

Verdeca Petition (17-223-01p) for Determination of Nonregulated Status for HB4 Soybean (Event IND-00410-5) Genetically Engineered for Increased Yield and Resistance to Glufosinate-Ammonium

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IND-00410-5**

Draft Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
C	carbon
CAA	Clean Air Act
CFR	Code of Federal Regulations
CH ₄	methane
CO	carbon monoxide
CO ₂	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
EA	Environmental Assessment
EO	Executive Order
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
GE	genetically engineered
HR	herbicide resistant
HRAC	Herbicide Resistance Action Committee
IP	Identity Preservation
IPPC	International Plant Protection Convention
lb/A	pounds per acre
lbs	pounds
LMO	living modified organisms
MGs	maturity groups
MT	metric tons
N ₂ O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NAPPO	North American Plant Protection Organization

ACRONYMS AND ABBREVIATIONS (continued)

NEPA	National Environmental Policy Act
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NO ₂	nitrogen dioxide
NOP	National Organic Program
O ₃	ozone
Pb	lead
PDP	Pesticide Data Program
PIPs	plant-incorporated protectants
PM	coarse particulate matter
PM _{2.5}	fine particles less than 2.5 micrometers in diameter
PM ₁₀	particles greater than 2.5 micrometers and less than 10 micrometers in diameter
PPRA	Plant Pest Risk Analysis
SDWA	Safe Drinking Water Act of 1974
SO ₂	sulfur dioxide
SOM	soil organic matter
SSA	Sole Source Aquifer
T&E	threatened and endangered species
TMDL	total maximum daily loads
TSCA	Toxic Substances Control Act
U.S.	United States
U.S.C.	United States Code
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
WPS	Worker Protection Standard

1 PURPOSE AND NEED

Verdeca, LLC of Davis, California (referred to as Verdeca in this document) submitted a petition (17-223-01p) to the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) in May 2017 (Verdeca, 2017) to request a determination of nonregulated status for genetically engineered (GE) HB4 Soybean Event IND 00410-5 (referred to as IND 00410-5 soybean in this document). Supplemental information was added to the petition in June 2018 (Verdeca, 2018)

IND 00410-5 soybean is stacked with two GE traits: increased yield and resistance to the herbicide, glufosinate-ammonium, (referred to as glufosinate in this document). The petitioner, Verdeca, is a U.S.-based joint venture between Bioceres, S.A., Santa Fe, Argentina and Arcadia Biosciences, Inc., Davis, California.

IND-00410-5 soybean is currently regulated by USDA APHIS under (7 CFR part 340) as a GE organism. Consistent with these regulations, importation into, interstate movement within, and field trials of IND-00410-5 soybean in the United States require permits issued by APHIS or notifications acknowledged by the Agency. Since 2011, field trials of IND-00410-5 soybean have been conducted in diverse growing regions within the United States and Argentina. Results from these field trials are described in the IND-00410-5 soybean petition (Verdeca, 2017) and the supplement to it (Verdeca, 2018), and analyzed for plant pest risk in an APHIS draft Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2018e).

The petitioner asserts that APHIS should not regulate IND-00410-5 soybean because it does not pose a plant pest risk as defined by the Plant Protection Act of 2000 (PPA), as amended (7 United States Code (U.S.C.) 7701–7772) and regulated under 7 CFR part 340. If a determination of nonregulated status is made, it would pertain to IND-00410-5 soybean, as well as to any progeny derived from crosses between IND-00410-5 soybean and conventional soybean and from crosses between IND-00410-5 soybean and other GE soybean varieties that are not regulated under 7 CFR part 340. APHIS prepared this Environmental Assessment (EA) to determine if its regulatory decision could have any significant impacts on the human environment, as required by the National Environmental Policy Act (NEPA). As part of the evaluation of Verdeca's petition, APHIS has developed this EA to seek public comment, which will help inform the APHIS decision regarding the regulatory status of IND-00410-5 soybean.

1.1 PURPOSE OF IND-00410-5 SOYBEAN

HB4 soybean Event IND-00410-5 soybean has increased yield potential across the current range of growing conditions that occur in environments where soybeans are grown in the United States (Verdeca, 2017). It also has resistance to the herbicide, glufosinate (Verdeca, 2018), which allows growers to treat seedling soybeans with that herbicide without injuring an emerging field crop.

To develop IND-00410-5 soybean, a gene variant (*HaHB4v*) from the sunflower (*Helianthus annuus*) was inserted into a non-GE soybean variety, Williams 82, using *Agrobacterium*-mediated transformation. Another gene, the *bar* (herbicide bialaphos resistance) gene from

Streptomyces hygroscopicus that confers resistance to the herbicide active ingredient, glufosinate, was also inserted (Verdeca, 2017; 2018).

In IND-00410-5 soybean, the sunflower gene, when expressed at very low levels, maintains yield under severe environmental stress that might otherwise have reduced soybean yield (Verdeca, 2017). According to Verdeca, the sunflower gene (*HaHB4v*) expressed in IND-00410-5 soybean makes the plant more adaptable to the environment, which promotes greater yield than is currently available in other commercial soybean varieties (Verdeca, 2017).

The *bar* gene encodes the PAT (phosphinothricin-N-acetyltransferase) enzyme that makes IND-00410-5 soybean resistant to glufosinate. In non-resistant plants, glufosinate inhibits an enzyme that prevents accumulation of ammonia in plants. When ammonia levels become too high in plants they cause cell and ultimately plant death.

1.1.1 Coordinated Framework for the Regulation of Biotechnology

On June 26, 1986, the White House Office of Science and Technology Policy issued the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), which outlined 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 U.S. Environmental Protection Agency (U.S. EPA), and the U.S. Food and Drug Administration (FDA). On January 4, 2017, the USDA, U.S. 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 Plant Protection Act (PPA), as amended (7 U.S. Code (U.S.C.) 7701–7772), and implementing regulations at 7 CFR part 340.

The purpose of U.S. EPA oversight is to protect human and environmental health. The U.S. 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 U.S. 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 2015; US-EPA 2018b). In addition, U.S. EPA regulates certain GE microorganisms (agricultural uses other than pesticides) 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 and drugs are safe and sanitary. 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 Food Safety Modernization Act.

1.2 PURPOSE AND NEED FOR APHIS ACTION

As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as IND-00410-5 soybean. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk. The petitioner is required under § 340.6(c)(4) to provide information related to plant pest risk that the Agency may use to compare the plant pest risk of the regulated article to that of the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA, when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to a May 2017 petition (17-223-01p) from Verdeca (Verdeca, 2017); it must make a determination of the regulatory status of IND-00410-5 soybean, as requested by Verdeca, consistent with 7 CFR 340.6. APHIS has prepared this EA to document possible environmental effects of the Agency's decision, and evaluate the potential for effects to cause significant impacts on the quality of the human environment consistent with the Council of Environmental Quality's (CEQ) NEPA regulations (40 CFR parts 1500-1508), the USDA departmental and APHIS NEPA-implementing regulations and procedures (7 CFR part 1b, and 7 CFR part 372).

1.3 PUBLIC INVOLVEMENT

APHIS seeks public comment on draft EAs through notices published in the *Federal Register*. On March 6, 2012, APHIS announced in the *Federal Register* updated procedures for the way it solicits public comment on petitions for determinations of nonregulated status.¹ Details on policy and procedures for public participation in the petition review and NEPA process are available in the *Federal Register* notice and on the APHIS website (USDA-APHIS, 2018a).

