GE plants that produce pharmaceutical or industrial compounds (PMPI-producing plants). A recent, well-publicized example of such a plant is tobacco, *Nicotiana benthamiana*, which was genetically engineered to produce antibodies to the Ebola virus, and used in the development of an Ebola vaccine (Zahara et al. 2017). 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, EPA, and/or FDA.

APHIS has authority to evaluate PMPI-producing plants 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 FIFRA (7 U.S.C. 136 et seq.), and plant made industrial products under the Toxic Substances Control Act (TSCA, 15 U.S.C. 2601 et seq.). While APHIS may regulate the plant itself, products obtained from PMPI-producing plants may be regulated by the FDA (authority over food and drugs) or the EPA (authority over certain industrial compounds), depending on their use or intended use.

Under current 7 CFR part 340, APHIS has regulated all PMPI-producing plants that were submitted to the agency for review because they were developed using genetic material from a plant pest, or a plant pest was part of the development process (e.g., *Agrobacterium*). Accordingly, APHIS has exercised oversight of field trials of all PMPI-producing plants known to the agency; this oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring.

Since 2003, APHIS has required additional permit conditions for field testing PMPI-producing plants (USDA-APHIS 2003), conducting seven inspections for every field trial, review of design and handling protocols, and requirements for training of personnel. In particular, APHIS authorizes releases only in low production areas for the particular crop at issue so as to enhance confinement conditions (USDA-APHIS 2003), and has never granted nonregulated status to a PMPI-producing plant.

Currently, there are no federal statutes (either singularly or collectively) that specifically require regulation of all PMPI-producing plants. For PMPI-producing plants whose products are subject to FDA oversight, there are no regulations describing oversight of planting of such crops. For plants genetically engineered to produce human drugs, companies generally go to the FDA only 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 field testing and growing the pharmaceutical-producing plant in the field. Under TSCA, the EPA has authority to regulate new chemical substances, including industrial compounds. However, the EPA has not promulgated regulations that cover GE plants that produce industrial compounds.

We stated in the June 2019 proposed rule that the likelihood existed that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined to be not regulated if regulatory status review (RSR) found them to be unlikely to pose a plant pest risk (USDA-APHIS 2020d). We also noted that our proposed rule envisioned that were this to occur, such plants could be grown outdoors without the need for APHIS permits and without APHIS oversight. In light of these considerations, and as further explained in the preamble to the final rule, APHIS is using its authority under the PPA to maintain regulatory oversight over PMPIs and eliminate any potential gap in oversight. The final regulations have been revised to specify in 340.2(e) that any plant that encodes a product intended for pharmaceutical or industrial use is subject to the regulation and requires a permit for movement.

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 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 any size acreage. To date, the EPA has largely relied on USDA oversight and inspections of field trials under 10 acres. 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 (final 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 subject to the regulation. Rather, the GE plant would be subject to regulation if it had a plant-trait-MOA combination that APHIS found had a plausible pathway to increased plant pest risk. It is expected that many of the GE PIP producing plants that APHIS evaluates will be found unlikely to pose a plant pest risk and will no longer require APHIS permits.

Because EPA generally requires Experimental Use Permits only for field tests on 10 acres or more of land, only APHIS has historically exercised regulatory oversight of plantings of PIP-producing plants on 10 acres or less of land. Under the Preferred Alternative, there would be a likelihood that many PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not to be covered by the regulations after RSRs, because such plants are unlikely to pose greater plant pest risks by comparison with their comparators. Such plants could therefore be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight. Thus, Federal oversight over small-scale (10 acres or less) outdoor field test plantings of some PIP-producing plants would rest solely with EPA. APHIS inspections cost approximately $800/inspection. 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 the 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 rule is finalized).

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

The EPA registers and has oversight of the herbicides used on HR crop plants, but does not regulate 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 subject to the regulation. 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 risks.

Commenters to the previous 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 nonregulated 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.

Typically, APHIS decisions on nonregulated status for an HR crop occurs within a few months of a registration decision for the herbicide on that crop by the EPA. In the case of dicamba resistant corn and soybean, APHIS's decision preceded that of the EPA by over a year and during that time, there was a considerable amount of illegal dicamba application to dicamba resistant soybean that resulted in extensive crop injury from herbicide drift (Bradley 2018). Under the Preferred Alternative, the gap in decision making is expected to further increase. This coordination presents challenges because once APHIS finds that a GE organism does not represent a plant pest risk, APHIS does not have the authority under the PPA to require permits with regulatory controls for the movement and outdoor planting of that GE HR plant during those subsequent years. Nor is it within APHIS' authority for APHIS to withhold making a finding for several years and require permits for field testing during that time. APHIS will work with the EPA to explore possible solutions to the challenges associated with the asynchronous regulatory actions on the part of APHIS and the EPA and to better coordinate the commercial availability of seed for HR crops 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 HR crop basis (e.g., glyphosate resistant cotton) so that the EPA and APHIS are making decisions on the same specific HR crop/herbicide combinations.

However, the issue has not been the illegal use of pesticide during the field testing of GE HR crops by developers but instead is the illegal use of pesticide by farmers on commercially available seed before the commercial availability of the herbicide designed for those crops, over which APHIS has no authority. 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 HR crops before the herbicide registrations for use on those crops were completed. Another option might involve a voluntary agreement by seed developers to withhold selling seed of HR crops until the EPA registrations are completed for the herbicide products designed for those crops. In cases where APHIS would, under the No Action Alternative, make a determination of nonregulated status or, under the Preferred Alternative, make a finding of unlikely to pose a plant pest risk for an HR crop, and no herbicide product has been registered by the EPA for use on that HR crop, APHIS would indicate this fact on its website and note that it is illegal to use any herbicide product on these crops unless registered by the EPA for such use. In addition, APHIS would include language in letters sent to the developer, and in *Federal Register* notices associated with final determinations or findings, indicating it is illegal to use herbicides on these crops until the herbicide product is registered by the EPA for use on the HR crop.

4.8.2 Interactions with Federally-Recognized Tribes

APHIS consultations with federally-recognized tribal entities[167] 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 June, 2018 notifying them of APHIS' intent to prepare this PEIS. In addition, APHIS held a conference call for Tribal leaders in November 2018 to provide information and answer questions regarding its plan to publish a proposed rule.

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. APHIS consults with appropriate tribal entities prior to issuing permits if tribal resources may be impacted. Under both of the Alternatives, the opportunity for APHIS consultation with tribal representatives would continue. APHIS would continue to share notifications (for the No Action Alternative) and applications for permits (for both Alternatives) with tribal representatives when there are GE organisms within the authority of 7 CFR part 340 proposed for release on or in proximity to tribal lands. Under the Preferred Alternative, 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

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

[167] 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.

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 may impose further measures 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 the APHIS-BRS Regulatory Operations Programs branches, APHIS' Plant Protection and Quarantine 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 PPA, which 7 CFR part 340 implements, contains a preemption clause (7 U.S.C. § 7756) that prohibits state regulation of any, "movement in interstate commerce of any article, means of conveyance, plant, biological control organism, plant pest, noxious weed, or plant product in order to control a plant pest or noxious weed, eradicate a plant pest or noxious weed, or prevent the introduction or disseminations of a biological control organism, plant pest or noxious weed if the Secretary has issued a regulation or order to prevent the dissemination of the biological control organisms, plant pest or noxious weed within the United States." There are two exceptions to the preemption: 1. States may impose prohibitions upon the movement in interstate commerce of articles, means of conveyance, plants, biological control organisms, plant pests, noxious weeds or plant products that are consistent with and do not exceed the regulations or orders issued by the Secretary; 2. "A State may impose prohibitions upon the movement in interstate commerce (of the above) that are in addition to the prohibitions imposed by the secretary, it the State demonstrates to the Secretary and the Secretary finds that there is a special need for additional prohibitions based on sound scientific data or through 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.

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 (NRC 2002; Taylor and Tick 2003; Taylor et al. 2004; Wieczorek and Wright 2012). Consequently, farmer access to products of agricultural biotechnology is of strong economic interest for many states (Taylor 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 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 for ensurance of 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 on 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 stringent 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 potentially 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 summarizes 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 GE 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 GE. States are preempted from creating different standards. Congress determined that the USDA will develop regulations in this area and a final rule was published December 21, 2018.[168]

4.8.6 State Regulations and Analysis of the Alternatives

The revision of 7 CFR part 340 would not impact APHIS partnerships with states in the oversight of GE organisms, specifically in regulation of interstate movement and environmental releases. Under both 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 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. State level regulation would need to be consistent with the PPA particularly concerning preemption (7 U.S.C. § 7756). State regulation is not the expected outcome. For example, states have not declared their intention to regulate any of the GE organisms which APHIS has concluded did not fall under 7 CFR part 340 through the "Am I Regulated Process." 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.

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

[168] National mandatory bioengineered (BE) food disclosure standard (NBFDS or Standard): https://www.federalregister.gov/documents/2018/12/21/2018-27283/national-bioengineered-food-disclosure-standard

to change as a result of the adoption of either of the Alternatives considered. APHIS expects that states would be required to adjust to minor programmatic and procedural changes under the Preferred Alternative. For both 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 nonregulated status, or finding of unlikely to pose a plant pest risk, for GE organisms that are not subject to regulation. In this sense, those potential environmental impacts associated with 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 associated socioeconomic impacts
- Development of PIP resistance in target plant pests and pathogens
- Development of herbicide resistant weed populations
- A potential increase in the use of pesticides and fertilizers commensurate with population increase and demand for 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

Although management practices are meant to preclude or limit gene flow, 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 impacts 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 might be required to return to 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 an 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 programs to mitigate development of resistance. This is not only an EPA requirement for some GE crops, but in the farmer's best interest. Therefore, it is expected most cropping systems will practice insect resistant management where there is the risk for development of resistance.

Herbicide Weed Resistance

As with PIP resistance, development of HR 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 nonregulated status or finding of unlikely to pose a plant pest risk, herbicides will be used on that crop plant if it is approved by the EPA and produced commercially. For this reason, 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 the 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 for 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 nonregulated status or finding of unlikely to pose a plant pest risk, pesticides used on that crop would be subject to the EPA registration and use requirements. Some GE crop plants may require less insecticide, fungicide, and fertilizer use, and so, 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 hydroelectric power or fossil fuels. Under both of the Alternatives AHIS activities would involve the use of fossil fuels, fossil products (e.g., plastics), electronic devices, and electricity 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 around 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 impacts 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 by 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 PEIS will comprise a rulemaking decision as to revisions of 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 GE organisms within the authority of 7 CFR part 340. Future Agency decisions and actions will be those related to compliance with and enforcement of 7 CFR part 340, and findings 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 resulting from the final revisions are reviewed and analyzed in this chapter.

Interstate Movement and Importation

As discussed in Chapter 4, there are no significant differences between the No Action and Preferred Alternatives in regard to impacts on APHIS regulation of the importation and interstate movement of GE organisms. These types of activities involve APHIS specified shipping practices to move GE organisms (e.g., seeds, microorganisms) from one location to another (as stated in the final rule). GE organisms found to be within the authority of 7 CFR part 340 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.

Authorized Environmental Release

There are no reasonably foreseeable impacts of a cumulative nature that could derive from APHIS authorized field testing of GE organisms. Field tests are typically limited in size and duration and any impacts on the local environment are, at most, transient in nature. APHIS is only aware of one unauthorized release that has persisted in the environment, namely glyphosate resistant creeping bentgrass described in Section 4.1.2.3. Even in that case, the environmental and socioeconomic impacts have been minimal.

Environmental Release after a Determination of Nonregulated Status or a Finding of Unlikely to Pose a Plant Pest Risk

In one sense, continued determinations of nonregulated status (No Action Alternative) or findings of unlikely to pose a plant pest risk (Preferred Alternative) for GE organisms may contribute to potential impacts on the human environment that could be considered cumulative in nature. Agency decisions that render a GE organism not subject to regulation commonly lead to large scale commercial plantings of GE crop varieties, and use of associated agronomic practices and inputs, as discussed in Chapter 3. Cultivation of GE crops at the commercial scale, as with non-GE crops, can have environmental impacts that are largely derived from agronomic practices and inputs used in crop production. The subtle difference in any potential cumulative impacts would derive from how GE crops affect agronomic practices, and the types and quantities of inputs, relative to the non-GE variety. The discussion below addresses these subtle differences.

5.2 Cumulative Impacts: Physical Environment

The availability of GE crops influences how crop producers decide to implement certain management practices, such as crop rotations, tillage, and use of cover crops, all of which impact soil erosion and quality.

5.2.1 Soils

Most cumulative impacts on soils involve tillage, cover crop selection, crop rotation, irrigation practices, and pesticide and fertilizers inputs used in conjunction with the particular type of crop and cropping system. These contribute to cumulative impacts on soil quality as discussed in Chapter 3. These practices can beneficially or adversely impact 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 weeds resistant to the herbicide. 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 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-ERS (Fernandez-Cornejo 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 cropping systems in the Southeast), conventional tillage has increased to help control HR weed populations, and conservation tillage has diminished. Surveys of regional tillage patterns and expert assessments indicate that GR-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.[169] As discussed above in the section on HR weeds, GE innovation is expected

[169] See Monsanto FEIS for petitions 10-188-01p and 12-185-01p (determinations of nonregulated status for dicamba resistant soybean and cotton varieties), Appendix 9 - Monsanto tillage Report; https://www.aphis.usda.gov/brs/aphisdocs/dicamba_feis_appendices.pdf

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 impacts from practicing conservation tillage are also expected to continue.

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). As described in Section 4.2.1, there is a major effort underway to engineer pennycress to be a more valuable cover crop to use in a corn-soybean rotation. It is likely that under either the No Action Alternative or the Preferred Alternative, farmers will be able to make a profit from growing a cover crop. As a result, it can be expected that the use of cover cropping will increase in the Midwest and this in turn may have the beneficial cumulative impacts of reducing glyphosate dependence for weed control and improving soil quality.

GE crop varieties, or other GE plants or organisms, that will become available to the market/public are not expected to much differ between the Alternatives. Thus changes in practices and inputs used for the production of GE crop varieties (e.g., tillage, cover crop selection, crop rotation, irrigation practices, and pesticide and fertilizers inputs), are not expected to much differ. Consequently, there is no difference in how these crops or other GE plants or organisms would contribute to potential cumulative impacts, beneficial or adverse.

5.2.2 Water Resources and Quality

Agriculture is one of the leading causes of impairment in U.S. waterways (US-EPA 2019b). The impacts of agriculture on water quality and water resources are inherently cumulative in nature. The biggest cause of impairment is pathogens followed by sediment and then nutrients. Pesticides are 16th on the list (US-EPA 2019b). The adverse impacts from agriculture on water quality are a function of agriculture in general and are not attributable to GE cropping systems per se, as described in more detail below.

The largest source of impairment, pathogens, comes from runoff of manure applications and animal operations-neither of which is associated with GE crops. The second most common source of impairment is from sediment. Agriculture contributes to sediment in streams primarily from tillage operations. Nutrient runoff ranks third as the cause of impairment of rivers and streams. A significant adverse cumulative impact attributable in part to nutrient runoff is the Gulf of Mexico dead zone, an area of low oxygen in the Gulf of Mexico that can kill fish and marine life. One of the principal causes of the dead zone is runoff of nitrogen and phosphorous fertilizer applied to farmland in the Midwest. The deadzone results when nutrient runoff stimulates algal growth that is unsustainable. When the algae die off, algae and oxygen dissolved in water are both consumed by microorganisms, which results in depletion of oxygen below the level that can support fish. In 2019, the dead zone was 6,952 square miles, the 8th largest dead zone since mapping began there in 1985 (NOAA 2017; NOAA 2019).