1.3.1 Public Involvement for Petition 17-223-01p

APHIS announced a comment period and the availability of the Verdeca petition for IND-00410-5 soybean for public review in a *Federal Register* notice² (82 FR 52873) on November 15, 2017. The 60-day public comment period closed on January 16, 2018. APHIS received six comments³ during the period the petition was available for public review.

One comment supported a determination by APHIS of nonregulated status for IND-00410-5 soybean. Four comments expressed opposition to nonregulated status for IND-00410-5 soybean based on general opposition to the use of GE organisms. No objections specific to the IND-00410-5 variety were cited. One additional comment cited opposition to IND-00410-5 soybean based on the incorrect assertion that it was developed using Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) Cas9 (a type of endonuclease) technology.

¹ FR Vol. 77, No. 44, Tuesday, March 6, 2012, p.13258: Available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

²This notice can be accessed at: <https://www.federalregister.gov/documents/2017/11/15/2017-24634/verdeca-llc-availability-of-a-petition-for-determination-of-nonregulated-status-of-soybean>

³The docket can be accessed at: <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0075>

One of the opposing comments was submitted on by the Keweenaw Bay Indian Community (KBIC). Because the KBIC is a federally recognized tribal nation, APHIS proposed a consultation with the tribe consistent with current U.S. government policy and is awaiting their response.

APHIS determined from its initial review of the petition or IND-00410-5 soybean (Verdeca, 2017) that the final review process for the draft PPRA and draft NEPA documents (EA and FONSI) should follow Approach 2. This decision was made because APHIS has not previously analyzed potential plant pest risk associated with the *HaHB4v* transcription factor gene from sunflower (*H. annuus*) and the HAHB4v protein it expresses in any previous analyses performed by the Agency for GE organisms.

1.4 ISSUES CONSIDERED

The issues addressed in this draft EA were developed by considering similar ones identified and addressed in prior NEPA documents, those identified in public comments for Verdeca's petition and other petitions for GE organisms, information in the scientific literature on agricultural biotechnology, and issues identified by APHIS as specific to soybean. These issues were addressed in this EA under the following subject categories:

Agricultural Production:

- Areas and Acreage of Soybean Production
- Agronomic Practices
- Soybean Seed Production
- Organic Soybean Production

Environmental Resources:

- Soil Quality
- Water Resources
- Air Quality
- Animal Communities
- Plant Communities
- Soil Microorganisms
- Biological Diversity
- Gene Movement

Animal Health:

- Animal Feed Quality
- Livestock Health

Human Health:

- Public Health
- Worker Health and Safety

Socioeconomics:

- Domestic Economic Environment
- Trade Economic Environment

Cumulative Impacts

Threatened and Endangered Species

Other U.S. Regulatory Approvals and Compliance with Other Laws

2 ALTERNATIVES

NEPA implementing regulations (40 C.F.R. § 1502.14) require agencies to evaluate all alternatives that appear reasonable and appropriate to the purpose and need of an agency's action (in this case, a regulatory decision). Two alternatives were evaluated in this EA: (1) No Action Alternative, which would continue the current regulated status of IND-00410-5 soybean if selected; (2) Preferred Alternative, which would result in nonregulated status for IND-00410-5 soybean if selected.

2.1 NO ACTION ALTERNATIVE: CONTINUE REGULATING IND-00410-5 SOYBEAN

Under the No Action Alternative, APHIS would deny the petition request by Verdeca (USDA-APHIS, 2018f), so there would be no change in the regulatory status of IND-00410-5 soybean; it and any soybean varieties derived from it would continue to be regulated articles under 7 CFR part 340. APHIS would continue to require permits for introductions of IND-00410-5 soybean grown in the United States. Because APHIS has concluded from its PPRA (USDA-APHIS, 2018e) that IND-00410-5 soybean is unlikely to pose a plant pest risk, choosing this alternative would not be an appropriate response to the petition for nonregulated status because it would not satisfactorily meet the purpose and need for making a science-based regulatory status decision pursuant to the requirements of 7 CFR part 340.

2.2 PREFERRED ALTERNATIVE: NONREGULATED STATUS FOR IND-00410-5 SOYBEAN

Under the Preferred Alternative, IND-00410-5 soybean and any varieties derived from crosses between it and other soybean varieties that are not regulated would no longer be regulated under 7 CFR part 340. APHIS has determined that IND-00410-5 soybean is unlikely to pose a plant pest risk based on available scientific evidence (USDA-APHIS, 2018e), therefore, if this alternative is selected, permits or notifications acknowledged by APHIS would no longer be required to grow IND-00410-5 soybean or progeny derived from it in the United States. This alternative best meets the purpose and need to respond appropriately to the petition for nonregulated status of IND00410-5 soybean based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA.

2.3 ALTERNATIVES CONSIDERED BUT EXCLUDED FROM FURTHER DETAILED ANALYSIS IN THIS EA

APHIS has evaluated several other alternatives for consideration in this and other EAs for petitions for nonregulated status of GE organisms. These alternatives included: approval of the petition only in part as provided for in § 340.6(d)(3)(i) of the regulations (e.g., allow nonregulated status for IND-00415 soybean crops grown in limited regions of the United States); establishment of mandatory rules for isolation or geographic separation of GE and non-GE cropping systems; requirements for testing for the presence of GE crop plant material in non-GE crops and commodities.

Based on the draft PPRA (USDA-APHIS, 2018e) for IND-00415 soybean and the Agency’s experience with GE and non-GE soybean varieties, APHIS concluded that it is unlikely to pose a plant pest risk. Therefore, the imposition of testing, release, and/or isolation requirements on IND-00415 soybean would be inconsistent with the Agency’s statutory authority under the plant pest provisions of the PPA, implementing regulations at 7 CFR part 340, and the federal regulatory policies of the Coordinated Framework. Because it would neither be reasonable nor appropriate for APHIS to evaluate alternatives for actions that exceed its statutory authority, the alternatives summarized above were excluded from further detailed analysis in this EA.

2.4 COMPARISON OF ALTERNATIVES

Table 1 includes a summary and comparison of possible impacts associated with selection of each of the alternatives evaluated in this EA. Details about the impact assessment reviewed in this EA are in Chapter 4, Environmental Consequences.

Table 1. Summary of Potential Impacts and Consequences of Alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need, and Objectives:	No	Yes
Unlikely to pose a plant pest risk:	Satisfied by regulated field trials.	Satisfied by risk assessment (USDA-APHIS, 2018e)
Management Practices		
Acreage of Soybean Production:	Current trends in acreage and areas of production are likely to continue to be driven by market conditions and federal policy that influences demand for U.S. soybeans (e.g., demand for animal feed and biodiesel). U.S. soybean acreage is projected to remain level at 90.1 million acres through 2028 (USDA-OCE, 2018); selection of the No Action Alternative would not be expected to change this estimate, so would not increase or decrease soybean acreage.	IND-00410-5 would only replace other herbicide resistant (HR) soybean varieties and/or lower yielding varieties in the United States, so soybean acreage under the Preferred Alternative would be the same as for the No Action Alternative.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Agronomic Practices:	Soybean management practices and methods that increase yield such as fertilization, crop rotation, irrigation, pest management, and plant residue management would be expected to continue as currently practiced. Some conservation tillage practices may be replaced by conventional tillage, where this is the only alternative to control increasing HR weed problems.	The agronomic characteristics and cultivation practices used for the production of IND-00410-5 soybean are the same as those used for the cultivation of other commercially available soybean varieties, so they would remain unchanged from the No Action Alternative.
Pesticide Use:	The EPA approves and labels uses of pesticides on soybeans. Commercial soybean growers would continue to use the same pesticides for soybean insect pests and weeds as are currently used	The EPA regulatory oversight of pesticides would not change. IND-00410-5 soybean is susceptible to the same insect and other invertebrate pests that affect other commercially available conventional and GE soybean varieties, so pest management practices would not change from the No Action Alternative. Growers with weeds resistant to herbicides with other modes of action (MOAs) may choose glufosinate for weed management.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Organic Farming:	Methods currently used for certified seed production to maintain soybean seed identity and meet National Organic Standards (NOP) would continue unchanged. The availability of GE soybean is unrelated to the proportion of organic soybean market share.	Measures used by organic soybean producers to manage, identify, and preserve organic production systems would not change. Similar to other commercially available GE soybean varieties, IND-00410-5 soybean does not present any new or different issues or impacts for organic soybean producers or consumers. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not be expected to change.
Soybean Seed Production:	Quality control methods, such as those of the Association of Official Seed Certifying Agencies (AOSCA, 2012c) for certifying seed to ensure varietal purity would continue to be available.	Practices to ensure varietal purity would remain the same as for the No Action Alternative. Tests would be available to determine the presence of genes that convey increased yield and glufosinate-resistance traits in IND-00410-5 soybean.
Physical Environment		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil Quality:	<p>Most cropping practices that impact soil such as tillage, contouring, cover crops, agricultural chemical management, and crop rotation would continue unchanged, but some tillage practices (e.g., conservation), may change to conventional where this is the only alternative to control increasing HR weed problems.</p>	<p>Production of IND-00410-5 soybean is not expected to change cropping practices. Increased demand for nutrients, such as phosphorus and potassium by IND-00410-5 soybean, would be mitigated no differently from methods currently used for other high-yield varieties. Use of glufosinate would likely offset the need to change tillage practices to control HR weeds resistant to currently available herbicides, which would prevent soil quality losses from erosion. Application of EPA-registered glufosinate formulations would prevent unacceptable risks to current soil quality conditions.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Water Resources:	<p>Agronomic practices that could impact water resources (e.g., irrigation, tillage practices, and the application of pesticides and fertilizers) would be expected to continue. The use of EPA-registered pesticides for soybean production in accordance with label directions would continue to prevent unacceptable risks to water quality. Historic trends of increased soybean yields on existing cropland would continue unchanged, so any current impacts on water resources from soybean production would not change significantly.</p>	<p>Except for new uses of glufosinate, the production of IND-00410-5 soybean is not expected to change current agronomic practices, acreage, or the range of production areas, so current impacts on water resources would not change. Increased demand for nutrients, such as phosphorus and potassium from the production of IND-00410-5 soybean, would be mitigated no differently from methods currently used for other high-yield varieties, so nutrient impacts from runoff would not change significantly. Use of glufosinate would likely offset the need to change tillage practices to control HR weeds resistant to currently available herbicides, so soil erosion impacts on water quality from soybean production may be reduced or would not change. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. Application of EPA-registered glufosinate formulations in accordance with label instructions would prevent unacceptable risks to water quality from runoff.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Air Quality:	Current soybean agronomic practices that impact air quality, such as tillage, application of farm chemicals, and use of exhaust-emitting mechanized equipment would not change, so current environmental impacts would not change significantly.	Except for new uses of glufosinate, agronomic practices for the production of IND-00410-5 soybean are not expected to differ significantly from the No Action Alternative. Use of glufosinate would likely offset the need to change tillage practices to control HR weeds resistant to currently available herbicides, so soil erosion impacts on air quality from soybean production may be reduced or would not change significantly from that of the No Action alternative. Application of EPA-registered glufosinate formulations in accordance with label directions would prevent unacceptable risks to air quality.
Biological Resources		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal Communities:	<p>Non-GE and GE soybeans that are not regulated have been shown to have no allergenic or toxic effects on animal communities.</p> <p>Soybean agronomic practices such as tillage, cultivation, farm chemical applications, and the use of mechanized agricultural equipment would continue to impact animal communities unchanged.</p>	<p>There are no allergenicity or toxicity risks from IND-00410-5 soybean on animals or animal communities. Field trials demonstrated that growth and disease characteristics of IND-00410-5 soybean are not significantly different from non-GE or other GE soybean varieties that are not regulated, so no changes to soybean agronomic practices potentially impacting animal communities would occur other than the use of glufosinate applications, where HR weeds resistant to currently available herbicides are a problem.. The use of EPA-registered glufosinate formulations in accordance with EPA-approved label recommendations would ensure that there would be no unacceptable risks to animals or animal communities.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Plant Communities:	<p>Most commercial soybean acreage is planted with GE varieties, and this would continue unchanged. Most agronomic practices would not change except where the continuing increasing problem of HR weeds forces growers to modify methods (e.g., tillage; herbicide choices) to control weeds. Herbicide use in accordance with the EPA registration requirements would continue to ensure that no unacceptable risks to non-target plants and plant communities would occur.</p>	<p>Field trials and laboratory analyses show no differences between IND-00410-5 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases that may impact plant communities. Except for the option to substitute glufosinate for other herbicides used, agronomic practices to cultivate IND-00410-5 soybean would not differ from the No Action Alternative. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. As with other herbicides used for soybean cultivation, glufosinate used in accordance with the EPA registration requirements would continue to ensure that no unacceptable risks to non-target plants and plant communities would occur.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Gene Movement:	<p>IND-00410-5 soybean would continue to be cultivated only under regulated conditions. The availability of GE, non-GE, and organic soybeans would not change as a result of the continued regulation of IND-00410-5 soybean. Because there are no wild soybean relatives in the United States, and soybeans are mostly self-pollinated at rates that decrease significantly with distance, gene flow and introgression from soybean to wild or weedy species are highly unlikely. Any risk is further limited because soybeans are not frost tolerant, do not reproduce vegetatively, exhibit poor seed dispersal, and any volunteers that persist in warmer U.S. climates can be easily controlled with common agronomic practices.</p>	<p>Field and laboratory test results show that there are no significant differences among the traits in IND-00410-5 soybean that influence gene flow or weediness, when compared to non-GE and GE soybean varieties that are not regulated. Traits for increased yield and glufosinate resistance would not change gene movement characteristics nor increase weediness significantly, so there would be no significant impacts compared to the No Action Alternative.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil Microorganisms:	<p>The availability of GE, non-GE and organically grown soybeans would not change if IND-00410-5 soybean continued to be regulated. Agronomic practices used for soybean production, such as soil inoculation, tillage and the application of agricultural chemicals (pesticides and fertilizers) that potentially impact microorganisms would continue unchanged.</p>	<p>Field and greenhouse tests show no significant differences from other nonregulated soybean varieties in the parameters measured to assess the symbiotic relationship of IND-00410-5 soybean with its Rhizobium sp. symbionts. IND-00410-5 soybean would not result in any significant changes to current soybean cropping practices that may impact microorganisms except that glufosinate may be substituted for other herbicides, where HR weeds are a problem. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. As with other herbicides used for soybean cultivation, glufosinate used in accordance with the EPA registration requirements would continue to ensure that no unacceptable risks to non-target microorganisms would occur.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Biological Diversity:	<p>The availability of GE, non-GE and organic soybeans would not change.</p> <p>Agronomic practices used for soybean production and yield optimization, such as tillage, the application of agricultural chemicals (pesticides and fertilizers), timing of planting, and row spacing, would be expected to continue unchanged.</p> <p>Agronomic practices that benefit biodiversity both on cropland (e.g., intercropping, agroforestry, crop rotations, cover crops, and no-tillage) and on adjacent non-cropland (e.g., woodlots, fencerows, hedgerows, and wetlands) would remain the same.</p>	<p>IND-00410-5 soybean would not change current soybean cropping practices that may impact biodiversity because field and laboratory testing demonstrate its growth, reproduction, and interactions with pests and diseases are the same as or not significantly different from other nonregulated varieties. IND-00410-5 soybean poses no potential for naturally occurring, pollen-mediated gene flow and transgene introgression, so is not expected to affect genetic diversity.</p>
Public Health		