GE crops do not use more fertilizer than non-GE crops; both cropping systems equally contribute to the problem of nutrient runoff. The adverse environmental impacts of nutrient runoff is recognized and technical solutions have been proposed to mitigate the problem for both types of cropping systems. Fertilizer inputs are expensive, and, if technology can reduce fertilizer requirements, it is likely to be adopted. As described in Section 4.2.2, it is expected that future GE crops will require less fertilizer. Crops are being engineered to use fewer nutrient inputs. Another innovation being explored allows engineered plants to use phosphite instead of phosphorous. Phosphite is toxic to non-engineered plants and so could act as both a fertilizer and an herbicide. As it would not stimulate algal growth, phosphite runoff would not be expected to contribute to the Gulf of Mexico dead zone and could potentially also decrease herbicide runoff. In addition, there are private-sector reports of finding promising microbes that synthesize and deliver nitrogen to the crop, reducing the amount of nitrogen fertilizer than needs to be applied (Pivot Bio 2020).

Pesticides are 16th on the list of sources that contribute to the impairment of U.S. rivers and streams. Although pounds of glyphosate use has increased in the last decade and most of this increase has been due to the increased use of glyphosate on GE crops (Atwood and Paisley-Jones 2017), glyphosate is not listed by the EPA as one of the 69 pesticides that contribute to the impairment of streams and rivers (US-EPA 2019b). Of the pesticides that do contribute to the impairment of streams and rivers, 47 are insecticides and 16 are herbicides. Of the 16 herbicides noted by the EPA that cause river and stream impairment,[170] none are used exclusively on GE crops or represent the cognate herbicide for the corresponding HR trait. Indeed, the pesticide impairing the greatest length of river and streams, is the herbicide atrazine, whose use has leveled or decreased with the increased adoption of HR crops (Atwood and Paisley-Jones 2017). Therefore, HR GE crops are not having a significant adverse cumulative impact on water quality. Since GE crops reduce insecticide use (Carpenter 2011; Klümper and Qaim 2014; Brookes and Barfoot 2016), GE crops reduce the negative cumulative impact of pesticides on water quality.

To the extent conservation tillage is more commonly practiced with GE HR crops, relative to non-GE crops, as discussed in Section 4.2.1 (Fernandez-Cornejo et al. 2012), the continued or even expanded use of GE HR crops is expected to limit adverse cumulative impacts on impairment of water quality, via reduced sediment, pesticide, and fertilizer run-off. As noted above, GE traits may make cover cropping more profitable for farmers and increase their adoption. Increased cover cropping in the Midwest is expected to reduce nutrient runoff and improve water quality. As discussed in Chapter 3, GE IR cropping systems commonly use much less insecticide than their non-GE counterpart, and can even reduce insecticide use area-wide via reductions in pest populations. Thus, in this sense, contributions to cumulative impacts on water quality via run-off would be expected to be reduced in GE IR cropping systems, too.

5.2.3 Air Quality

As summarized in Chapter 3, crop production practices can generate air pollutants that can potentially impact the environment and human health and can challenge regional NAAQS. These emission sources include: smoke from crop 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 et al. 2009; US-EPA 2013b). One of the most significant sources of emissions from cropping systems is soil based

[170] Atrazine, Simazine, Diuron, EPTC, Methoxychlor, Alachlor, Prometon (Prometone), Terbacil, Trifluralin, Pronamide, 2,4,5-Tp (Silvex), Dinoseb, 2,4,5-Trichlorophenol, Acrolein, Oxyfluorfen, Prometryn

N_2O. For example, 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% or emitted N_2O.[171] CO_2, and CO, is also released during use of farm equipment and transport of products, growers, scientists, and APHIS officials to and from field sites. Crop residue is also burned on some farms, and burning is a source of CH_4, N_2O, CO, and NOx.

The area from which emissions are released as a result of field trial activities would be limited to less than 450,000 acres per year; in recent years, the collective annual acreage of authorized field trials has been around 350,000 to 450,000 acres as noted in Section 3.3.3.

APHIS determinations of regulatory status are not federal actions that will directly result in atmospheric emissions. Rather, APHIS' regulatory status decisions can impact the availability of certain GE crop varieties to the agricultural community, which may influence the volume of emissions, relative to any differences in agronomic practices and inputs. The collective actions of all producers of the GE crops and their production practices (such as rotation crops, tillage choices, fertilizer use, pesticide use) and the timing associated with these practices impacts emissions. Such actions are based on regional pest and disease pressures, the prevalence and variety of weed species, soil quality, and market forces. Considering these factors, although the sources of emissions and potential impacts on air quality are well understood, attempting to predict how grower choices will contribute in adverse or beneficial ways to impacts on cumulative emissions from crop production would be highly speculative.

As discussed in Chapter 3, conservation tillage is associated with GE HR cropping systems, a trend that would be expected to continue under both the No Action and Preferred Alternatives. Conservation tillage practices reduce emissions by reducing the use of internal combustion engines and soil disturbance (e.g., PM). GE crops with pest resistant traits require fewer pesticide applications thereby reducing fossil fuel consumption and associated emissions. Newly developed GE crop plants with improved nitrogen or phosphorous use efficiencies could facilitate reduction in fertilizer needs. Under both the No Action and Preferred Alternative, there may be varieties of GE crop plants with such traits developed and available for commercial production. These types of crops could potentially contribute to reduction in the cumulative emissions from U.S. agriculture. If APHIS determines such plants are unlikely to pose a plant pest risk, and they are cultivated for commercial purposes, subject to review and approved use by the EPA and likely having gone through voluntary consultation with the FDA, we expect that such GE plants will help reduce contributions to cumulative emissions.

Under either of the Alternatives considered, the factors discussed would contribute to overall cumulative emissions of NAAQS pollutants, N_2O, and CH_4. The collective actions of all growers relative to the selections of crops and production practices (e.g., rotation crops, tillage choices, fertilizer use, pesticide use, and the timing associated with these practices) will continue to impact emissions from GE and non-GE cropping systems. APHIS regulatory status decisions would have little indirect impacts on cumulative emissions from U.S. cropping systems.

[171] EPA - greenhouse gas emission: https://www.epa.gov/ghgemissions

5.3 Cumulative Impacts: Biological Environment

5.3.1 Soil Biota

Agronomic practices and inputs 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 and inputs can potentially impact soil biota both positively and negatively. Although the types of practices and inputs used are the same, the intensity of these agronomic practices are likely to differ depending on the type of cropping system used (i.e., GE, non-GE conventional, and organic). 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 et al. 2006; Gupta et al. 2007) and tillage (Gupta et al. 2007; Roger-Estrade et al. 2010). Soil biota are typically tolerant of pesticides when they are applied at recommended rates, with only minor, transient impacts on soil populations (Locke and Zablotowicz 2004). Cover cropping, especially if used for weed control, could reduce pesticide applications and tillage.

APHIS determinations of nonregulated status or findings of unlikely to pose a plant pest risk under either Alternative could potentially lead to the availability of new crops that facilitate more sustainable agricultural practices and this may in turn have a positive impact on soil biota. If more sustainable practices are adopted under either the No Action Alternative or Preferred Alternative, such that there is less tillage, more cover cropping, and less use of certain pesticides, beneficial cumulative impacts on soil biota would be expected to ensue. If not, the cumulative impacts on soil biota would not be expected to change.

5.3.2 Invertebrates

Invertebrate populations will always be affected by commercial scale crop production systems, both GE and non-GE. Adverse impacts on non-target invertebrate communities can result from applications of insecticides, which occurs in both GE and non-GE cropping systems. GE IR crops have reduced insecticide use resulting in a reduction in adverse cumulative impacts on invertebrate communities. That trend is expected to continue under both the No Action and Preferred Alternatives.

However, as discussed in Chapter 3, there will be a continued contribution of crop production, particularly GE IR crops, to cumulative impacts on the emergence of insecticide-resistant populations. Emergence of pests resistant to IR crops could lead to use of more insecticides, a negative cumulative impact on invertebrates. The contribution or impact of GE IR crops on the emergence of insecticide-resistant populations, and the management of this issue, is not expected to differ under either Alternative.

By making weed control more effective, GE HR crops may have indirectly impacted monarch populations. Milkweed plants, which are the sole food source for monarch caterpillars are estimated to have declined in Iowa by 58% from 1999 to 2010 (Pleasants and Oberhauser 2013). Over a similar time period, monarch populations overwintering in Mexico have also declined (Brower et al. 2012b). The cause–effect relationship between lower abundance of milkweed in the United States and decreasing overwintering populations is uncertain. The National Academy of Sciences (NAS 2016b) cites a number of studies that suggest that the declining monarch population overwintering in Mexico is compensated by increased reproductive output which allows the subsequent generations of monarchs to fully recolonize their breeding range in eastern North America (Howard and Davis 2015). Inamine et al. (2016) also could find no evidence that lower abundance of milkweed resulted in monarch decline.

In general, there has been debate on the potential impact of herbicides (primarily glyphosate) on milkweed and monarch butterfly populations. As yet, there is no consensus among researchers that increased glyphosate use is associated with decreased monarch populations. Most studies on monarch butterfly migratory dynamics have not shown that suppression of milkweed by glyphosate is the cause of monarch decline (NAS 2016b). More recent findings indicate that other factors, such as habitat fragmentation and the availability of late season nectar plants, are likely responsible for the observed decline in migratory monarch populations (Agrawal 2017). Findings by Agrawal (2017) also suggest that planting milkweed is not going to increase populations or save monarch populations from demise (Maeckle 2016).

Due to the population decline, the NRCS and others – including the USFWS – have developed a collaborative landscape level partnership to benefit the Monarch Butterfly.[172] The primary focus of the partnership is the design and application of selected NRCS conservation practice standards and enhancements to benefit the Monarch Butterfly. These conservation practice standards and enhancements are applied by the NRCS when providing technical and financial assistance to eligible landowners using its Farm Bill authorities. Other actions implemented by the NRCS include the conversion of suitable monarch butterfly habitat types to other land uses, including crop production; and implementation of certain conservation practice standards and enhancements as part of the application of pesticides/herbicides to benefit the monarch butterfly, including but not limited to Integrated Pest Management and Herbaceous Weed Control. Given the uncertainty of the impact of milkweed decline on monarch populations, APHIS cannot draw conclusions on cumulative impacts of glyphosate use on monarch population.

GE crops do not appear to have any adverse cumulative impacts on honeybees. A review on the potential impacts 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 impacts, 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).

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 impacts, such as disruption of invertebrate populations and plant communities, have been reported in the literature (Icoz and Stotzky 2008; Wolfenbarger et al. 2008; 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 both of the Alternatives. The intensity and significance of the impact is not likely to differ under either

[172] https://www.fws.gov/savethemonarch/pdfs/MonarchConferenceReport2016.pdf

Alternative because the EPA-required resistance-management practices will remain in place regardless of which Alternative is selected.

5.3.3 Wildlife

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. Improper use of herbicides on HR crops, especially the over-reliance on a single herbicide MOA can facilitate the selection of HR weeds that can ultimately lead to higher use of herbicides and tillage, thereby resulting in adverse cumulative impacts on air and water quality, affecting wildlife habitat. As mentioned in Section 4.2.2, some biotech crops that can lead to lower reliance on the herbicides commonly used today are under development.

As discussed in Chapters 3 and 4, runoff of sediment and agricultural inputs such as pesticides and nutrients can have cumulative impacts on wildlife. The Gulf of Mexico dead zone and its impacts on marine wildlife are a well-recognized cumulative impact that can result from U.S. crop production.

Atrazine, the herbicide noted by the EPA as causing the greatest impairment to rivers and streams, has been linked to amphibian declines. Surfactants in glyphosate formulations can also harm amphibians. However, whether amphibians are exposed to glyphosate formulations in crop fields and runoff that are at harmful levels is still controversial.

The adverse cumulative impacts on wildlife are caused by agricultural practices and inputs common to both GE and non-GE cropping systems. Certain GE crop traits, such as insect and disease resistance, and nitrogen and phosphorous use efficiency are expected to reduce the cumulative impacts of crop production on wildlife, relative to current crop varieties and associated practices and inputs. Varieties of GE plants incorporating these traits are expected to be developed under both the No Action and Preferred Alternatives, and if widely adopted may help mitigate adverse cumulative impacts.

Under either of the Alternatives considered, the factors discussed would contribute to overall cumulative impacts on wildlife. The collective actions of all growers relative to the selections of crops and production practices (e.g., rotation crops, tillage choices, fertilizer use, pesticide use) and the timing associated with these practices will continue to impact wildlife in both GE and non-GE cropping systems.

5.3.4 Cumulative Impacts: Pest and Disease Management

The production of insect- and pathogen-resistant GE crop varieties may have direct and indirect effects on pest and disease management. Cumulative impacts arise from grower choice of these insect- and pathogen-resistant GE crop varieties and their impacts on the emergence of insect- and pathogen-resistant populations, and their management.

In terms of beneficial cumulative impacts associated with these varieties, GE IR and disease resistant crops can and do reduce reliance on pesticides used to suppress plant pests and pathogens. The beneficial impacts are both direct within the GE crop, and indirect on crops nearby due to an overall area-wide, reduction of the pest or pathogen 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 can promote eradication of plant pests–a beneficial cumulative impact. One example is the way that virus-resistant papaya has benefited the Hawaiian papaya industry by reducing virus pressure on non-GE papaya in Hawaii. Under both the No Action and the Preferred Alternatives, increased options are expected in the variety of GE crops available to growers for managing plant pests and disease, with a reduction in adverse cumulative impacts on pest and pathogen resistance management.

In terms of adverse cumulative impacts associated with these varieties, as GE IR and disease resistant crops become more widely used, there is an increased potential for development of resistance to the introduced traits through the emergence of insect and pathogen resistant populations. This applies 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 for individuals in the population resistant to that agent. Thus, it is not unique to the GE IR or pathogen resistant crop itself (there are in fact disease resistant varieties of canola and wheat, for instance, that have been conventionally bred, that likewise face the problem with emergence of resistance).

These factors considered, when PIP-based strategies for pest and disease management are not utilized, APHIS expects that more synthetic chemical use will ensue for control of pests and diseases, which can also result in selection of resistant pests. 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.

In response to development of resistance to Bt-based PIPs, the EPA instituted insect resistance management (IRM) requirements for Bt crops (US-EPA 2020a). 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 (US-EPA 2017a).

Cumulative impacts under the No Action and Preferred Alternative are expected to be about the same. Cumulative beneficial impacts 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, animal foods, and fiber nationwide.

5.3.5 Cumulative Impacts: Agricultural Weeds and Herbicide Resistant Weeds

Development of HR weed populations is a notable example of a cumulative impact that can derive from crop production. This 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.

Crops with glyphosate resistance traits have been widely adopted, and those conveying resistance to other herbicides such as glufosinate, 2,4-D, dicamba, and potentially other herbicides, are expected to increase in use under both the No Action and Preferred Alternatives, particularly stacked-trait varieties. For example, in 2019, single trait GE HR cotton comprised 6% of upland cotton acreage, GE IR cotton (also referred to as Bt cotton) comprised about 3%, and GE cotton varieties stacked with both HR and IR traits about 89% (USDA-ERS 2019). Similarly, approximately 80% of corn acres were planted with stacked-trait seeds in 2019 (USDA-ERS 2019).

Many of the newer GE HR crop plants are stacked-trait varieties resistant to two or more herbicides. 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 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. However, where these crops are adopted by growers for commercial use, a greater variety of herbicides will be applied, and in some instances an increase in the amount applied. Depending on the herbicide rotation and use practices applied, this could potentially increase the selection pressure for HR weeds.

APHIS acknowledges that although stacked-trait varieties, of which numerous different varieties can be expected (Duke 2015), may be useful in managing agricultural weeds, and allaying development of weed resistance to herbicides, they will not prevent development of herbicide resistant weed populations (NAS 2016b). Prevention will require collective integration of cultural, biological, and limited chemical controls in crop specific IWM programs. Some argue that stacked traits will exacerbate management of HR weeds. If growers fail to use a diversity of approaches, the value of these HR traits are likely to diminish quickly (NAS 2016b). Harker et al. (2017) argue that more research on herbicide alternatives is required and that research on allelochemicals and biofumigants, diverse crop rotations, higher crop seeding rates, intercropping, competitive cultivars and planting patterns, physical weed control, weed seed destruction, and reducing weed seed and vegetative propagule dormancy is crucial for sustainable weed management systems (Harker et al. 2017). Fundamentally, sustainable weed management will only be achieved if there is diversity in both the agroecosystem and in the herbicide and non-herbicide tools employed for weed control (IWM) (Harker and O'Donovan 2013; Shaner and Beckie 2014).

IWM strategies for managing and avoiding the development of HR weed populations are becoming increasingly well-developed and IWM guidance is provided by the crop protection and crop seed industries, the USDA, university extension services, the EPA, state departments of agriculture, and Weed Science Society of America. Developers of GE HR varieties provide stewardship and IWM guidance to crop producers (e.g., (Bayer-CropScience 2016; Pioneer 2016)) that is in accordance with and responsive to the EPA guidance and WSSA recommendations (US-EPA 2017c; WSSA 2020). These practices must be consistently implemented to avert the future development of HR weed populations. IWM practices include using a variety of herbicides with different MOAs, rotation of herbicides, and crop rotation. 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 2020).

While there have not been herbicides released with new modes of action in at least 30 years, there are still opportunities to find resistance traits to existing herbicide chemistries that can be inserted into new GE HR crop varieties (US-EPA 2016d). For example, GE plants are being developed to use phosphite as both an herbicide and a nutrient as the phosphite is expected to be toxic to plants lacking the enzymes to metabolize it to phosphate. Novel herbicides and technologies such as RNA interference (RNAi) (branded BioDirect™ by Monsanto), biologicals/natural products, application of 'omics' for resistance management, and robotics for weed scouting and removal, are emerging (Shaner and Beckie 2014). It is expected that other strategies will also be pursued (Shaner and Beckie 2014) that will expand the options for better management of HR weeds. For example, it has been suggested that gene drives can be used to manage outcrossing weed populations so that they remain sensitive to preferred herbicide MOAs (NAS 2016a).

The EPA has recently embarked on a widespread effort to combat and slow the development of pesticide resistance, developing a Pesticide Registration Notice (PRN) "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, the 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. State extension agents, seed providers, herbicide suppliers, and other professionals such as researchers affiliated with the WSSA, will also provide advice and training to growers, who are becoming aware of the needs for sustainable weed management and are therefore 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 the EPA guidance by individual growers.

Under both the No Action and Preferred Alternatives, APHIS expects 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. This trend has been documented by recent polls (Prince et al. 2012). Both Alternatives would have little impact in a cumulative manner on how HR weed development is managed. Under both the No Action and Preferred Alternatives, effective weed resistance management will rely on the grower's effective implementation of crop specific strategies, and support from industry, federal and state governments, and university extension. Research and development on non-herbicidal weed management strategies and strategies that integrate other weed management practices with herbicide use has increased since 1990 (Harker and O'Donovan 2013; Shaner and Beckie 2014; Harker et al. 2017). However, growers have been slow to adopt these strategies (Shaner and Beckie 2014; Harker et al. 2017). In the future, weed management by growers will require more knowledge, planning, time, cost and risk than in the past, in spite of ever-increasing farm size. Those growers who are able to adapt to this reality will have farm enterprises that survive and are profitable.

5.3.6 Gene Flow and Weediness

The likelihood 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; the outcrossing rate for plants; pollen viability; 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.

The particular species of GE plant and occurrence and proximity of sexually compatible species is the primary factor in reviewing the likelihood of gene flow (for more details see the review in Section 3.4.1.1).

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 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 et al. 2007; Ellstrand 2014).

APHIS is concerned with gene flow from the standpoint of whether a plant with weedy characteristics will result from the formation of a unique GE plant-trait hybrid via cross-pollination between a GE plant and a sexually compatible species, or through the dissemination of a GE plant with weedy characteristics.

It is generally assumed that 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 impact on the local ecology. This could be the case for a number of introduced traits.

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 et al. 2011; Ellstrand 2014).

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 impacts on ecosystem dynamics.

In summary, 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 crosses 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. 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.

Neither Alternative would have a cumulative impact on the issue of gene flow between GE plant varieties and sexually compatible wild relatives or other crops; with the exception of matters of weediness associated with GE plants, discussed following. To date, there are no GE plants that have created significant weed problems for agriculture. However, GE HR crops such as corn, cotton, or soybean, do volunteer (considered and treated as a weed) in rotation crops and are typically controlled with herbicides. As HR traits are stacked, it is necessary to plan accordingly for the control of volunteers that may have multiple resistance traits. Under both the No Action and Preferred Alternatives, it is expected that new plant species will be engineered that are themselves weedier or have sexually compatible relatives.

5.3.7 Biodiversity

For the reasons discussed following, there are no reasonably foreseeable cumulative impacts on biodiversity under either Alternative. 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 the protection of T&E species under the ESA,[173] EPA regulations protecting air and water quality, and various State requirements for protection of wildlife and T&E species. APHIS authorizations for notifications (No Action Alternative only) and permits (both Alternatives) 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 species or within habitat proposed for designation under the ESA. These requirements would not change under either of the Alternatives.

Under both Alternatives, there is a reasonable likelihood that more sustainable agricultural practices will be more widely practiced in conjunction with the availability of new GE crops that facilitate the adoption of sustainable practices as described in Section 4.2.2. As discussed in

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[173] By example, see http://www.fws.gov/endangered/laws-policies/regulations-and-policies.html, and https://www.fws.gov/permits/ltr/ltr.html

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).[174] 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.[175] 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;[176] and a SARE-supported network of sustainable agriculture educators in every state and island protectorate—comprised of expert farmers, ranchers, and agriculture professionals.

5.4 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. As discussed in Chapter 3 and Chapter 4, 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.

Considering the existing domestic, and regulatory review and authorization processes in other countries, for food and feed safety (summarized in Sections 3.7 and 4.4 – Human Health), and the efficacy of these review and authorization processes in ensuring the safety of food and feed, there are no potential adverse cumulative impacts on human health associated with either of the Alternatives considered, nor with the public consumption of current or future foods derived from GE crop plants.

5.5 Cumulative Impacts: Animal Food and Welfare

Considering the human and animal health data reviewed and analyzed in Sections 3.7 and 4.4, there are no adverse cumulative impacts on animal health and welfare that are expected under either of the Alternatives. The FDA will continue to oversee the food 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

[174] USDA - Sustainable Agriculture: https://afsic.nal.usda.gov/sustainable-agriculture-information-access-tools-1
[175] USDA - Conservation: http://www.usda.gov/wps/portal/usda/usdahome?navid=conservation
[176] SARE- Sustainable Agriculture Grants: http://www.sare.org/Grants

program. The EPA will continue to regulate and establish tolerance limits for pesticides used on human and animal food crops.

One of the major applications of GE corn and soybean is for use in animal food.[177] Corn is the primary U.S. feed grain, accounting for more than 95% of total feed grain production and use in the United States. 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 is intended to improve the digestibility of alfalfa.[178] Similarly, a phytase-modified corn has been developed that shows efficacy in reducing the need to supplement chicken feed with phosphorous (Gao et al. 2013). Phytase-modified corn is also expected to improve phosphorous assimilation by pigs. Not only is this 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.

It is widely recognized that fish contain nutrients of benefit to the human diet including omega-3-long chain polyunsaturated fatty acids (omega-3-LC-PUFA((FAO 2016). The primary source of these nutrients are global oceanic fish stocks which are at the limits of sustainable management and/or suffering from pollution (Usher et al. 2015). Fish consumption is increasingly driven by an expanding human population and changes in dietary consumption (Usher 2015). Aquaculture now produces more than 50% of all fish consumed (FAO 2016) . Farmed fish must have a dietary source of omega-3-LC-PUFA and these are primarily derived from other fish. Over 20 million tons of fish are harvested for non-food purposes such as fish meal, nutritional supplements and feed for aquaculture (FAO 2016) resulting in adverse cumulative impacts on fish stocks. Sustainable aquaculture requires a sustainable production of omega-3-LC-PUFA. Canola has been genetically engineered to produce omega-3-LC-PUFA that potentially can substitute for fish stocks harvested for feed for use in the aquaculture industry. It is possible that plant based sources of omega-3 LC-PUFAs, such as GE canola, could help address a growing global demand for omega-3 and omega-6 LC-PUFAs, and relieve, to some degree, the adverse cumulative impacts of aquaculture on wild fish stocks.

Under the No Action and Preferred Alternatives, it is likely that GE plants that have improved nutritional profiles for animal feed will continue to be developed and commercially produced.

5.6 Cumulative Impacts: Socioeconomics

5.6.1 Domestic Markets

5.6.1.1 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 unauthorized presence of GE alfalfa material in non-GE alfalfa (DuPont-Pioneer 2020). When an unauthorized release occurs, APHIS and industry may undertake actions to remove the unapproved material from the commercial supply, which may be costly. Under the No Action

[177] ERS: http://www.ers.usda.gov/topics/crops/corn/background.aspx

Alternative, APHIS would continue these actions even in cases where there are no harms other than those resulting from the mere presence of a GE trait. Under the Preferred Alternative, many fewer unauthorized releases are expected to occur because APHIS would only regulate GE organisms that posed risks as a plant pest. By focusing regulatory oversight on those field trials that have a plausible pathway to increased plant pest risk, APHIS is expected to reduce the cumulative risks to agricultural resources from unintended releases of GE organisms that pose plant pest risks.

5.6.1.2 Determinations of Regulatory Status/Findings of Unlikely to Pose a Plant Pest Risk

When APHIS makes a determination of nonregulated status under the No Action Alternative, or a finding of unlikely to pose a plant pest risk under the Preferred Alternative, it advances the possibility that these crops will be widely adopted by the U.S. agricultural community. Availability is also dependent upon regulatory decisions by the EPA and FDA consultation. The potential cumulative impacts result from how GE and non-GE cropping systems (including organic systems) coexist in providing food, feed, and fiber to various markets. Coexistence practices are well-coordinated in some crops such as alfalfa (NAFA 2008), while in others practices vary depending on cooperation between neighboring farms.

Both the organic and "non-GMO" verified sectors are increasing in value, 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, a lower regulatory burden on developers would be expected, so there would be a possible increase in research, development, and innovation in the agricultural biotechnology sector, and consequently, more options available to growers to meet 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 socioeconomic benefits to growers, consumers, and the environment (by reducing externalities).

Under both the No-Action and Preferred Alternatives, farmers catering to the non-GE market (growers of organic and "non-GMO" crops) who have had no neighboring GE crops could be impacted 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. These crops are subject to commingling during post-harvest processing, and susceptible to the introduction of GE traits during fertilization.[179] Other crops such as hops

[179] A variety of GE rice has been deregulated but not commercialized.

and peanuts could also be affected.[180] By reducing regulatory barriers for academics and small companies, the Preferred Alternative is expected to produce more innovation than the No Action Alternative. In this way, the Preferred Alternative may facilitate more development of new GE varieties that leads to more adoption of new varieties by growers and more incidences of unintended presence of GE plant material in non-GE crops. As a result, non-GE producers could be more negatively impacted under the Preferred Alternative.

Bearing these considerations in mind, because many of the new GE crop plants are expected to be developed through genome editing techniques, genetic engineering may not be easily detectable in the resulting modified plants unless the specific genetic changes are clearly known or distinguishable from conventionally bred crop varieties. Therefore, 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. As a result, it is difficult to predict the extent of the harm the non-GE sector will accrue from the unintended mere presence of products of gene-editing.

5.6.2 International Trade

5.6.2.1 Environmental Release

In some cases unauthorized releases of GE crop plants occurred at a low level in much of the commercial seed and grain supply. This occurred most notably in the case of LibertyLink rice and resulted in a significant adverse economic impact to the rice industry (Harris and Beasley 2011). In the case of LibertyLink rice, there was a large economic cost estimated to be between $741 million to $1.3 billion (US-GAO 2008) 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 presence at low levels (3 seeds in 10,000 seeds) (USDA 2006). In regard to the international trade, under the Preferred Alternative the cumulative socioeconomic impacts of such unauthorized releases are expected to diminish relative to the No Action Alternative, as APHIS would be regulating fewer GE crop plants with more oversight for those GE crop plants that APHIS did regulate.

5.6.2.2 Determinations of Regulatory Status/Findings of Unlikely to Pose a Plant Pest Risk

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 nonregulated 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 under the No Action Alternative. It is also expected that a greater variety of GE crop commodities will be grown in the United States. Whether a greater number will be exported in the future depends on acceptance by regulators internationally.

The Preferred Alternative represents a change from the current regulatory process, and this change could have either positive or negative cumulative impacts on international trade. For

[180] 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.

example, 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 regulations (S&P 2015). One possibility is that other regulatory bodies in other countries will either follow all or some of the changes being finalized by APHIS. Another possibility is that regulatory bodies in other countries 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 finalized by APHIS would not be acceptable to other key importing counties in which case international trade would be hindered because, prior to exporting a GE product, approval of a commercialized GE product in key importing counties 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 (LLP) 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 3.9.3 for more details).

Cumulative impacts could be seen across the international regulatory community under the Preferred Alternative. 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.

6 Endangered Species Act

The Endangered Species Act (ESA) of 1973, as amended, is a far-reaching wildlife conservation law. The purpose of the ESA is to prevent extinctions of fish, wildlife, and plant species by conserving endangered and threatened species and the ecosystems on which they depend. To implement the ESA, the U.S. Fish and Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), together "the Services", as well as other federal, state, and local agencies, tribes, non-governmental organizations, and private citizens.

Before a plant or animal species can receive the protection under 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 PEIS section is an evaluation for an entire regulatory program to ensure that APHIS addresses—as required by the ESA—anticipated, project-level actions. The regulatory 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 on listed species at a programmatic level. For specific project-level actions carried out under 7 CFR part 340, 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.

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 ESA 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):

> <u>Direct Effects</u> – 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.
>
> <u>Indirect Effects</u> – 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.
>
> <u>Interrelated Effects</u> – 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.
>
> <u>Interdependent Effects</u> – 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.
>
> <u>Cumulative Effects</u> – 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

Environmental 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, via notification or permit, after considering the organism, the nature of the genetically 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 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 or EIS for public review and comment prior to making a decision on whether to approve its introduction.

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 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 discussion addressed 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 developed as a result of this discussion 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.

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 reviewed its policy for ESA effects analysis for environmental releases under notification. The primary intent was to determine if it is 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 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.

These discussions helped define and clarify policies and procedures that APHIS uses 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 uses a modified version of these procedures when reviewing environmental releases of GE organisms other than plants.