<p>Human Health:</p>	<p>Compositional and nutritional characteristics of nonregulated GE soybean varieties have been determined to pose no risk to human health. EPA-approved pesticides would continue to be used for pest management in both GE and non-GE soybean cultivation. Use of registered pesticides in accordance with EPA-approved labels protects human health and worker safety. The EPA also establishes tolerances for pesticide residue that give a reasonable certainty of no harm to the general population and any subgroup from the use of pesticides at the approved levels and methods of application.</p>	<p>Laboratory and field testing demonstrated that there are no biologically meaningful differences for compositional and nutritional characteristics between non-GE and IND-00410-5 soybean. Testing showed that the IND-00410-5 soybean HAHB4v and PAT proteins have no amino acid sequences similar to known allergens, and are not toxic to mammals. Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4v protein produced by IND-00410-5 soybean ((FDA, 2015); NPC 000016; HAHB4). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017. On May 22, 2018, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for the PAT protein expressed by IND-00410-5 soybean. An FDA response is pending. The EPA has concluded (40 CFR 174.522) that the PAT protein is exempt from a food and feed tolerance, when it is expressed in plants.</p>
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Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Farm Worker Safety and Health:	Farm workers are exposed to potential allergens associated with soybean plants, hazards from farm equipment used to cultivate and harvest soybeans, and pesticides applied to soybeans. The EPA sets conditions for pesticide use to maintain a standard of no unreasonable risks to worker health and safety. Hazards to farm workers would not change from selection of the No Action Alternative.	The EPA Worker Protection Standards (WPS) (40 CFR Part 170) implement protections for agricultural workers, handlers, and their families. IND-00410-5 soybean would not change current soybean cropping practices, so any associated hazards would not change under the Preferred Alternative, nor would current EPA registration label requirements for other glufosinate-resistant soybean varieties that are designed to maintain a standard of no unreasonable risks to worker health and safety.

<p>Animal Feed:</p>	<p>IND-00410-5 soybean would remain regulated and not be allowed for distribution to the animal feed market. Soybean-based animal feed would still be available from currently cultivated soybean crops, including both GE and non-GE soybean varieties. Nonregulated GE soybean varieties used as animal feed have been previously determined to not pose any risk to animal health.</p>	<p>Safety testing of the IND-00410-5 soybean HAHB4v and PAT proteins show they have no amino acid sequences similar to known allergens, no toxic potential to mammals, and are degraded rapidly and completely in simulated gastric fluid, indicating no potential risk, when present in animal feed. Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4 protein produced by IND-00410-5 soybean (FDA, 2015); NPC 000016; HAHB4). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 Soybean (BNF 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017. On May 22, 2018, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition on May 22, 2018 for the PAT protein expressed by IND-00410-5 soybean. An FDA response is pending. The EPA has concluded (40 CFR 174.522) that the PAT protein is exempt from a food and feed tolerance, when it is expressed in plants. Based on available evidence, IND-00410-5 soybean grain and forage are similar to currently available soybean varieties.</p>
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Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Socioeconomic Environment		
Domestic Economic Environment:	<p>IND-00410-5 soybean would remain regulated by APHIS. Domestic growers would continue to utilize GE and non-GE soybean varieties based upon availability and market demand. U.S. soybeans would likely continue to be used domestically for animal feed, with lesser amounts and byproducts used for oil or fresh consumption. Agronomic practices and conventional breeding techniques using GE herbicide- and pest-resistant varieties currently used to optimize yield and reduce production costs would be expected to continue. Average soybean yield is expected to continue to increase without expansion of soybean acreage while grower net returns are estimated to increase.</p>	<p>Field tests show the performance and composition of IND-00410-5 soybean is not substantially different from that of other conventional soybean reference varieties and although yield potential is increased, it would be similar to other commercially available soybean varieties and subject to the same variables affecting agronomic practices and yields as other varieties. IND-00410-5 soybean would likely only replace other varieties of GE soybean on existing cropland and not impact organic soybean production or markets. As IND-00410-5 soybean is another GE soybean variety potentially increasing farm productivity without altering soybean’s nutritional value, potential allergenicity, or toxicity, no change to U.S. consumer attitudes towards GE crops is expected. No adverse impact to the domestic economic environment would occur under this alternative.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Trade Economic Environment:	<p>U.S. soybeans will continue to have a role in global soybean production, and the United States will continue to be a supplier in the international market if IND-00410-5 soybean remains regulated by APHIS (USDA-NASS, 2016d). Although U.S. exports are expected to increase overall, increasing competition and tariffs on U.S. soybean exports are expected to reduce the U.S. export share (Hubbs, 2018).</p>	<p>A determination of nonregulated status of IND-00410-5 soybean is not expected to adversely impact the current trends affecting the trade economic environment and may have a negligible impact through increased yields. Verdeca plans to seek biotechnology regulatory approvals for IND-00410-5 soybean from all key soybean import countries that have a functioning regulatory system. Any impact to soybean market prices from the potential increase to yield from the production of IND-00410-5 soybean would likely be negligible because the increased yield of IND-00410-5 soybean is similar to other high yielding soybean varieties already available, so the same variables related to yield that currently affect other commercially available varieties would not change.</p>
Other Regulatory Approvals		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
U.S. Agencies:	Existing approvals for other nonregulated GE soybeans would not change.	<p>FDA Consultation:</p> <p>Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4 protein produced by IND-00410-5 soybean (FDA 2015; NPC 000016; HAHB4). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017.</p> <p>Verdeca submitted a request for consultation with the FDA for the PAT protein on May 22, 2018, and an FDA response is pending.</p>
Other countries	The existing status of other GE soybeans regulated in other countries would not change.	No Change from the No Action Alternative
Compliance with Other Laws		
CAA, CWA, EOs:	Fully compliant	Fully compliant

3 AFFECTED ENVIRONMENT

This section includes a review of the current status of the human environment as defined in the CEQ regulations for NEPA (at 40 CFR §1508.14). The components of the human environment that may be affected if IND-00410-5 soybean were no longer regulated under 7 CFR part 340 were reviewed for this EA and include those listed under “Issues Considered” in Chapter 1. The description of the Affected Environment that follows was used as the basis for comparison to identify possible effects that may result from a determination about the regulatory status of IND-00410-5 soybean, and to analyze the effects identified for their potential to cause significant impacts.

3.1 AGRICULTURAL PRODUCTION OF SOYBEANS

Soybean (*Glycine max* (L.) Merr.) is an economically important leguminous crop that is a source of vegetable oil and protein. Soybeans are grown for their seed, which is processed to yield oil and meal. Among oil seed crops, soybeans are ranked first in the world as a source of oil production (Chung and Singh, 2008). In the United States, soybeans are also a major source of livestock animal feed and biodiesel fuel (USB, 2012).

The genus *Glycine*, includes two subgenera and more than 25 species (Sherman-Broyles *et al.*, 2014). The subgenus *soja* consists of only two species, the cultivated *G. max* and its annual wild soybean progenitor, *G. soja* Sieb. & Zucc. The subgenus *glycine* includes at least 26 species. Most are perennials native to Australia and its surrounding islands. The domestication of *G. max* from its wild progenitor soybean (*G. soja* Sieb. & Zucc.) occurred in China or Southeast Asia between 3,000 and 9,000 years ago (Hymowitz, 1970; Hymowitz and Newell, 1981; Sedivy *et al.*, 2017).