Petitions for Nonregulated 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 nonregulated status" for the organism. APHIS may determine the GE organism has nonregulated 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 nonregulated status under 7 CFR part 340, it may be moved, planted or released into the environment without the requirement of permits or notifications. APHIS may also extend nonregulated status to other GE organisms if it is determined they are similar to organisms previously found to have nonregulated 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

The major change in regulation under the Preferred Alternative is that certain organisms, particularly plants, derived from genetic engineering would be reviewed by a "regulatory status review." If APHIS determines that a GE plant is unlikely to pose a plant pest risk and therefore has no regulatory authority, the GE plant could be grown or released anywhere in the United States and its territories. Section 7(a)(2) of the ESA applies to discretionary actions made by federal agencies. APHIS will have no regulatory authority over any GE organism that it determines is beyond its authority to regulate. In such instances, the requirements of Section 7 (a)(2) of the act are not applicable because APHIS has no discretion in its determination that a GE organism is unlikely to present a plant pest risk.

In addition to this regulatory status review, there are several types of actions that APHIS may carry out under the Preferred Alternative that would require ESA consideration once an organism is deemed subject to 7 CFR part 340. These include:

- Issuance of permits for environmental release, importation, and interstate movement.
- 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 revised 7 CFR part 340 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 impose conditions that the applicant must implement to protect T&E species (fulfilling the requirements of Section 7 (a)(1) of the ESA), and APHIS would enforce these supplemental permit conditions. The notification process does not allow for supplemental permit conditions.

It is impossible to predict all varieties of GE organisms 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 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 prior discussions with USFWS. 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 to determine the appropriate level of ESA consultation.

APHIS recognizes 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 risks 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 final revisions to regulations under the Preferred Alternative 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. 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 final revisions to regulations under the Preferred Alternative do not result in any changes to the ESA effects analysis process APHIS uses to analyze the 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 final 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 final 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 final revisions to regulations under the Preferred Alternative 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 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.

6.4 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 of the New Rule

The revisions to regulations under the Preferred Alternative do not change the processes APHIS would use to analyze the potential effects of GE organisms on T&E. 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 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:

- As discussed in the preamble to the revised 7 CFR part 340, discontinuing the notification process for releases (currently 7 CFR § 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 (§ 340.5 – Permits) 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 the Preferred Alternative in and of itself would not result in direct or indirect impacts to T&E species. However, individual decisions made during implementation of the revised regulation could potentially impact T&E species, as under the current regulation. APHIS will consider these decisions 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.

7 Federal Statutes, Regulations, Executive Orders, Memoranda, Standards, and Treaties Related to the 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 Federal Laws and Regulations

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). Compliance with the requirements of the ESA has been addressed in Chapter 6. Compliance with the requirements of NEPA, CWA, SDWA, CAA, and NHPA, as well as the Regulatory Flexibility Act of 1980, are specifically addressed in the following subsections.

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 PEIS is prepared specifically to comply with the requirements of NEPA (42 United States Code (U.S.C) 4321, et seq.).

7.1.2 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 final 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 groundwaters and surface waters.

7.1.3 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 final 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.

7.1.4 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 final rule and Alternatives (USDA-APHIS 2020f).

7.1.5 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 final 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

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 regulations. 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 PEIS, APHIS conducted a Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the final rule and Alternatives (USDA-APHIS 2020f).

Executive Order 12988 - Civil Justice Reform: This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this 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.

APHIS has assessed potential adverse impacts to such populations and find that the final rule, and alternatives considered, are not expected to disproportionately impact low income, minority, or Tribal populations. EO 12898 will be thoroughly assessed when specific actions are proposed following final rulemaking.

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.

The EPA recently revised 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 strengthened 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, 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 the 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.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined that this rule has tribal implications; however, OTR has determined that tribal consultation under EO 13175 is not required at this time. If a tribe requests consultation, APHIS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress. . In light of this determination, APHIS sent correspondence to the Tribe to ascertain whether formal Tribal consultation was requested, and on July 10, 2019, APHIS invited Tribal nations to a conference call regarding the content of the proposed rule, as well as an opportunity to express concerns regarding this content. Two Tribes participated, and there were no comments or questions.

13751 – Safeguarding the Nation from the Impacts of Invasive Species: Invasive species are a significant issue in the United States, causing both adverse economic and environmental impacts. This EO directs actions to continue coordinated federal prevention and control efforts related to invasive species. This order maintains the National Invasive Species Council (Council) and the Invasive Species Advisory Committee; expands the membership of the Council; clarifies the operations of the Council; incorporates considerations of human and environmental health, climate change, technological innovation, and other emerging priorities into federal efforts to address invasive species; and strengthens coordinated, cost-efficient federal action.

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 USFWS that promotes the conservation of migratory bird populations. On August 2, 2012, APHIS and USFWS signed an 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 final 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 final 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 2015). 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.

7.3.3 International Venues Related to Biotechnology Information Exchange in Support of Harmonization

U.S. exporters must comply with the regulations of importing countries pertaining to biotechnology; therefore, harmonization of such regulations supports international trade. Regulations are applied in the context of multiple factors, including relevant laws, 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 part 340.

8 List of Preparers

APHIS-PPD-ERAS

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Ph.D., Public Health, Capella University
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Project Role
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Project Role
Provided initial project management logistics for the PEIS.

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9 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 co-operators. 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: Otherwise known as CERCLA or Superfund -- provides a Federal "Superfund" to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other emergency releases of pollutants and contaminants into the environment. Through CERCLA, EPA was given power to seek out those parties responsible for any release and assure their cooperation in the cleanup.

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 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 modify or create a genome. For the purposes of this PEIS, genetic engineering does not include conventional 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.

Groundwater: 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 or field site 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

Mechanism of Action: The specific biochemical process(es) by which a chemical or other molecular entity produces a biological effect.

Microorganism: Living organisms, usually so small that individually they only can be seen through a microscope. Microorganisms include bacteria, fungi, archaea, protists and viruses, and are among the earliest known life forms.

Migratory Bird Treaty Act (MBTA): Is a United States federal law for the protection of migratory birds. 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 microorganism 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. The possibility of harms resulting from introducing, disseminating, or exacerbating the impact of a plant pest. Parasitic plants can pose plant pest risks directly by injuring plants themselves, while other types of plants pose plant pest risks indirectly, either by serving as reservoirs which can increase the numbers or distribution of plant pests, or by serving as hosts in which new plant pests can be created.

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 pest risks.

Product of Biotechnology: An organism developed using biotechnology.

R

Recipient Organism: The organism whose nucleic acid sequence will be modified 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 § 340.2. This term 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

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 the soil, 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: In reference to the ESA, "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect or attempt to engage in any such conduct."

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.

Trait. The observable (able to be seen or otherwise identified) characteristic of an organism.

Unauthorized Release- The intentional or accidental movement of an organism under a permit issued pursuant to 7 CFR part 340 in a manner not authorized by the permit.

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.

10 Index

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Appendix 1: Stakeholder Meetings and Public Outreach

Previously, APHIS published proposed rules in 2008 and 2017 for potential changes to the regulations at 7 CFR part 340. APHIS withdrew both proposed rules in response to public comments and to reengage in a fresh dialogue with stakeholders on the regulation of biotechnology. A summary of public outreach and engagement in development of the proposed rule changes is provided below.

For the 2017 proposed rule, 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 the 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 available on APHIS' website (USDA-APHIS 2020).22 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 the proposed new rule. As part of the stakeholder meeting, APHIS-BRS leadership held 8 one-on-one meetings with stakeholders to continue to answer questions. Transcripts and related materials from the 2015 stakeholder meeting are also available on the APHIS website (USDA-APHIS 2020).

On February 5, 2016, APHIS-BRS published a Notice of Intent (NOI) in the *Federal Register* to inform stakeholders and the public of its plan to develop and publish a PEIS. The notice also provided more information on the Alternatives that the Agency was considering for analysis in the 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 the PEIS.

APHIS held three public comment meetings on the 2017 proposed revisions to our biotechnology regulations on June 6, 2017, in Kansas City, MO; June 13, 2017, in Davis, CA; and June 16, 2017, in Riverdale, MD. APHIS received approximately 13 verbal comments at these meetings. Transcripts of the public meetings are available on the APHIS-BRS website at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/stakeholder-meetings/proposed_rule_meetings/2017_proposed_rule/340_public_meetings_2017.

As discussed in 1.7.1 – Public Involvement, APHIS published an NOI, advising the public that APHIS intended to prepare a programmatic environmental impact statement (PEIS) in connection with the revisions to the regulations. The NOI solicited public comment to help define the issues to be considered in the PEIS and scope of Alternatives to consider in revision of 7 CFR part 340 regulations. Public comments received are discussed following, in Appendix 2 and Appendix 3.

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Appendix 2: Public Comments – NOI

Members of the public were invited to participate in the scoping process for this PEIS 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. 83, No. 126, p. 30688, Friday, June 29, 2018). The notice solicited public involvement in the form of written comments, which were accepted through July 30, 2018. APHIS received 35 submissions from the public. The submissions were from individuals from academic organizations (2), professional organizations (2), trade groups (2), commodity groups (4), industry (4), NGOs (4), federally recognized Tribes (2), and unspecified individuals (15). Full text of the comments are available online at: https://www.regulations.gov/document?D=APHIS-2018-0034-0001.

Issues Raised

Several commenters were generally supportive and agreed with the need to update the regulations. Additionally, these commenters liked the concept of a science and risk based approach, noting that this approach would provide regulatory relief and promote agricultural innovation.

Two comments were from federally recognized Tribes concerned about the impacts of GE organisms to tribal lands.

Regarding the Proposed Rule

Several commenters raised concerns about adopting noxious weed authority within the 7 CFR part 340 regulations. Some commenters were supportive of using the noxious weed authority to regulate GE organisms while others were opposed to this approach.

One commenter was concerned about how APHIS would regulate GE animals and GE insects.

One comment suggested that APHIS change the regulatory trigger to be any genetic engineering.

One comment suggested that the proposed rule should be both process and product based.

Regarding Communication

Several commenters were concerned about international coordination during the rulemaking process and how APHIS would communicate with its international counterparts. Additionally, several commenters suggested that APHIS do more outreach to improve public perception of GE products.

Regarding Current and Future NEPA Processes

Commenters noted that the PEIS must contain a clear scope, clearly defined purpose and need, cumulative impacts section, clear definitions, and a need for long comment periods and public meetings to allow for appropriate public input.

Several commenters also raised concerns about how NEPA would apply under the new rule and stressed that this needed to be clearly addressed in the PEIS.

Regarding Alternatives to be Considered in Revision of 7 CFR part 340

One commenter suggested an Alternative that should be analyzed in the PEIS should be one in which APHIS eliminates 7 CFR part 340 and moves to a voluntary system similar to the FDA's.

Regarding Issues to be analyzed in the PEIS

Several commenters noted that the following impacts should be analyzed in the PEIS:

- agronomic and economic impacts
- animal health impacts
- climate change (impacts to and from agriculture)
- cross-pollination/gene-flow
- disease and pest impacts
- environmental impacts
- herbicide resistance
- herbicide resistant weeds
- human health impacts
- impacts associated with gene drives
- impacts from pesticide use
- impacts from unintended presence
- impacts to biodiversity
- impacts to forests from GE trees
- impacts to organics/non-GE
- non-target impacts including T&E species and pollinators
- off-target impacts
- socioeconomic impacts
- trade impacts

Appendix 3: Response to Public Comments on the Draft PEIS

On June 6, 2019, APHIS published a notice in the *Federal Register* (84 FR 26514-26541, Docket No. APHIS-2018-0034) announcing the availability of the proposed rule, draft PEIS, and supporting documents for a 60-day public review and comment period. The comment period closed on August 6, 2019. APHIS received a total of 6,151 public submissions. All comments submitted on the dPEIS are available on the regulations.gov website at https://www.regulations.gov/docket?D=APHIS-2018-0034.

Comments and Responses

All comments were compiled by related issue and are summarized below along with the APHIS response.

1. One commenter claimed that the agency's purpose and need for the Proposal is flawed and overly-narrow because: it "only considers plant pest authority" [and not noxious weed authority]. The commenter further stated, "In past rulemaking, APHIS has repeatedly admitted that GE plants may carry noxious weed risks and should be evaluated for such risks. By declining to apply the noxious weed authority granted by the PPA, APHIS has plainly failed to consider the myriad of serious threats posed by GE organisms to American agriculture. And by failing to heed PPA's directive to regulate noxious weeds, USDA is effectively delaying the implementation of statutorily required regulations, in direct contravention of Congressional directive in enacting the PPA"

   Response: *APHIS disagrees with the commenter. As part of the regulatory status review, APHIS will continue to consider whether the plant-trait-MOA combination might change plant pest interactions, establishment, and persistence for both the plant engineered, and any other plants with which it can interbreed. If the plant had the potential to be a truly troublesome and impactful weed, we will consider whether the plant-trait-MOA combination being reviewed should be considered for regulation pursuant to the noxious weed authority of the PPA and the regulations issued under that authority. The SECURE regulation does not change this analysis.*

2. One commenter stated, "In providing the rationale for the proposed regulations, APHIS fails to mention the PPA, instead claiming that the proposed revisions is to address advances in biotechnology, the recommendations of the 2005 and 2015 OIG reports, the mandates in the 2008 Farm Bill, and to address the risks of GE technology as described in the National Research Council."

   Response*: APHIS disagrees with the suggestion that it failed to mention the PPA in the Purpose and Need section. In Purpose and Need Section 1.1, APHIS states that 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. Thus, it is* *implied that any change to regulations is subject and pursuant to the PPA. Section 1.2 of the Purpose and Need further describes APHIS statutory authority under the PPA.*

3. One commenter stated, "The PPA has a broad definition of noxious weed harms, which expressly includes direct and indirect injury and damage to crops, livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment, and which encompasses harms caused by non-viable 'plant products' as well as plants. APHIS is statutorily obligated to integrate and apply this authority to GE crops. In doing so, APHIS must apply the statutory authority coherently, applying it in a meaningful and logical way to address GE organisms' adverse environmental and agronomic impacts, which are expressly cognizable under the PPA's definition. APHIS must define and apply its statutory noxious weed authority in a manner that is consistent with the statute's language, and which encompasses the broad types of noxious weed harms as defined by the PPA."

***Response**: APHIS disagrees that APHIS is statutorily obligated to integrate noxious weed authority into a revised 7 CFR part 340. In the PPA, Congress identified plant pests and noxious weeds as separate concerns, and delegated authority to the Secretary to determine how to best use this authority.*

4. A commenter states, "The Proposal also does not meet the stated purpose and need of updating in order to meet the advances in biotechnology since 1987 and the original rules, nor meet the mandates of the 2008 Farm Bill and OIG recommendations. Just the opposite, both the 2008 Farm Bill and OIG recommendations acknowledged the need for APHIS to enact more rigorous regulations and monitoring over field trials, and to assess GE plants for their noxious weed harms. The Proposed Rules significantly loosen regulations, despite the foreseeable (and current) arrival of new and novel types of GE organisms that present different risks and impacts, such as GE grasses and trees. To the extent the purpose and need is not to address the current and future adverse impacts of GE organisms, the purpose and need are unlawfully narrow and improper. Nor does the Proposal fulfill the stated purpose and need of making regulations commensurate with the risk assessment methodologies of the National Research Council in 2002." The commenter further states, "APHIS should adopt the use of genetic engineering as the trigger for regulation, as we recommend supra. Alternatively and in addition, the noxious weed authority can and should also be used to regulate all GE crops that are not covered by the plant pest provisions of the proposed rule."

***Response**: APHIS agrees that the 2008 Farm Bill and OIG recommendations called for more rigorous regulation of field trials, and APHIS is codifying more rigorous regulation of field trials in the SECURE rule. The Preferred Alternative will allow APHIS to focus its oversight to field trials where it is warranted, such as over new and novel GE organisms that may pose plant pest risks. As a result, APHIS expects to be able to inspect* *a higher percentage of the field test sites authorized. This rule eliminates notifications, allowing APHIS to establish customized permit conditions for all authorizations. Because permit conditions specify which actions need to be taken by the responsible person to be in compliance with the regulations and do not rely as much on subjective determinations by both the responsible person and APHIS personnel as do performance standards, the permitting system provides more risk-appropriate oversight, better regulatory enforcement, and improved transparency than under the notification process. Another area where APHIS increased oversight is in revised reporting requirements. APHIS will now require a report of no release. APHIS thinks that the submission of a report of no release can help the agency track the status of all authorized test field locations in order to account for and sufficiently monitor all such locations, thereby preventing the accidental release of GE organisms into the environment. Additionally, this requirement satisfies recommendations issued by USDA's OIG following audits performed in 2015. The provisions for record retention, compliance and enforcement have been strengthened in order to manage compliance with the regulations more efficiently, to augment the approaches that can be used to prevent or remediate risks of plant pests, and to utilize appropriate enforcement strategies. These changes improve the efficiency and clarity of the regulations.*

APHIS disagrees with the commenter's assertion that the proposed regulation is incompatible with proper oversight of GE grasses and trees. The regulatory status review considers the biology of each GE organism and its potential to pose plant pest risks. APHIS recognizes that genetic engineering may be used to introduce a trait that increases the distribution, density, or development of a plant or the weedy impacts of the plant, factors that are considered aspects of a plant's weediness. Accordingly, we would continue our current practice of considering the weediness of the unmodified plant and whether the new trait could in any way change the weediness. We would also consider potential effects on the weediness of other plants with which the engineered plant can interbreed, because it is relevant to the assessment of the plant's plant pest risk. Consideration of weediness in this manner has long been a part of the plant pest risk assessments conducted in response to petitions for nonregulated status since the 1990s, under the regulations that we are replacing in this final rule. This final rule does not change this analysis, and does not expand the scope of APHIS' consideration of weediness in evaluating plant pest risks as compared with the scope of consideration that was present in APHIS' exercise of its authority under the regulations that we are replacing.

APHIS disagrees that a regulatory burden should be imposed on all GE crops. The National Research Council (NRC 2002) proposed a system where "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." These regulations establish a system where organisms that pose a plausible plant pest risk are rapidly distinguished from those that do not, focusing regulation on the former. The revised regulations are consistent with the recommendation of the National Academy of Sciences study.*

5. A commenter stated that, "APHIS also improperly relies on extra-statutory factors and improper bases in setting the purpose and need. APHIS claims that the proposed regulations will increase efficiency, reduce regulatory burdens, and avoid actions that "inhibit innovation, stigmatize new technologies, or create trade barriers." The PPA mandates that APHIS prevent and regulate noxious weed risks and plant pests risks to protect U.S. agriculture and economy; it says nothing about promoting technology or reducing regulatory burdens. Moreover, contrary to APHIS's misrepresentation, past contamination events have shown that the inadequate regulatory review of GE crops' contamination risks have created trade barriers."

***Response**: The Plant Protection Act (7 USC 7701) states: "(3) 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;(4) decisions affecting imports, exports, and interstate movement of products regulated under this title shall be based on sound science." APHIS disagrees that extra-statutory factors such as increasing efficiency and reducing regulatory burdens are improper bases to set the purpose and need. (Executive Order 13563 2011) provides: "When no significant oversight issue based on a sufficiently distinguishing attribute of the technology or the relevant applications can be identified, agencies should consider the option not to regulate. Where possible, regulatory approaches should promote innovation while also advancing regulatory objectives, such as protection of health, the environment, and safety." (Executive Order 13874 2019), states: "It is the policy of the Federal Government to protect public health and the environment by adopting regulatory approaches for the products of agricultural biotechnology that are proportionate responses to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies." It specifically calls for the Secretary of Agriculture to "take steps appropriate and necessary to accomplish [regulatory] streaming" and to "use existing statutory authority as appropriate, to exempt low risk products of agricultural biotechnology from undue regulation."*

6. One commenter claimed "the agency fails to analyze the reasonably foreseeable results of its programmatic decision here, namely the impacts of individual GE crops going unregulated in the future and cannot lawful defer consideration those impacts to later, particularly when the agency is proposing to abdicate its regulatory duties in some instances."

***Response**: APHIS disagrees with the commenter's characterization. GE plants that qualify for the exemption, and therefore do not come before the agency, are no different, as a class, in terms of plant pest risk from comparable plants that are made through conventional breeding and also do not come before the agency, or have the same plant-trait-MOA as GE plants that were previously reviewed by the agency. Other GE plants will be reviewed by the agency and impacts, as appropriate, can be assessed at that future date.*

7. One commenter asserts that "APHIS's failure to define a legitimate purpose and need, and its consequent failure to consider an adequate range of alternatives led APHIS to include only two alternatives, No Action / status quo, or the Preferred Alternative, implementation of the Proposed Rules as envisioned by APHIS. This is too narrow to comply with NEPA."

***Response**: APHIS disagrees with the comment and with the commenter's characterization of the requirements of NEPA under the circumstances presented here. NEPA regulations at 1500.2(e) state that Federal agencies shall to the fullest extent possible identify and assess the reasonable alternatives to a proposed action. What constitutes a reasonable range of alternatives depends on the nature of the proposal and the facts in each case. In this instance, the agency focused principally on two reasonable alternatives and the reasons for choosing these particular alternatives were given in the Notice of Intent to prepare a PEIS and detailed in the PEIS. Section 2.3 of the PEIS considered a range of alternatives that were rejected with an explanation for doing so.*

8. A commenter stated that, "Significantly, APHIS listed, but refused to consider, an alternative that the agency had previously considered in the draft environmental impact statement for its prior proposed revisions in 2017, an alternative for "regulation to facilitate coexistence." APHIS rejected the "coexistence" alternative despite having previously recognized it as a viable alternative that must be examined in detail in the Draft PEIS. This was arbitrary and capricious.

   APHIS rejected this alternative from being analyzed in the Draft PEIS, without conducting an actual cost-benefit analysis, on two chief grounds: that it is improperly based on the need to reduce economic harm to non-GE producers from GE contamination events; and would impose costs on GE crop developers. The benefits of this alternative stem from rigorous measures to facilitate "coexistence" – that is, measures that would mitigate GE contamination of organic and non-GE crop supplies, but that would also protect producers of GE crops approved in major export markets from contamination with GE crops that are NOT approved in those markets. Coexistence thus benefits ***all*** farmers, contrary to APHIS."

***Response**: The coexistence alternative was carefully considered in the 2017 PEIS and was rejected. APHIS has never regulated based on economic impacts alone in the absence of any actual biological, chemical, or physical damage. This regulatory role would have been inconsistent with the Agency mission, with the limits of pertinent statutory authority, and with current APHIS programs which are aimed at protecting plants from biological, chemical, and physical damage. In addition from the 2017 PEIS,* *APHIS concluded that this Alternative was expected to increase regulatory costs to the agency and industry, to increase cost to consumers for food production, to decrease competitiveness of the U.S. biotech industry, and to lead to a loss of environmental benefits from plant breeding innovation (USDA-APHIS 2020). APHIS does not agree that the coexistence alternative would benefit all farmers economically. APHIS believes that the vast majority of farmers, namely those who utilize GE crops, would find it too onerous to grow GE crops under that Alternative.*

9. The same commenter noted that "APHIS also rejected from further consideration, an alternative to withdraw the current Part 340 regulations and instead regulating GE crops under Parts 330 and 360 regulations. APHIS claims that such a regulatory scheme would result in lack of international acceptance for GE products that only undergo "voluntary consultation" with APHIS, as well as "creating a regulatory vacuum" that would have to be filled by other federal or state agencies. Yet, those are the very same outcomes under the Proposed Rules, since APHIS is authorizing GE developers to self-determine whether their GE plants would need further regulation, exempting the vast majority of GE plants from any regulatory oversight, and relying on other federal and state agencies to cover loopholes of such a voluntary, "deregulatory" scheme."

***Response**: APHIS disagrees with the characterization by the commenter that most GE plants would be subject to self-determination and exempted under the Preferred Alternative. Under the Preferred Alternative, APHIS expects either that most GE plants would be subject to a Regulatory Status Review or that the developer would defer the review and be subject to permitting. In cases where the plant was exempted, either the plant had the same plant-trait-MOA combination as that of a plant previously reviewed where the Agency was unable to identify a plausible pathway by which the GE plant could pose an increased plant pest risk, or the plant modification was comparable to what could otherwise be achieved through conventional breeding and also posed no greater plant pest risk.*

10. One commenter stated that, "APHIS also failed to consider other reasonable alternatives entirely, such as alternatives that would address not just the economic harms of contamination, but also the environmental harms of GE crops directly, including but not limited to the harms of resistant weed proliferation associated with GE HR crops, or the harms to farmers and the environment caused by GE HR crop systems, such as pesticide drift and runoff, and other human health and environmental harms detailed in our prior comments. The agency should consider an alternative that restricts GE crops by permit in order to directly address these harms. APHIS fails to offer any alternative that protects against environmental harm from escapes from GE organisms into the wild, such as genetically engineered bentgrass. NEPA requires that APHIS examine policy alternatives that take into account environmental values. APHIS's failure to include and fully analyze alternatives to protect against the environmental harms of GE organisms violates NEPA's alternatives mandates, the heart of any EIS."

Response*: One commenter faults APHIS for not considering an alternative that protects the environment by limiting pesticide use or the deployment of HR crops. As pesticide use falls under EPA's jurisdiction and not APHIS', an alternative limiting pesticide use would exceed APHIS authority. Likewise, APHIS disagrees that HR crops are noxious weeds because herbicide use on these crops selects for HR weeds. Noxious weeds are typically invasive, or multiply quickly, or display adverse effects through contact or ingestion. HR crops do not share these characteristics with noxious weeds and therefore should not be regulated as noxious weeds. The commenter also faults APHIS for not including and fully analyzing alternatives to protect against the environmental harms from escapes of GE organisms into the wild, using creeping bentgrass as an example. APHIS notes that the impacts to the environment from escaped creeping bentgrass and mitigations were considered under the No Action Alternative (see FPEIS sections: 3.4.1.1.2; 3.4.8; 4.1.2.3; 4.3.6.1.2). Under both Alternatives, risk assessments would be completed to assess environmental impacts from escaped GE organisms and permit conditions would be mandated where warranted.*

11. A commenter noted that "APHIS also failed to consider an alternative that included measures specific to other, newer GE organisms under its purview that are not traditional crops, such as GE grasses, GE trees, and GE insects. These types of GE organisms are more than reasonably foreseeable, they are currently being proposed for commercial approval or field trials (GE bentgrass, Ge Eucalyptus, GE moths). These types of GE organisms are creating different types of risks than previous GE crops that should necessitate new analyses and oversight mechanisms that APHIS has not considered."

Response*: APHIS disagrees that its Alternatives under consideration are not able to accommodate newer GE organisms. Both Alternatives use risk assessments that have the flexibility to consider issues associated with GE grasses, trees, and insects. APHIS already has experience with these types of organisms and has completed EISs on Roundup Ready creeping bentgrass, Cold tolerant eucalyptus, and a programmatic EIS for GE insects (USDA-APHIS 2008, 2016, 2017). APHIS considers in the FPEIS that in addition to crop plants, GE trees, grasses, ornamental plants, and GE plant pests (bacteria, fungi, insects, nematodes) will also be evaluated for plant pest risks.*

12. One commenter noted "According to the agency, APHIS's determinations of the regulatory status of GE crops are not considered the driving factor in grower adoption of GE crop plants. This is patently false. Under the current regulatory scheme, growers cannot commercially adopt a GE crop plant unless and until after APHIS affirmatively determined that the GE crop plant is unlikely to pose a plant pest risk. The Preferred Alternative would exempt the majority of GE crop plants from any APHIS regulatory determination, with significant impacts on the availability of varieties of GE crop plants for commercialization. And without any regulatory trigger, such crop plants will also never be analyzed for their noxious weed harms, which APHIS is required to consider under the PPA."

Response: *APHIS disagrees that its regulatory decision is the rate limiting factor in the adoption of GE crops. For one thing, there are two other agencies making regulatory decisions as well. Furthermore, adoption depends on many factors including market demand for food, feed, fuel, and fiber products, insect pest, disease, and weed pressures, potential yield, and commodity market value. The key driver for adoption is economics, i.e. whether the crop is in demand because farmers believe they will make a profit raising the crop. There are many examples where APHIS deregulated a GE crop and the GE crop was never commercialized or was withdrawn from the market (GE rice, GE potato, GE tomato, GE chicory, GE tobacco) because the demand was lacking. As stated in RTC #9, APHIS does not expect most GE plants to be exempted from the regulation.*

13. One commenter noted, "APHIS's also failed to analyze the impact of the Preferred Alternative on the number, location, and total acreage of field trials of GE plants in the United States."

Response*: APHIS disagrees. This topic is covered in the FPEIS in sections 4.1.3.3, 4.1.3.4, and 4.1.3.5.*

14. One commenter noted, "APHIS admits that the impacts to land and land uses depend on "the species of GE organisms tested, the GE trait, and the environment in which the field trial is conducted," and claims that such impacts "would be considered on a case-by-case basis." Yet under the Preferred Alternative, APHIS will no longer require regulated field trials for the vast majority of GE organisms. NEPA requires that these impacts be considered now, not indefinitely into the future, to be tiered to future agency actions that are being eliminated by APHIS's very Proposal."

Response: *Environmental impacts will be considered in every case where there is a plausible pathway to increased plant pest risk or where initial review is waived by the developer. Plants that qualify for the exemptions are either no different, from a plant pest risk assessment perspective, from conventionally bred plants that have acceptable risk or the same as plants that have been previously reviewed for environmental impacts by the agency.*

15. One commenter noted, **"**APHIS also admits that the Preferred Alternative would leave outdoor field trials of GE Plant- Incorporated protectants (PIPs) of less than 10 acres without any regulatory oversight, but does not analyze the potential impacts of such deregulation. This is arbitrary and capricious, and contrary to sound science."

Response*: It is not true that field trials of PIPs less than 10 acres would not be subject to any regulatory oversight. First, EPA has regulatory oversight authority over these field trials. Second, APHIS will continue to conduct oversight of PIPs at all scales until it determines that a PIP does not pose a plant pest risk. If APHIS determines that the PIP does not pose a plant pest risk, the decision will be up to EPA as to whether and, if so, how to exercise its oversight authority over field trials under 10 acres. APHIS has avenues for cooperation with EPA. APHIS would be open to an Economy Act agreement should EPA decide that oversight of small PIP field trials is appropriate. This topic is discussed in the FPEIS at 4.3.1.*

16. One commenter noted, *"*APHIS's analysis of the impacts of potential altered weather patterns as a result of climate change is also woefully inadequate. APHIS's discussion focuses on how altered weather patterns may impact growers' farming decisions, without any analysis of how the Preferred Alternative may *contribute* to climate change."

    "Moreover, APHIS simply assumes that the types of GE crops will be able address the problems associated with altered weather patterns/climate change, despite the lack of such traits on the market and no evidence that they will be successfully developed in the future, as opposed to more of the same pesticide-resistant varieties. APHIS selectively highlights GE drought tolerant crops as a potential benefit to growers under altered and extreme weather conditions, but as discussed in CFS's comments, the vast majority of the GE crop technologies focus on conferring pesticide resistance, yet APHIS entirely fails to analyze how the impacts of herbicide-resistant GE crop systems, from increase in pesticide use, increased weed resistance and the corresponding increase use of tillage practices and even more pesticides, may exacerbate altered weather events and worsen the impacts of global warning. APHIS's analysis falls woefully short of NEPA's "hard look" requirement, and is entirely contrary to sound science."