Soybean is a self-pollinating species, propagated commercially by seed (OECD, 2000). Soybean seeds contain about 18% oil and 38% protein (Hartman *et al.*, 2011). Nearly all soybean meal (98%) is used for livestock or aquaculture feed (Hartman *et al.*, 2011). Soybean is grown worldwide, and the United States is the world’s leading soybean producer followed by Brazil, Argentina, China, and India (USDA-FAS, 2017).

Soybean acreage increased rapidly after World War II until the late 1970s as a result of increased vegetable oil demand and higher meat consumption (USDA-ERS, 2006). U.S. soybean acreage stabilized in the 1980s mostly because of farm programs that encouraged planting other crops. In the 1990s, changes in farm programs, overseas demand, and lower production costs associated with herbicide-resistant (HR) crops, resulted in an increase in soybean acreage (USDA-ERS, 2006). From 1992 to 2012, U.S. soybean acreage increased 31% from about 59.1 to 77.2 million acres (USDA-NASS, 2012g; 2012f).

U.S. soybeans are grown mostly in the Midwest (Figure 1) on about 89.5 million acres (Figure 2) in 2017 (USDA-NASS, 2016c; 2017). Soybean acreage in these states is commonly rotated with corn (Soyatech, 2011). Total soybean production in the United States has increased in recent years because of an increase in both the area under cultivation and yield per unit area (Figures 2 and 3) (USDA-NASS, 2017b; 2017). For example, in the past 20 years soybean

acreage increased from 70 million to nearly 90 million acres (Figure 2), and in the past 30 years soybean yields have increased about 53% (Figure 3). A significant factor contributing to these increases is that soybean cultivation has recently expanded into the northern and western parts of the country because yields from wheat usually grown in those regions have been stagnant, and new improved short-season soybean varieties have been developed that are better adapted to the climate, so provide better profits (USDA-ERS, 2010b) than wheat or older soybean varieties.

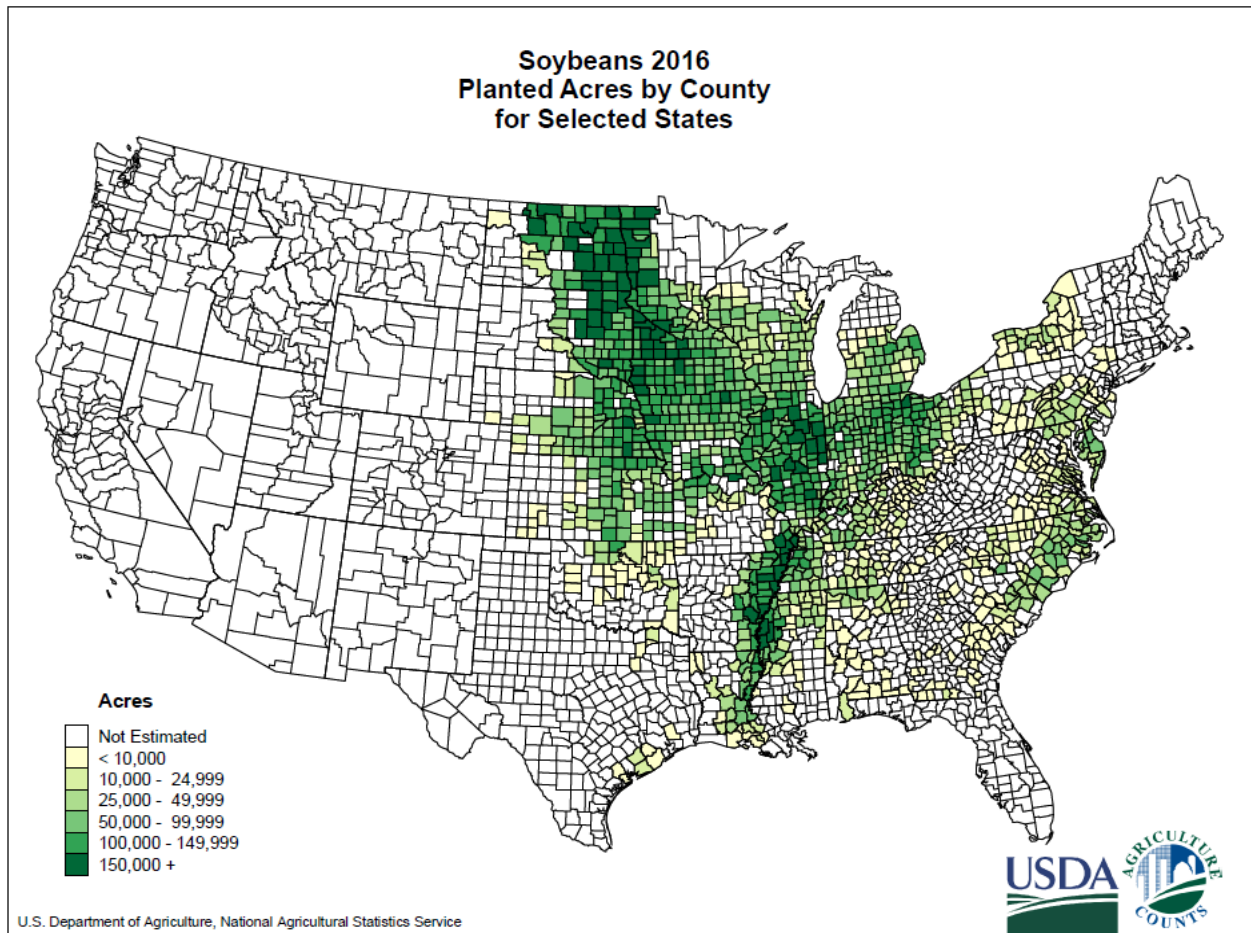


Figure 1. Soybean Planted Acres by County for Selected States.
Source: (USDA-NASS, 2016c)

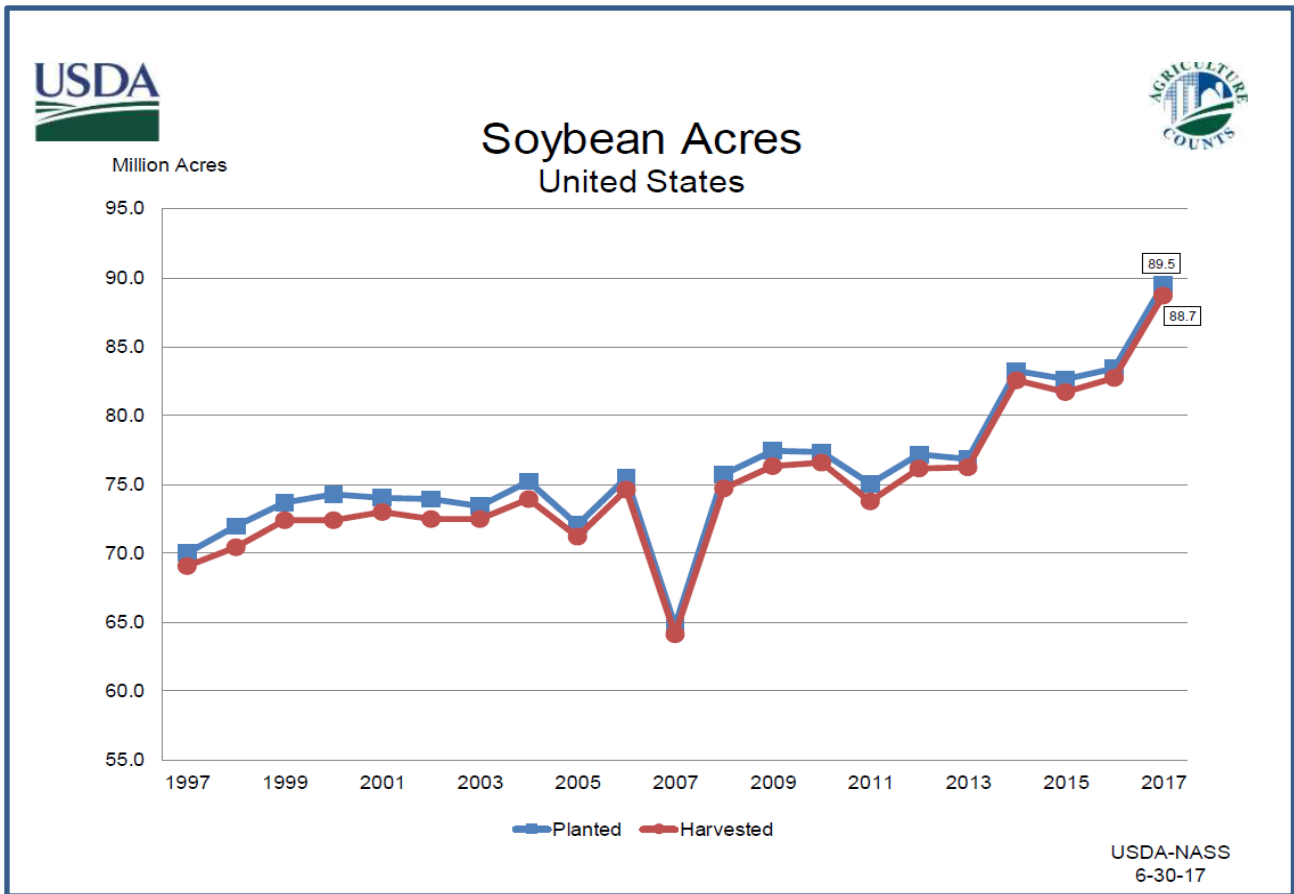


Figure 2. U. S. Soybean Acreage: 1997-2017.
 Source: (USDA-NASS, 2017)

Soybean production has increased 35.6%, from nearly 2.2 billion bushels or 59.88 million metric tons (MT) in 1992 to approximately 3.0 billion bushels (81.7 million MT) in 2012 (USDA-NASS, 2012f). From 1991 to 2011, average yield increased approximately 17.6% from 34.2 bushels per acre to 41.5 bushels, but declined nationally in 2012 to 39.3 bushels per acre compared to 2011 average yields (USDA-NASS, 2012f). By 2017, the harvest was 49 bushels per acre (USDA-NASS, 2018e).

USDA projects an estimated 3.6 billion bushels of soybeans (97.99 million MT) will be produced by the end of the 2021/2022 growing season. About 2.1 billion bushels (57.16 million MT) of this production will be used for domestic consumption and 1.6 billion bushels (43.55 million MT) will be exported (USDA-OCE, 2012).

Soybean varieties have for many years been developed using conventional plant breeding methods. Combined with improved agronomic practices, these varieties have resulted in improved yields. The multigene components of yield in relation to adaption of soybean varieties to lower yielding areas, and the need to develop regional soybean varieties adapted for specific environments limits the identification of traits that can provide yield improvements effective across the entire spectrum of soybean production environments.

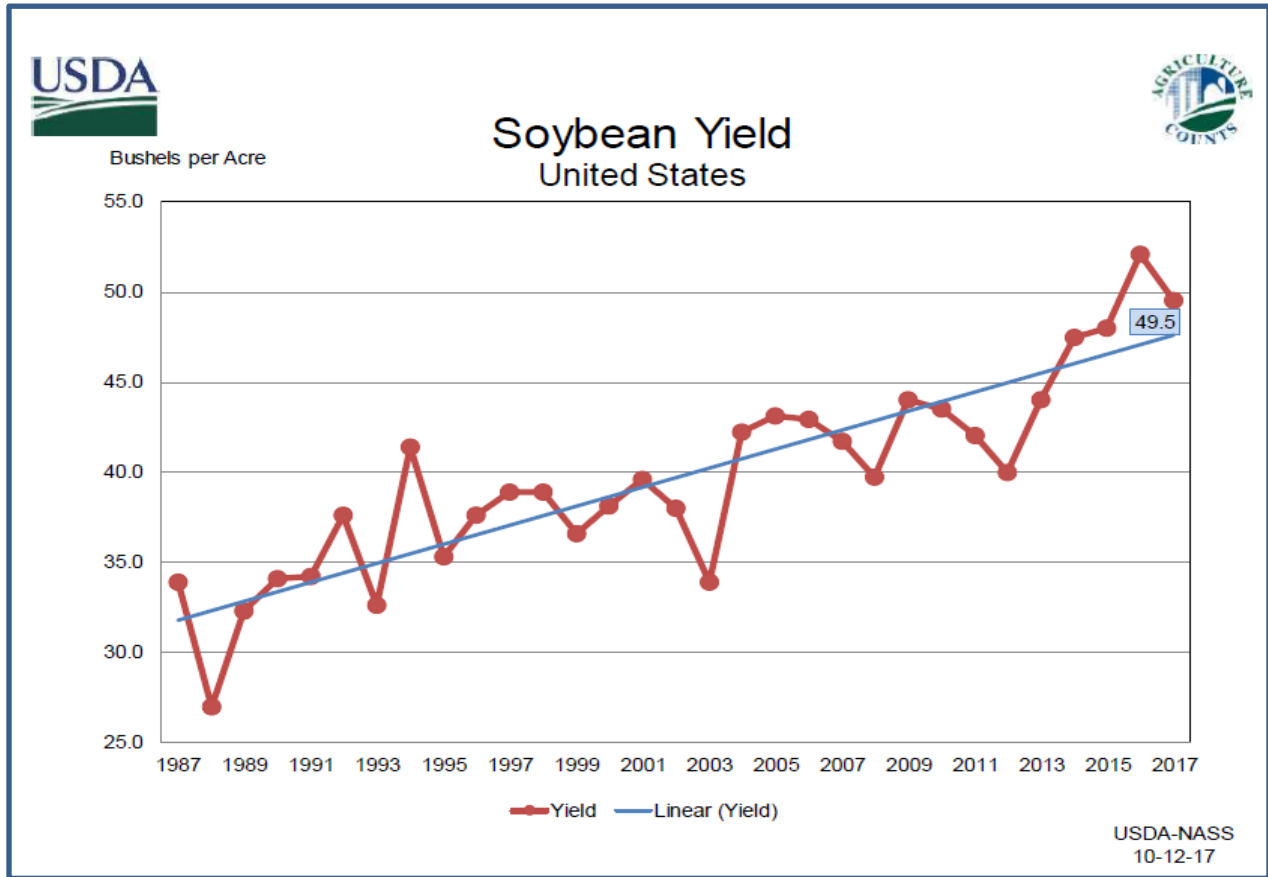


Figure 3. U.S. Soybean Yield: 1987-2017.
 Source: (USDA-NASS, 2017b)

Future improvements in soybean yield are challenged by both biotic and abiotic stress factors. Some typical abiotic stress factors include salinity, non-optimal temperatures, drought, flooding, and poor soil quality (Chung and Singh, 2008). One objective of soybean breeding programs is to develop varieties that maintain yield under a broad array of environmental conditions.