Response: *APHIS discusses how tillage and fertilizer applications contribute to climate change; see, e.g., FPEIS Section 5.2.3. APHIS disagrees with the commenter that tillage and fertilizer applications are greater with GE crops than without such crops. Furthermore, APHIS notes that under both alternatives, developers are actively utilizing biotechnology to reduce fertilizer inputs and reduce tillage, two farming practices that have major impacts on climate change.*

17. One commenter noted, "APHIS also completely failed to analyze the foreseeable impacts of the Preferred Alternative, which APHIS claims would promote development of the GE industry, to global concentrations in seed market and seed supply. This has led to increased privatization of the global seed supply as GE developers patent their products, and have in fact reduced research and development in the seed sector. APHIS thus also fails to analyze the direct and indirect impacts of seed market concentration on farmers' ability to choose and grow different types of crops in response to changing weather patterns."

Response: *APHIS disagrees with the commenter that the Preferred Alternative would lead to increased privatization of the global seed supply and reduce research and development in the seed sector. APHIS has concluded quite the opposite. One of the principal barriers to academic use of biotechnology has been the high regulatory burden on using the technology. One of the expected outcomes from the Preferred Alternative is a resurgence in academic institutions utilizing biotechnology to develop publicly available germplasm.*

18. One commenter noted, "Finally, as detailed in CFS's prior comments and summarized below, APHIS entirely fails to analyze the impacts of the Proposed Regulations on

farming practices, especially as they impact soil, water quality, and the environment, and the direct and indirect of such practices on the ability of U.S. agriculture to adapt and respond to altered weather patterns."

Response*: APHIS covers these topics in the following sections: Physical environment 3.5, 4.2, 5.2; Agronomic practices and inputs 3.4.2, pest and weed resistance 3.4.3, biological environment 4.3.*

19. One commenter noted, "In the 2019 DPEIS, APHIS continues to rely on false and misleading modeling studies conducted by pesticide industry contractors Brookes and Barfoot (2013, 2016, 2017) and others (e.g. Klumper and Qaim 2014). APHIS's treatment is sloppy and internally inconsistent, presenting contradictory figures on herbicide use trends for the major crops in which GE HR varieties dominate, soybeans, cotton and corn, on different pages. For instance, total herbicide use on corn in 2016 is reported as 2.61 lbs/acre (correct) at Draft PEIS 3-58, and incorrectly as 2.40 lbs/acre at Draft PEIS 3-68." "Similarly, cotton herbicide use is reported to have "remained fairly constant since 1991, around 1.2 lbs a.i./acre" (Draft PEIS 3-68), when in fact it has increased dramatically over the period of GE HR crop adoption, reaching 3.06 lbs/acre in 2015, as APHIS notes just a few pages earlier (Draft PEIS 3-65)."

Response*: APHIS thanks the commenter for pointing out that on page 3-68 of the dPEIS we did not mention that herbicide use in cotton reached 3.06 lbs/acre in 2015 though we did correctly note the herbicide use on page 3-65 of the dPEIS. This error has been corrected in the FPEIS. APHIS wishes to clarify that USDA-NASS data was used to analyze pesticide use. Our findings are consistent with the findings of the authors noted in the comment.*

During the 1996–2018 time frame, herbicide use on corn has tended to increase, albeit modestly. GE HR corn was first planted in 1997; as of 2000, 19.89 million acres were planted to GE HR corn. From 1997 to 2014, total herbicide use in lbs a.i./acre remained fairly steady, around 2.04 lbs a.i./acre (average). It increased to 2.40 lbs a.i./acre in 2016, and 2.41 lbs a.i./acre in 2018. Due to the increase in lbs a.i./acre during 2016-2018, the trend line increases as assessed from 1996.

Per USDA-NASS data, cotton herbicide lbs a.i./acre has been relatively steady, with a modest increase from 2.09 lbs a.i./acre in 2001 to 2.34 in 2017. Though, it peaked in 2016 to 3.06 lbs a.i./acre, the fact that it markedly declined from 2016 to 2017 suggests the increase is much more modest than stated by the commenter. Herbicide use on U.S. cotton was an average 2.23 lbs a.i./acre in 2010.

20. One commenter noted, **"**APHIS chooses false frames of reference to misrepresent the herbicide use impacts of herbicide-resistant crops. For instance, APHIS notes that herbicide use on corn has declined from 2.67 lbs/acre in 1996] to 2.61 lbs/acre in 2016 (Draft PEIS 3-58), yet fails to note that GE HR corn's influence on herbicide use patterns was negligible through 2002, the first year it was grown on more than 10% of total corn acres (11%) (Fernandez-Cornejo et al. 2014b). HR corn's rapid adoption since 2002 has driven a substantial increase in herbicide use, from less than 1.87 to

2.61 lbs/acre from 2002 to 2016. GE HR soybeans have driven an even greater increase in herbicide use, as even APHIS admits. The HR crop-driven increase in herbicide is also reflected in EPA figures, which show that overall herbicide use in U.S. agriculture rose by an astonishing 34% over just the seven years from 2005 to 2012, from 420 to 564 million lbs."

***Response*:** *APHIS disagrees with the commenter that it has misrepresented herbicide use by choosing false frames of reference. APHIS provides in the FPEIS discussion of herbicide use in corn from 1960 to 2018. (FPEIS 3.4.2.2 3) Herbicide use in corn actually peaked from around 1980 to 1994, and has generally declined since that time. While there may be an upward trend in herbicide use with corn during the last two years, from 2000 [when 19.89 million acres were planted to HR corn] to 2014, herbicide use on GE corn was fairly steady; averaging around 1.93 lbs a.i./acre in 2000, 1.95 lbs a.i./acre in 2014, with a peak of 2.31 lbs a.i./acre in 2008. In the latest year where data is available, 2018, 214,721,000 lbs a.i. were applied to 91,700,000 million acres of corn for an avg. use of 2.34 lbs/acre.*

APHIS disagrees with the commenter's suggestion to use 2002 as a starting point for analysis of trends in herbicide use. This starting point would omit the fact that farmers had weed issues prior to the introduction of GE HR crops, resulting in higher herbicide use than at the present time, as well as the fact that the increases in herbicide use noted by the commenter are in part due to a loss of benefits gained from the use of GE HR traits. It also undermines the central argument of the commenter that selection of HR weeds are a unique characteristic of HR crops.

21. One commenter noted, "APHIS's cursory treatment provides no assessment of dicamba use on Monsanto's dicamba-resistant soybeans and cotton, plantings of which have risen dramatically from just a few million acres in 2016, to 25 million acres in 2017, 50 million acres in 2018 and an estimated 60 million acres in 2019. EPA reports a greater than 12-fold increase in dicamba use on soybeans and cotton in 2017 (10 million lbs) relative to the average for those crops over 2012 to 2016, with "significantly more dicamba" expected in 2018. CFS discusses the impacts of this surge in dicamba use infra."

Response: *In the FPEIS, APHIS provides a general overview of pesticide use in corn, soybean, cotton, and other crops, relative to GE crops.*

According to USDA-NASS data, dicamba was used on less than 20% of U.S. corn acres in 2018 (Table 3-19 FPEIS). Dicamba (all forms of salts collectively) comprises about 1.6% of total herbicide use on corn crops (Table 3-19 FPEIS).

Volatility and drift, and adverse effects on adjacent crops, have been an issue with dicamba use (Hartzler 2017). APHIS discusses the socioeconomic impacts of dicamba drift in the FPEIS in sections 3.4.2.2.4; 4.2.3.1.5; and 4.8.1.

During 2016-2018, the EPA received numerous reports of crop injury alleged to be related to off-target movement of dicamba. These reports were from various states;

Arkansas, Iowa, Nebraska, Georgia, Mississippi, Missouri, and Tennessee. Upon investigation the EPA and product registrants agreed to additional label changes for dicamba to further minimize the potential for off-site movement of dicamba products (US-EPA 2018a). The federal registrations for dicamba products (e.g., XtendiMax®, FeXapan™, Engenia®) now require that prior to applying these products, the applicator must complete dicamba specific training (UW-M 2019). Certain states, such as Alabama, Georgia, Mississippi, Illinois, and North Carolina, require that an applicator complete mandatory training conducted by the state. Only dicamba products registered for use on dicamba-resistant cotton and soybeans can be applied over-the-top. It is a violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to treat any dicamba-resistant crop with a dicamba product that is not registered for use on genetically engineered crops. Further details regarding the EPA's dicamba registration extension decision, required label updates, and the rationale for the mitigation measures to be implemented with dicamba use can be found in the EPA decision document (US-EPA 2018b, a).

22. One commenter noted, "APHIS fails to link its discussion of herbicide use increases driven by GE HR crops to the epidemic of glyphosate-resistant weeds that have resulted, discussed infra, or other serious impacts."

    "APHIS's discussion of herbicide toxicity is also deeply flawed. With respect to glyphosate, APHIS extensively discusses a paper by a plant scientist with no expertise in human toxicology (e.g. Kniss 2017) for the proposition that glyphosate is less toxic than other herbicides, while practically ignoring the growing consensus that glyphosate is "probably carcinogenic to humans," as determined by the world authority on carcinogens, the World Health Organization's International Agency for Research on Cancer, and supported by 94 leading medical scientists. Several recent studies have strengthened the evidence of glyphosate's genotoxicity (one element in carcinogenicity analyses), and the link between exposure to glyphosate formulations like Roundup and the often deadly immune system cancer, non-Hodgkin lymphoma. This is hardly the profile of a "less toxic" herbicide." As evident in the dPEIS, APHIS cites professor A. Kniss, a weed scientist, in reference to herbicide use patterns, not as a human health expert."

Response*: Herbicide resistant weeds are thoroughly discussed in section 3.4.3.2 and 4.3.5 including the development of weed resistance and use of GE HR cropping systems (here we note that the selection of herbicide resistant weeds through herbicide use is not regulated by the USDA; rather, herbicide use is regulated by the EPA). A. Kniss understands that, as stated in his peer reviewed publications, when evaluating the variety of different herbicides used in crop production, each with different use rates and toxicity profiles, simply reporting the weight of pesticide applied, lbs a.i/acre or lbs a.i./year, is dubious at best, and can be misleading at worst. Lbs a.i/acre provides no meaningful information on health risks, absent data on toxicity, and the dose, duration, and frequency of human exposure. A recent National Academy of Sciences report strongly discouraged using such approaches: "Researchers should be discouraged from publishing data that simply compares total kilograms of herbicide used per hectare per year because such data can mislead readers" (NAS 2016).*

Relative to Glyphosate: APHIS disagrees with the commenter that there is a growing consensus that glyphosate is probably carcinogenic in humans. APHIS reviewed 10 studies summarized in the FPEIS (chapter 3.4.2.2.4). Of the 10 studies, 7 did not report a linkage between glyphosate use and cancer.

23. One commenter noted, "EPA's [APHIS note: APHIS assumes the commenter meant USDA] treatment of insecticide use trends over the GE crop era (Draft PEIS 3-52 to 3-53) fails to account for the dramatic rise in use of neonicotinoid seed treatments over roughly the same period that GE insect-resistant (Bt) corn and cotton came to dominate U.S. corn and cotton production (nearly always in varieties that also have herbicide-resistant traits). Thus, APHIS's Figure 3-16 grossly misrepresents overall insecticide use on corn and cotton. Entomologists generally find that neonicotinoid seed treatments offer little if any benefit to growers, who are for the most part not even given the option of purchasing untreated seeds; and that these seed treatments are widely applied by seed-chemical companies as a price point to help justify the steeply rising price of transgenic seed."

Response**:** *Under the Coordinated Framework, the EPA regulates pesticides to ensure environmental and public safety from their use, including pesticide residue on food and animal feed. The EPA considers the effects of herbicide use on natural resources and living organisms. The EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. The EPA, not USDA, regulates the use of pesticides under FIFRA. APHIS relies on the EPA's risk assessments and expertise because these are the best sources of comprehensive analyses of available information. APHIS uses this and other information from the scientific literature in its impact assessment in compliance with NEPA. APHIS has no statutory authority to authorize or regulate the use of herbicides on GE HR crops.*

Increased use of neonics is not unique to nor driven by GE crops. Neonicotinoids are used for a large variety of crops such as vegetables, pome and stone fruits, citrus, rice, cotton, corn, potato, sugar beet, canola, wheat, and soybean, among other crops (Craddock et al.et al. *2019). In the United States, clothianidin (1850 US tons, with corn accounting for 95% in 2014) and imidacloprid (1000 US tons, with soybeans, vegetables, and fruit accounting for 60% in 2014) are the most commonly used neonicotinoids in agriculture. In addition to crop protection, application of neonicotinoids has expanded to home, lawn, and garden products to control termites, ants, cockroaches and turf pests, and flea and tick preventatives for dogs and cats (Craddock* et al.et al. *2019).*

Neonicotinoids replaced carbamate and organophosphate pesticides because: they have lower mammalian toxicity, are more persistent, are active against a broad spectrum of insect pests, are systemically distributed (e.g., they move into all parts of treated plants, including pollen, nectar and guttation fluids, and the parts of the plant consumed as food), can be applied as foliar sprays, soil treatments, or as seed coatings, have a high water solubility, and have lower impacts on fish and other wildlife (Goulson and Kleijn 2013; Craddock et al.et al. *2019).*

As described in the FPEIS, Figure 3-16 addresses over the top insecticide use on Bt crops, not Bt crop seed, or other crop seed. The insecticide use in Figure 3-16 includes the neonicotinoids acetamiprid, clothianidin, imidacloprid, and thiamethoxam. It is a fair point that if insecticide use on seed treatments are considered, the drop in insecticide use shown in Fig 3-16 would not be as great.

24. A commenter noted, "APHIS considers only glyphosate associated with first-generation HR crops; and fails to assess the astoundingly rapid rise in the use of dicamba associated with Monsanto's dicamba-resistant crops, much less project the herbicidal impacts of other new next-generation GE HR crops resistant to 2,4- D and a host of other herbicides that are only now being introduced, and which are expected to be very widely adopted and have enormous adverse impacts. The Preferred Alternative will allow more herbicide-resistant GE crops to be commercialized without any further regulatory oversight, which in turn may massively increase GE HR crop acreage and pesticide use."

Response: *APHIS does not expect differences in herbicide use between the No Action and Preferred Alternatives. HR traits represent the first generation of the technology. At least 7 HR traits were developed under the No Action Alternative since 1996. The science in this area is mature. While there could be some additional HR traits developed and HR traits introduced into new crops. APHIS sees no reason why the development would be any different under the Preferred Alternative compared to the No Action Alternative.*

25. A commenter noted, "APHIS fails to appreciate the widely-understood fact that because GE HR crops foster exclusive or near-exclusive reliance on the associated herbicide(s), and are grown so widely, they thereby promote much more rapid and widespread evolution of weeds resistant to these herbicides than would have possibly occurred in the absence of those crops. Indeed, much of its discussion is entirely off-point, as it relates to HR weed development prior to introduction of GE HR crops, with the clear intent of downplaying the rapid acceleration and spread of weed resistance those GE crops have fostered."