3.1.1 Acreage and Regional Distribution of Soybean Production

Field testing of GE crops began in the 1980s, (Fernandez-Cornejo and Caswell, 2006), and GE soybeans became commercially available in 1996 (Fernandez-Cornejo and Caswell, 2006; USDA-ERS, 2011a). By 2017, 94% of U.S. soybean acreage was planted in a GE variety (Table 2).

Table 2. GE Soybean Varieties as a Percentage of the Total U.S. Soybean Crop.

State	Percent GE HR Soybean Varieties Grown in:	
	2016	2017
Arkansas	96	97
Illinois	94	93
Indiana	92	92
Iowa	97	94
Kansas	95	94
Michigan	95	94
Minnesota	96	96
Mississippi	99	99
Missouri	89	87
Nebraska	96	94
North Dakota	95	95
Ohio	91	91
South Dakota	96	96
Wisconsin	94	92
Other States*	94	94
UNITED STATES	94	94
*All other states in the U.S. estimating program		

Source: (USDA-NASS, 2018c)

3.1.2 Agronomic Practices for Soybean Production

Soybean is an herbaceous annual in that grows as an erect bush (OECD, 2000). It is a short-day plant, so flowers when days have fewer daylight hours (OECD, 2000). As a result, photoperiod and temperature responses are important in determining areas of specific varietal adaptation. Soybean varieties are identified based on geographic bands of adaptation that run east-west, determined by latitude and day length. In North America, there are 13 described maturity groups (MGs), ranging from MG 000 in the north (45° latitude) to MG X near the equator. Within each maturity group, varieties are described as early, medium, or late maturing (OECD, 2000).

Soybean seed germinates when soil temperature reach about 50°F (10°C). Under favorable conditions, seedlings emerge in 5-7 days. Inoculation of soybean fields that were previously used to grow another crop with *Bradyrhizobium japonicum*, a nitrogen fixing bacterium that develops a symbiotic relationship with soybeans, dramatically increases plant production (Pedersen, 2007; OMAFRA, 2011; Missouri University of Science and Technology, No Date). Inoculation is necessary for optimum efficiency of the nodules that form on soybean root systems (Berglund and Helms, 2003; Pedersen, 2007). In the 1990s, the row spacing recommendation for soybeans was narrowed to seven inches to achieve greater yields. This has since been expanded to 15 inches to promote greater air circulation, which reduces diseases that impact yields (USDA-ERS, 2010b).

Soybeans require more moisture to germinate than corn, and seed-to-soil contact is important for good early season soybean growth. An adequate water supply is especially important at planting, during pod-filling, and seed filling (Hoeft *et al.*, 2000). Soybeans require approximately 20-25 inches of water during the growing season. In 2008, only 9% of harvested soybean acreage (about 12 million acres) was irrigated. States with the most (about 85%) irrigated soybean acreage are Nebraska, Arkansas, Mississippi, Missouri, and Kansas (USDA-NASS, 2010).

Soybeans tolerate a broad spectrum of growing environments, but maximum yields require optimum soil conditions that include a pH range of 5.8-7.0 (NSRL, No Date), and adequate levels of phosphorus, potassium, calcium, and magnesium, plus other minor nutrients. Because soybeans develop a symbiotic relationship with *B. japonicum* that promotes nitrogen fixation from atmospheric nitrogen, fertilizer nitrogen is not always required for optimum soybean production. In areas with increased amounts of salt or carbonates, or those that have no past history of soybean production, nitrogen amendments prior to or at the time of planting have been shown to increase yield if soil tests reveal levels that are not adequate (Franzen, 1999; Berglund and Helms, 2003). When grown in rotation with corn, a common practice is to fertilize the preceding corn crop with enough phosphorus and potassium to provide sufficient carry over for the subsequent soybean crop, so no supplemental fertilizer is needed (Franzen, 1999; Berglund and Helms, 2003; Ebelhar *et al.*, 2004). Adequate amounts of calcium and magnesium are normally present if soil pH is at or near the optimum pH or has been recently treated with dolomitic limestone to achieve an optimum pH (Frank, 2000; Harris, 2011).

Crop Rotation

Crop rotation is a sustainable agriculture practice of growing a series of different crops in the same field in succession, usually according to a planned cycle of plantings. The primary goal of crop rotation is to achieve maximum short term (annual or seasonal) crop yields in a system that sustains the long-term productivity of the fields. It is a strategy designed to prevent long-term profit loss from depletion of resources by maintaining them at a level that supports profitable crop productivity (Hoeft *et al.*, 2000). When applied effectively, rotating crops can improve soil quality and fertility. Since the roots of soybean plants share a symbiotic relationship with *B. japonicum* that fixes atmospheric nitrogen, this may decrease the requirements for fertilizer inputs for following crops, such as corn or wheat. Crop rotation also tends to reduce the incidence of plant diseases, insect pests and weed competition (USDA-ERS, 1997; Berglund and Helms, 2003). Crop rotation may also include fallow periods in which no crop is grown for a season, or seeding of fields with a cover crop that prevents soil erosion and can provide livestock forage (Hoeft *et al.*, 2000; USDA-NRCS, 2010a).

Maximizing economic returns results from rotating crops in a sequence that efficiently produces the most net returns for producers. Many factors at the individual farm level influence crop rotation choices, including soil type, anticipated commodity prices, farm labor requirements, fuel, fertilizer and seed costs, and regional climatic conditions (Langemeier, 1997; Hoeft *et al.*, 2000; Duffy, 2011).

Soybeans are commonly rotated with corn, winter wheat, spring cereals, and dry beans (OECD, 2000). Cropland used for soybean and corn production is nearly identical in many areas, such as Illinois, where more than 90% of the cropland is planted in a two-year corn-soybean rotation

(Hoeft *et al.*, 2000). Approximately 95% of U.S. soybean acreage is in a rotation system (USDA-ERS, 2005).

Soybean itself may also be a cover crop in short rotations for its fixed nitrogen contribution to soil (Hoorman *et al.*, 2009a). Where continuous soybean production is undertaken, yields may be reduced in the second or later years because pest and disease incidence may increase (Pedersen *et al.*, 2001; Monsanto, 2010). In the Midwest, the crops planted most often after soybean included corn, wheat, and soybean. Those soybean plantings in the Southeast that are grown in a rotation are most frequently followed by corn and cotton. Corn is most often the crop of choice for rotation with soybeans grown in the coastal states of the eastern United States. Double-cropping soybeans is also an option to increase returns. Soybeans are frequently planted in winter wheat stubble to produce a second crop in the same growing season. Double-cropping maximizes profits if high commodity prices can support it, but careful management to achieve uniform stands to sustain high yields and profitability is needed. These requirements include selection of appropriate varieties, a higher seeding rate, closer row spacing, and adequate moisture for germination (McMahon, 2011).

Tillage

Soybean growers till soil to prepare seedbeds, dislodge compaction, incorporate fertilizers and herbicides, manage drainage within and outside fields, and control weeds (Heatherly *et al.*, 2009). Tillage systems include conventional, reduced, conservation (including mulch-till, strip-till, ridge-till, and no-till), and deep. The primary purpose of conservation tillage is to reduce soil erosion (Heatherly *et al.*, 2009).