Response: *Herbicide resistant weeds are thoroughly discussed in section 3.4.3.2 including the selection of weed resistance and use of GE HR cropping systems (here we note that the selection of herbicide resistant weeds through herbicide use is not regulated by the USDA; rather, herbicide use is regulated by the EPA). APHIS discusses Agricultural weeds and noxious weeds in section 4.3.5.*

APHIS acknowledges the occurrence of herbicide resistant weeds in the United States. Weed resistance to herbicides is a concern in agricultural production. Using herbicides with alternate mechanisms of action can diminish the potential for the development of new glyphosate-resistant weeds. The use of multiple herbicides with different modes-of-action on crops (whether tank-mixed or applied sequentially) is already a common agricultural practice in order to manage weeds. The emergence of resistance to herbicides is not exclusive to glyphosate-resistant crops and corresponding weedy species, and presents continued challenges to growers to understand which herbicide-resistant species is present and the best agronomic practice available to manage the *weed. Updating the 340 regulations is not expected to change herbicide use and so would not be expected to change the selection of herbicide-resistant* weeds.

26. One commenter makes several points about the socioeconomic impacts from commingling between GE and organic and non-organic GE sensitive markets: "APHIS dramatically underestimates the frequency and economic impacts of GE contamination. APHIS improperly limits its assessment of contamination harms to the organic sector, when GE-sensitive export and domestic markets are also severely impacted by it.

Response: *APHIS did not limit assessment of impacts to the organic sector in the FPEIS. APHIS addresses costs to organic growers in 3.9.2.3; 4.6.2.1.3; and 5.6.1.2. APHIS addresses costs to the non-GMO market in 4.6.2.2.3; 4.6.3.1.3; and 5.6.1. The discussion of impacts included organic, other non-GE, and other identity-preserved crops. Potential impacts on the organic sector were highlighted because there is relatively little information detailing the economic harm incurred by growers of other non-GE crops because of the unintended presence of GE products. Losses reported by organic farmers in the United States were reported in the 2014 Organic Survey. Through contract requirements, growers of organic or other non-GE crops may supply products that do not exceed a threshold of GE content set by a private company, a strict export market, or a voluntary certifier. Because contracts between growers and buyers are private, it is difficult to find documented information about how extensively growers are contracting to meet specific non-GE standards or to what extent farmers of organic or other non-GE crops are incurring economic losses as a result of being unable to meet contracts because of commingling (NAS 2016). APHIS is unaware of studies documenting harm to the non-GMO food chain from commingling of GMO with non-GMO food. Furthermore, products bearing the Non-GMO Project Verified seal are in compliance with the Project's rigorous standards, but the seal is not a "GMO free" claim (https://www.nongmoproject.org/product-verification/verification-faqs/). It is not clear to what extent non-GMO food producers that are not organic are harmed by commingling.*

27. A commenter stated "APHIS fails to assess the full costs of GE contamination even to the organic sector, which include numerous costly measures to mitigate GE contamination, and lost market opportunities."

Response: *APHIS notes that organic crops and non-GE products that are kept separate from their GE equivalents are treated as value-added crops commanding premiums that vary according to prevailing supply and demand conditions. Organic and other identity-preserved crops generally receive a price premium, a premium adversely impacted by the unintended presence of GE traits. The premiums compensate farmers and traders for incremental costs they incur, including those borne to maintain the segregation of non-GE and other IP production from GE crops throughout the supply chain (through buffer zones, spatial and temporal isolation, etc.). In the United States, the coexistence of GE* *and non-GE production systems has been left to market forces. Non-GE growers bear costs of coexistence and, in turn, pass those costs on to purchasers of non-GE crops (Kalaitzandonakes and Magnier 2016).*

28. A commenter stated "APHIS also fails to assess the past and current, or project the future, impacts and costs of GE organisms that escape into wild or semi-natural habitats via seed dispersal, cross-pollination with sexually compatible relatives, or by other means."

***Response**: The only persistent GE organism that APHIS is aware has escaped into the wild is GE creeping bentgrass. APHIS discussed the impact of this example in the FPEIS on p. 3-42, 3-92, 4-10 and 4-11.*

29. One commenter stated that, "It is arbitrary and capricious for APHIS to claim that transgenic contamination and its socioeconomic impacts will decrease under the Preferred Alternative. "Less oversight will mean increased contamination and harm, not less." As discuss above, APHIS reaches this conclusion based on the fact that, under the Preferred Alternative, the majority of GE crops would no longer be considered "regulated article." However, contrary to APHIS's assertion, as discussed elsewhere in these comments, the complete deregulation of the majority of GE crops and elimination of field trials under APHIS's oversight is likely to significant increase, not decrease, the frequency and risks of transgenic contamination."

    "APHIS's analysis is also flawed because the agency excluded forms of contamination except field trial contamination from what it considers to be damaging, and, since it proposes to no longer regulate field trials, contamination from them will go down. But as we have explained, whether international markets will reject contaminated food supplies does not rest on whether the U.S. treats the GE contamination as from a field trial or a U.S.-approved crop, but instead with the regulatory status of the GE organism in the foreign or GE-sensitive domestic or foreign market. In its cost-benefit analyzes, APHIS fails to account for or analyze the substantially increased harm to the U.S. agricultural economy from increased transgenic contamination episodes and lost foreign markets. The failure to consider this important part of the problem means APHIS's baseline economic calculations of alleged benefits to U.S. agriculture from less APHIS regulation are all incorrect and fail to account for this considerable cost and downside to the agricultural industry and farmers."

***Response**: The commenter's statement does not accurately reflect the conclusions reached in the FPEIS.*

Unintended presence refers to the occurrence of GE plant material in harvested crops where it is not wanted or expected. Unintended presence of crops approved domestically may result in market impacts in crops intended for a GMO sensitive domestic market or in foreign markets where the GE crop has not been approved.

APHIS discusses two distinct scenarios of unintended presence in the FPEIS. One case involves the release of unauthorized regulated material into the commercial food and feed supply, the other involves the release of authorized material in commodities destined for export markets where the GE material is still regulated. In the first case, the presence of the regulated material makes the commodity illegal and unfit for domestic use; in the second the material is marketable domestically but not in export markets. APHIS concluded in the FPEIS that the Preferred Alternative would decrease the instances of the first type and that it could increase the instances of the second.

As discussed in section 4.6.2.2.3-of the FPEIS, APHIS stated that "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 be due to the possibility that there would be more crop types in production that would be targeted for specific markets and would need segregation. 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. The pace of commercialization of GE products commercialized is not expected to significantly change from current levels. Similarly, the developer's control over the development process is not expected to change. However, 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." Contrary to what is implied by the commenter, APHIS also acknowledges in section 4.6.3.2.4; "If more regulatory authorizations and commercial production of new GE crop plants in the United States occurs and these new GE crop plants have not been reviewed and authorized by foreign countries, then there is potential increased risk of unintended presence for certain commodities, such as corn and soybean." APHIS also noted that many of the new GE traits are expected to be introduced into crops that are predominantly GE and in such instances, incremental impacts on the GE sensitive market are expected to be slight. APHIS also noted that plants that are exempted from or not covered under this regulation, are still subject to oversight by FDA and EPA as appropriate, and that regulation by Coordinated Framework partners could slow commercialization of these GE plants.

APHIS considered both these factors-harm to exports and harm to the GE sensitive markets. APHIS described the costs from prior trade disruptions and impacts of GE on the organic sector. As stated in the FPEIS section 5.6.1.2, there are too many unknowns to predict future instances. One unknown factor is whether the approval process in other countries will change if USDA codifies the Preferred Alternative. Another unknown is the extent to which modifications made by US developers will be recognized by international regulators.

30. One commenter noted, "The PEIS fails to provide an empirical assessment of the future types of GE crops to be introduced under the various alternatives. Instead, APHIS repeatedly assumes that future GE crops would incorporate traits for disease and stress resistance as well as product quality. GE crops with these trait types have

been promised and field-tested for three decades, yet extremely few have been commercially introduced. APHIS provides no analysis explaining this fact, the reasons for it, or why it anticipates that the future course of GE crop development should be so radically different than past history. For instance, APHIS discusses GE drought-tolerant crops as likely developments, yet studies have found that traditional breeding is far more successful than genetic engineering in the development of this crop type. GE disease-resistant crops occupy such miniscule acreage that they are not even covered by USDA statistics on commercial GE crop cultivation."

Response*: APHIS believes the second generation of GE crops will be different from the first because 1. The domestic market is already saturated with the first generation GE crops. 2. There is an awareness in the scientific and agricultural community of vulnerabilities to the food supply from disease and environmental stresses and awareness of the need for more sustainable agricultural solutions (Ronald 2011). 3. As noted in the FPEIS, there are already proof of concept genetic modifications to improve resistance to disease and abiotic stresses, improve agricultural sustainability, and improve nutritional quality of food. 4. Regulatory barriers have limited academic participation in biotech trait development and they are expected to make significant contributions to agricultural sustainability (Bradford* et al.et al. *2005). 5. Trait development is likely to occur more rapidly with genome editing technology that has evolved over the past few years (Songstad* et al.et al. *2017)* .

Regarding whether conventional breeding will be better in developing drought resistant crops, biotechnology developers do not just rely on introducing traits by biotechnology- they all have active programs to improve germplasm by conventional breeding. As both approaches are used in coordinated fashion, it is not meaningful to conclude that one technique works better than another. Indeed genome editing is expected to accelerate conventional breeding programs.

31. One commenter noted, "APHIS fails to analyze the impacts of an overall increase in unregulated GE organisms and their impacts under the Preferred Alternative. As discussed prior in the Agricultural Land Use section, APHIS's conclusion that the Proposed Rules, which would exempt the majority of GE plants from regulatory oversight and can be planted and commercialized immediately, is belied by the evidence as well as contrary to common sense. It also conflicts with APHIS' economic analysis that there will be a lesser "regulatory burden" and thus more GE crops would be developed, more quickly. Similarly, the analysis that the rules revisions will not increase harms from field trials, and that there will be no change in experimental acreage, is illogical and contrary to the evidence that field trials will now go on without oversight."

Response*: APHIS does not expect all exempted GE plants to be immediately commercialized. For one thing, they are still subject to regulation by FDA and EPA as appropriate. Second, from our experience with the Am I regulated program, there have been 80 cases of plants that came through the AIR process since 2011 but only two are being grown in the US for commercial purposes, to our knowledge (High Oleic acid* *soybean and waxy corn). Third, there are economic drivers that limit how much crop development can occur in the United States. Agricultural production is limited by land use which is only getting smaller and there is only so much seed that can be sold. The infrastructure for crop development is therefore limited by these economic drivers so expansion of crop development, i.e. more area used for field trials is not expected. Much of the new GE traits are expected to be introduced into crops that are already predominantly GE (corn, soy, cotton, canola, alfalfa, sugarbeet) so these traits will not increase the amount of land devoted to GE crops. As noted in the FPEIS, we expect more crops to be developed using GE traits and this can be expected to result in land currently used for non GE field trials to be used for GE field trials.*

32. One commenter noted, "first-generation GE HR crop systems have generated extremely rapid and widespread emergence of HR weeds, which has in turn led to increases in the use of tillage as a means of control, and corresponding reductions in soil-saving conservation tillage, over the past decade. This analysis is supported by USDA soil erosion data, which show unequivocally that substantial reductions in soil erosion rates in the pre-GE HR crop era, fostered by federal farm policy, came to a virtual halt in the GE HR crop era, especially in the Corn Belt, where cultivation of these varieties is most intensive. APHIS's numerous claims concerning the purported benefits of GE HR crops in reducing soil erosion via promotion of conservation tillage are thus arbitrary and capricious, and in direct contradiction to unimpeachable, mostly USDA, data that demonstrate the opposite."

***Response**: APHIS disagrees as articulated in the FPEIS section 3.5.1*

33. One commenter noted, "It is arbitrary and capricious and contrary to sound science for APHIS to conclude that the Preferred Alternative would improve water quality by reducing runoff of soil sediments, pesticides and fertilizers into streams and other surface waters. The facts show precisely the reverse outcome. Because the Preferred Alternative increases introduction of GE HR crops, water quality will decline due to increased use and runoff of herbicides, and to increased runoff of soil sediments attributable to increased use of tillage to control HR weeds generated by GE HR crop systems. The increase in GE crops, and associated increase in pesticide use, will further contaminate our waterways."

"APHIS's suggestion that the Preferred Alternative may increase the agency's consideration of risks to water quality is also baseless. As detailed throughout these comments, the Preferred Alternative would leave the vast majority of GE crops without any regulatory oversight, including stacked GE HR crops that would significantly increase herbicide use and related herbicide resistance in U.S. agriculture. APHIS fails to meaningfully consider these impacts, and its summary conclusions are contrary to the evidence."

***Response**: The commenter assumes that there will be no technical innovation that leads to more sustainable agricultural practices under the Preferred Alternative. We disagree as articulated in the FPEIS sections 4.2.2 and 5.2*

34. One commenter noted, "As pointed out in CFS's prior comments, APHIS also completely fails to assess the air quality degradation that will be caused by the projected rapid adoption of the next-generation GE HR crop systems. Enlist crops resistant to 2,4-D, and Roundup Xtend crops resistant to dicamba. Use of both herbicides is projected to expand dramatically, both are known to be highly volatile. This means there will be large increases in volatilization of these herbicides, especially since they will be sprayed weeks to a month or more later in the season, when climatic conditions favor vapor drift. Dicamba volatilization has resulted in enormous crop injury in the very first year of (limited) planting of dicamba-resistant crops. Dicamba vapor drift degrades air quality, with associated adverse impacts to humans and non-target species."

Response*: APHIS does not expect differences in the use of dicamba and 2,4-D resistant crops between the No Action and Preferred Alternatives.*

35. One commenter noted, "first-generation GE HR crops resistant to glyphosate have led to substantial adverse changes in the rhizosphere (root-associated) microbial community, supported by reports of increased fungal disease in glyphosate-resistant soybeans. APHIS's conclusion that there would be no significant impact between the No Action alternative and its Preferred Alternative is tainted by its deficient alternative analysis, and is therefore arbitrary and capricious, and contrary to sound science."

Response*: APHIS does not agree that GE HR resistant crops have led to substantial adverse changes in the rhizosphere microbial community or that there is compelling evidence of increased fungal disease in glyphosate resistant soybean as explained in the FPEIS section 3.6.5. Herbicide impacts on microbial communities are assessed by the EPA and are outside the scope of this FPEIS.*

36. One commenter noted, "APHIS downplays the consensus view of leading monarch scientists that dramatically increased glyphosate use driven by GE glyphosate-resistant crops has been a leading factor in the two-decade decline in monarch butterfly populations. This consensus view is based on multiple lines of evidence: 1) Common milkweed is the primary host plant for monarch butterflies in their summer breeding range, which is centered in the Midwest corn belt where corn and soybeans dominate the landscape; 2) As recently as 1999, before widespread adoption of glyphosate-resistant crops, common milkweed was fairly common in Midwest corn and soybean fields, comprising a considerable portion of total milkweed available for monarch breeding; 3) Glyphosate is unique among row-crop herbicides in its ability to kill common milkweed; 4) The massive increase in glyphosate use accompanying near-universal adoption of glyphosate-resistant corn and soybeans in the Midwest led to near-eradication of common milkweed from those fields; 5) The same period of time saw a dramatic decline in the migrating eastern monarch population."

    "APHIS's discussion deals with none of this evidence. Instead, it is cursory and highly biased, giving considerably more prominence to the views of a few researchers who dissent from the consensus view of these leading scientists, who have studied monarchs and their decline for decades, and published numerous articles on the subject in highly-regarded journals. APHIS's view is also directly at odds with those of all other federal government scientists who have studied monarch decline. For instance, APHIS fails to mention that the U.S. Fish and Wildlife Service (USFWS), in response to a petition from public interest groups and renowned monarch scientist Lincoln Brower, has made a preliminary finding that monarchs may merit listing as a threatened species under the Endangered Species Act. That petition is pending at this writing. APHIS ignores the fact that USFWS finds glyphosate use with glyphosate-resistant crops to be a major contributing factor to monarch decline, as petitioners argued."

"APHIS fails to cite the finding of a team with two U.S. Geological Survey scientists that there was an 11% to 57% risk of quasi-extinction of eastern monarchs (meaning loss of a viable migratory population) over the next 20 years. While APHIS acknowledges a government-wide effort to "benefit the monarch butterfly" that involves its USDA sister agency, the Natural Resources and Conservation Service, it carefully avoids mentioning the fact that this effort is chiefly directed to restoring monarch habitat – common milkweed – to the landscape."

***Response*:** *Contrary to what is implied in the comment, APHIS acknowledges that GE HR crops may have indirectly impacted monarch populations as discussed in FPEIS sections 3.6.4; 4.3.2.1.4.; and 5.3.2. APHIS also presented an opposing view that glyphosate use is not the principal agent in monarch decline. APHIS does not have enough evidence to draw a conclusion for one view versus the other. Regardless, there is not likely to be a difference in glyphosate use between the two alternatives.*

37. One commenter noted, "neonicotinoid use as seed treatments on mainly GE corn, soybean and cotton seeds has risen dramatically over roughly the same period as GE crops; and one explanation for this trend is that the seed treatments, despite offering little or no benefits, serve as a price point to help justify the steeply rising costs of GE seeds, creating a linkage between GE seeds and use of these seed treatments. Neonicotinoids are highly toxic to a broad range of insects, and have been implicated as important factors in declining bee and pollinator populations, and been shown to suppress important natural enemies of crop pests, with negative effects on crop production."

Response*: APHIS disagrees as the commenter has reached the unsupported conclusion that the rise in neonic use is due to the widespread adoption of GE crops. For example in one paper cited by the commenter (ref 121), the author notes there is widespread use of neonics on wheat. Wheat is not GE. In RTC #23, we also note there is widespread use of neonics on vegetable and fruit crops which are also not GE. In the publication by Fausti* et al.et al. *(2011), the authors look at insecticide use in South Dakota and found that hay, and sunflower have also experienced a recent intensification of insecticide use despite the fact that neither of these crops are GE.*

38. A commenter noted, *"*APHIS admits risks to wildlife from unregulated PIPs plants under the new Proposed Rules, but fails to assess that risk. The agency's conclusion that the risk to vertebrates are the same for both Preferred Alternative and no action alternative is arbitrary and capricious because the Preferred Alternative will cause many more GE organisms and their pesticides to go completely unregulated and unrestricted. In addition, some Roundup formulations are highly toxic to amphibians, particularly frog species, and the massive use of these glyphosate formulations is thought to be one factor driving the worldwide decline in amphibian species (see Appendix A). To the extent that the Preferred Alternative is likely to result in greater cultivation of glyphosate-resistant crops without any regulatory oversight, it would likely result in greater harms to amphibians."

Response*: APHIS disagrees with the conclusions of the commenter. Pesticide use is regulated by the EPA not USDA. APHIS's new regulations will not change oversight of pesticide use by EPA. Furthermore, APHIS does not expect major changes in the amount of glyphosate resistant crops between the two alternatives. Most of the major crops are already glyphosate resistant. APHIS expects that the few remaining major crops could be engineered for glyphosate resistance under either Alternative. For example, glyphosate resistant potatoes were deregulated in 1999 and 2000 but never commercialized. Glyphosate resistant wheat and rice were also developed under the current regulations but did not complete the regulatory process because these GE crops were not considered to be commercially viable (Ungar 2004). In these cases, the limitation to development of glyphosate resistant crops was due to lack of demand and not the regulatory process. If demand were to increase in the future, APHIS expects that such crops would be equally likely to be developed under either Alternative.*

39. One commenter noted, "APHIS states that "the purpose of many of the GE organisms field tested is protection against plant pests and disease." This is contrary to fact. The vast majority of GE crops are engineered for herbicide- and/or insect-resistance (IR), with HR trait-crops exceeding IR-trait crops by roughly two to one. USDA tracks commercial adoption of GE crops, but limits coverage to crops containing these two traits because others (e.g. GE virus-resistant papaya and squash) are too insignificant to track. Thus, APHIS's undocumented claim that the Preferred Alternative would likely spur cultivation of more GE crops designed to protect against plant pests and disease is unfounded, and is thus arbitrary and capricious. *See also* "Types of GE Crops" above."

Response*: First, it should be noted that insects are plant pests. By the commenter's own measure, one third of all GE crops are designed to resist plant pests. Second, APHIS expects a large increase in disease resistant plants based on the huge success scientists have had in identifying the genetic basis for disease resistance in plants (see the FPEIS at 4.3.4.1.4.) as well as the fact that many of these traits are currently being field tested. One current field test involves a state wide release in Florida of a GE/attenuated Citrus tristeza virus to help control the bacterial disease that causes citrus greening. APHIS recently received a petition for granting nonregulated status to a chestnut resistant to chestnut blight. If nonregulated status is granted, the GE chestnut* *may be deployed on a national level. The fact that disease resistant traits are not currently on the market is not a predictor of the future. As noted in the comment from BIO (APHIS-2018-0034-5273), there is generally a lag of at least a decade between field testing and commercial release.*

40. One commenter noted, "APHIS arbitrarily and capricious claims that that the Preferred Alternative, including no field trial regulation and front-end commercial approval for many GE organisms, will have the same impacts on biodiversity as No Action Alternative. APHIS's proposal will lead to many more completely unregulated experimental GE crops and commercial GE crops, and consequentially much more harm to biodiversity. And as discussed above and in our prior comments, the epidemic of glyphosate-resistant weeds generated by GE HR crops has led to increased tillage over the past decade and thus these crop systems cannot be associated with conservation tillage benefits. APHIS also fails to project the considerable impacts on biodiversity of next-generation GE HR crops that were first introduced in 2016, with massive adoption projected over the next few years, accompanied by large increases in the use of environmentally toxic herbicides like 2,4-D and dicamba."

***Response**: APHIS does not expect much difference in the release of HR crops under the Preferred Alternative relative to the No Action. As of 2018, 82% of cotton, 80% of corn, and 94% of soybean were comprised of HR varieties. Several types of new HR crops have already been introduced in 2016 under the No Action Alternative. Thus, it is unlikely that the introduction of new GE HR crop varieties will result in the "massive adoption" of GE HR crops. Future GE HR crops are expected to be stacked-trait varieties using differing herbicide modes of action. As noted in the FPEIS section 4.3.7 biodiversity, APHIS expects that under both the No Action and Preferred Alternative, new types of GE insect and disease resistant crops, as well as crops with modified compositional characteristics, will be commercialized that reduce farmer inputs such as pesticides and fertilizer thereby reducing impacts on biodiversity.*

41. One commenter noted *"*APHIS fails to analyze impacts of the regulatory gap created by its abdication of regulatory authority over PMPI plants, and associated risks to the food supply, in the Preferred Alternative." "It is improper reliance for APHIS to defer entirely to FDA in its public (and animal) health assessment. The PPA's mandates and definitions of harm expressly include protecting the public health. Furthermore, FDA's process for GE food safety is entirely voluntary, and the agency undertakes no independent assessment of their safety. APHIS cannot rely on FDA to fulfil its own NEPA duties. The public health risks of the Proposed Rules are significant and require analysis. This includes the risks to the food supply from PMPI crops, which APHIS at the same time is proposing to discontinue regulating. Given what the Proposed Rules will do, the conclusion that the preferred alternative would increase protection of public health is arbitrary and capricious and country to the evidence."

    "Similarly, as highlighted above, throughout the Draft PEIS, APHIS improperly relies on the potential actions of other agencies, namely the FDA or the EPA, as well as the possibility of Congressional actions that have yet to occur, as solutions to the impacts of its Preferred Alternatives, without any meaningful assessment of whether and now these other agency actions and/or acts of Congress may occur."

Response*: APHIS appreciates the commenter's concerns. APHIS recognizes that a gap in regulatory oversight of PMPIs has existed in the past and will continue to exist in the future absent another solution. Accordingly, APHIS has revised the final rule such that plants producing PMPI will not be eligible for an RSR and will require a permit for movement. We note the following considerations: 1) APHIS will continue to regulate PMPIs under our new regulatory framework. 2) The scale of PMPI field trials are limited; the total US planted acreage averaged 44 acres/year for the past 5 years and is not expected to increase. 3) Furthermore, the types of substances that are produced are typically substances to which humans are frequently exposed in their diet: avidin, lactoferrin, and lysozyme. For these three reasons, APHIS does not expect harmful impacts from PMPI field trials under the new rule. APHIS concluded that the public health impacts of the Preferred Alternative were net positive because innovation can lead to food with enhanced nutrition and diminished anti-nutrients such as cyanide, lectins, and allergenic proteins. Such foods have the potential to greatly improve public health.*

In RTC #15, APHIS explains that EPA has the authority to regulate PIPs under 10 acres. Therefore, APHIS is not improperly relying on EPA to fulfill this oversight role. As noted, like any other GE plant submitted for an RSR, a PIP would be subject to the Part 340 regulations if we find that there is a plausible pathway to increased plant pest risk in reference to its comparator and we cannot determine that the GE plant is unlikely to pose such a risk.

42. A commenter noted, "It is arbitrary and capricious, and a violation of NEPA/APA and the Endangered Species Act, for APHIS to conclude that the wholesale change of its regulations would have no effect on protected species or their habitat. It is arbitrary and capricious and contrary to the evidence and sound science, that APHIS' proposed change to its regulations will not cause any material change from the current regulations as to potential impacts on protected species and their habitat."

    "APHIS itself in the DPEIS acknowledges that the Proposed Rules may affect listed species and critical habitat. The agency states that "individual decisions made during implementation could impact T&E species." "Could impact" is synonymous with "may affect," thus triggering the consultation requirement. Nor can APHIS avoid its ESA duties for the programmatic decision it is now making by deferring it to some future agency actions, as APHIS claims, especially since one of the key features of the Preferred Alternative is the elimination of the majority of GE plants from any further regulatory review or agency action that would trigger ESA protections. The ESA requires compliances at the programmatic level regardless of what may come at the later individual implementation decision level. The failure to enter consultation here is *even worse*, since APHIS is proposing to effectively deregulate GE organisms, negating any future possible regulatory engagement point for GE organisms. APHIS recognizes that its ESA obligation at the programmatic stage is broad: "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," APHIS is obligated to engage in consultation on how its rule "could impact" species based on anticipated GE plant types that may be tested and commercialized in the near future. APHIS has failed to analyze these impacts and ignored an important part of the problem."

Response*: APHIS disagrees with the suggestion that on a programmatic basis APHIS should reach a "may affect" determination and that APHIS thus must consult with the FWS under the ESA. It is not the rule itself that (potentially) could have impacts on T&E species, but the individual actions under the rule. As discussed in Chapter 6 of the FPEIS: "This FPEIS 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."*

Furthermore, the commenter has incorrectly concluded that the majority of GE plants would not undergo any further regulatory review. The agency expects that most GE plants would undergo a regulatory review at which time direct and indirect impacts to T and E species will be assessed in cases where a plausible plant pest risk is identified.

43. A commenter noted, "APHIS fails to include in its scope of analysis, not just U.S. agricultural farmland but also all surrounding ecosystems and natural habitats, as well as reasonably foreseeable expansions of farmland acreage, due to other agronomic changes, climate change, and potentially due to APHIS' proposed rule change. APHIS fails to consider in its scope also forests and grasslands that can be affected by current and reasonably foreseeable future GE grasses and forest trees."

Response*: APHIS disagrees with the proposition that the scope of our analysis, discussed in the introduction to chapter 3, must extend outside of agricultural lands and agriculturally important resources. APHIS states in the FPEIS that land use for agriculture is not expected to significantly increase under either Alternative. Crop acreage is determined by market demand for food, feed, fuel, fiber, and industrial commodities, independent of APHIS' regulatory status decisions. Impacts from GE grasses and trees are discussed in the FPEIS.*

44. A commenter noted, "Repeatedly and throughout, APHIS improperly relies on the agricultural biotechnology industry's "best interests" and their "stewardship" efforts to self-regulate GE experimental and commercial organisms without meaningfully assessing how they would do that."

***Response**: It is reasonable to assume that there is some self-regulation within the agricultural industry. Self-regulation can be accomplished independently through stewardship practices or with support from BRS through its BQMS program. As an example of typical stewardship practices in the biotechnology industry, APHIS describes how the sugarbeet industry uses best practices to maintain varietal purity in the FPEIS at section 4.8.1 Federal Oversight. Most biotechnology product developers are members of Excellence Through Stewardship (ETS)®, a global non-profit organization that promotes the universal adoption of product stewardship programs and quality management systems for the full life cycle of agricultural technology products [https://www.excellencethroughstewardship.org/our-members]. Membership is available to organizations engaged in discovering, developing, handling or commercializing biotechnology-derived plant products. This includes technology companies, academic institutions, public and private research organizations, seed producers, licensees and other service providers to the industry. ETS members must undergo ETS Global Stewardship Audits, conducted to verify that appropriate stewardship programs and quality management systems are in place.*

45. A commenter noted, "A proper cumulative impacts discussion includes both an appropriate scope of impacts to the affected resource(s) and an adequately detailed/quantified discussion of those impacts. A discussion of only the direct impacts of a proposed action on the affected resource, without taking into account the combined effects that can be expected as a result of other present impacts, and other foreseeable projects, in addition to the proposed action itself, does not satisfy the requirements of NEPA. Moreover, agencies cannot provide general conclusions without the supporting objective data upon which such conclusions are based."

***Response**: APHIS carefully considered the possible cumulative impacts of the proposed rule change in chapter 5, and is satisfied that the FPEIS is adequate and sufficient. The FPEIS follows all applicable laws, regulations, and guidelines in analyzing potential impacts of this action, including those established by NEPA. In making an informed decision of potential environmental impacts, APHIS used the best available scientific information, data and expert advice. The analysis presented for each of the alternatives provides the agency decisionmaker and the public with as full a picture as practicable of the impacts of its determination. The agency's analysis of the alternatives in this document provides the decisionmaker and public with the potential cumulative impacts of each of these alternatives and differences in environmental impacts that would result.*

46. A commenter noted, "APHIS claims that the toxicity of herbicides used in U.S. agriculture has declined with GE HR crops because they have led to "less toxic" glyphosate displacing some "more toxic herbicides," citing agricultural economists with no evident qualifications in toxicology (PEIS, 3-54). Glyphosate is only "less toxic" as measured by the misleading LD50 metric discussed above. The world's leading cancer authority, the World Health Organization's International Agency for Research on Cancer (IARC), has found glyphosate to be "probably carcinogenic to humans" (Guyton et al. 2015), a determination endorsed by 94 leading medical scientists (Portier et al. 2016). Environmentally, some glyphosate formulations are

extremely toxic to amphibians, and their use is thought to be one factor driving the worldwide decline in amphibians (Relyea 2005). Glyphosate is also a major contributor to the dramatic decline in the monarch butterfly population over the past two decades (Pleasants and Oberhauser 2012). These are hardly the effects one would expect from a "less toxic" herbicide. APHIS's treatment of glyphosate is flawed and inadequate."

***Response**: APHIS discusses potential herbicide toxicity, to include glyphosate, in the FEIS section 3.4.2.2. Glyphosate is used in ecologically sensitive areas for restoration. Such a use is consistent with the assessment that it is one of the less toxic herbicides. APHIS agrees that glyphosate is a very effective herbicide in eradicating milkweed, a food source for monarchs. However glyphosate has low toxicity to insects such as bees (https://www.epa.gov/ingredients-used-pesticide-products/glyphosate).*

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