In conventional tillage, after harvest crop residue is plowed into the soil to prepare a clean seedbed for planting and to reduce the growth of weeds, leaving less than 15% of crop residue on the surface (Heatherly *et al.*, 2009; Towery and Werblow, 2010). Conservation tillage uses tools that disturb soil less and leave more crop residue on the surface (at least 30%). No-till farming only disturbs the soil for planting seed (USDA-NRCS, 2005; Towery and Werblow, 2010). Crop residue includes materials left in an agricultural field after the crop has been harvested, including stalks and stubble (stems), leaves and seed pods (USDA-NRCS, 2005). Residue aids in conserving soil moisture and reducing wind and water-induced soil erosion (USDA-ERS, 1997; USDA-NRCS, 2005; Heatherly *et al.*, 2009). No-till systems are not meant to control weeds or dislodge soil compaction, so other strategies such as herbicide applications and track management of heavy machinery must be used in no-till fields for these problems.

Since 1996, the use of a no-till has increased more than any other reduced tillage system. Nearly all of this shift is attributable to reliance on HR crop varieties (e.g., soybean, corn, cotton, canola) (Fawcett and Towery, 2002). A 1997 survey revealed that farmers using no-till practices were more likely to adopt HR soybeans as an effective weed control practice. However, the same study also found that the reliance on HR soybean varieties did not encourage adoption of no-till practices. Surveys between 1996 and 2001 found that producers using HR seed varieties were more likely to use conservation tillage than producers that did not grow HR crops (Fawcett and Towery, 2002). A survey of 1,195 producers conducted between November 2005 and January 2006 by (Givens *et al.*, 2009) reported that 56% of farmers who had been using

conventional tillage had shifted to either no-till (25%) or reduced-till (31%) after adopting GE glyphosate-resistant (GR) crops.

There has been a corresponding increase in the use of no-till production practices (Carpenter *et al.*, 2002; Sankula, 2006) with the increase in availability of GR soybean varieties. From the introduction of GR soybeans in 1996 until 2004, no-till practices increased by 64% (Sankula, 2006). Use of conservation tillage practices by U.S. soybean growers increased by 12 million acres (4.9 million hectares) from 51% in 1996 to 63% in 2008 (NRC, 2010).

No-till soybean production is not suitable for all producers or areas. For example, no-till soybean production is less successful in heavier, cooler soils more typical of northern latitudes (Kok *et al.*, 1997; NRC, 2010) where the potential for increased weed and insect pests and disease requires careful management (Peterson, 1997; Pedersen *et al.*, 2001).

Agronomic Inputs

Agronomic inputs, including water, soil and foliar nutrients, inoculants, fungicides, pesticides, and herbicides, are used in soybean production to maximize yields (Hoeft *et al.*, 2000; OECD, 2000; Clevenger, 2010; OMAFRA, 2011). Soil and foliar macronutrient applications to soybean primarily include nitrogen, phosphorous (phosphate), potassium (potash), calcium, and sulfur, with other micronutrient supplements such as zinc, iron, and magnesium applied as needed (Whitney, 1997; USDA-NASS, 2007; NSRL, No Date). Irrigation provides essential water for growth where rainfall is insufficient or erratic (see sections on Water Resources in this chapter, and Soil Quality in Chapter 4 for further details).

Nutrients and Fertilizers

Fertilizer and nutrients may be applied to the soil or sprayed on foliage in soybean production. Soil fertilizers have differential availability to plants based upon soil characteristics and moisture. For example, in a drought year, potassium may become fixed between clay layers until water moves through the soil again (Corn and Soybean Digest, 2012). Fertilizers such as nitrogen, potassium and phosphorous may be incorporated into the soil at soybean planting by tillage or drilling (Vitosh *et al.*, 2007). Fertilizer may be purposefully concentrated in bands at varying depths in the soil to enhance nutrient availability at different growth stages (Vitosh *et al.*, 2007; Fernandez and White, 2012). In conservation tillage, phosphorous and potassium may become vertically stratified from use of surface broadcast fertilizers that minimize soil disturbance. Therefore, there is a trend among farmers to enhance nutrient availability to sustain higher yields (Fernandez and White, 2012).

On average, soybean removes 0.85 lbs of phosphate (phosphorous) and 1.2 lbs of potash (potassium) per bushel of seed produced (CAST, 2009). Table 3 includes a summary of removal rates of nitrogen, phosphate and potassium for soybean, and corn and wheat that are commonly rotated with soybean (Silva, 2011). The data show that soybeans remove more nitrogen, potassium and phosphorous than either corn or wheat. The comparisons in Table 4 are for nutrients removed for different soybean yield rates, and indicate that higher yields remove more nutrients from the soil (Snyder, 2000).

Table 3. Nutrient Removal Rates for Commonly Grown U.S. Grain Crops.

Crop	Pounds of Fertilizer Removed/Bushel Produced/Acre:		
	Nitrogen	Potash	Phosphate
Corn	0.9	0.37	0.27
Soybean	3.8	0.8	1.4
Wheat	1.2	0.63	0.37

Source: Silva (2011)

Table 4. Soybean Nutrient Removal from Soil at Different Bushel/Acre Yield Rates.

Yield: Bushels/ Acre	Amount of Fertilizer Removed (pounds/acre)				
	Nitrogen	Potash	Phosphate	Magnesium	Sulfur
40	220	38	140	16	14
55	290	53	190	22	18
70	360	67	220	28	22

Source: Snyder (2000)

Research summarized by the Council for Agricultural and Science Technology indicates that adding nitrogen displaces rather than supplements natural cost-free nitrogen production in soybean cultivation, as the size, weight, and number of nitrogen-fixing nodules formed on soybean roots are actually reduced (CAST, 2009). Application of nitrogen under drought conditions in acid subsoil conditions, in soils having low residual nitrogen, in a high-yield environment, or in late or double crop plantings has raised soybean yields, but not enough to offset the added cost. Potassium may change considerably from one testing time to the next, so it should also be regularly monitored to ensure optimum yields (CAST, 2009). Phosphorous should be applied at least at the crop removal rate determined by regular soil testing.

There is some public concern that phosphorous used for crop fertilizer is depleting phosphate rock deposits, which are a finite resource. However, finite does not necessarily mean that world reserves are being depleted. Price fluctuations for phosphorous crop fertilizer are not caused by phosphate rock depletion; they result from numerous market factors (Heckenmueller *et al.*, 2014).

Soybeans are often grown in rotation with corn, and soil nutrient supplements applied to corn are often adequate to support soybean crops the following year without additional supplementation (Bender *et al.*, 2013), making it more economical to apply nutrients such as nitrogen, potassium and phosphorous ahead of the corn crop in two-year corn-soybean rotations (CAST, 2009). Other research has found that annual supplementation of potassium and phosphorous is most beneficial in the South where soybean to soybean rotation is more common (Heatherly, 2012). Corn and soybean take up nutrients and both concentrate different nutrients in different parts of

the plants (Mallarino *et al.*, 2011). In plants, potassium is located mainly in the cytoplasm of cells and cell vacuoles where it activates enzymes, regulates stomata functions, and assists in transfer of compounds across membranes. In contrast, most phosphorous is located in cell membranes and nucleic acids, which is incorporated into plant organic matter, and is a major component of the metabolic, energy-rich compounds that drive plant metabolism.

Compared to potassium much more phosphorous is absorbed from the soil by soybeans (Table 4). Some portion of these nutrients absorbed by the crop may be returned to the soil by leaving plant residue such as soybean foliage in the field (Mallarino *et al.*, 2011). However, by maturity, soybean seed contains approximately 65% of the nitrogen, 73% of the phosphorous, and 55% of the potassium absorbed during the season (Snyder, 2000), so harvesting the seed removes considerable portions of nutrients from the field.

Data for average chemical fertilizer application rates (USDA-NASS, 2018d) for 2017 for USDA program states showed that nitrogen was applied at 18 pounds per acre (lb/A), and phosphate and potash were applied at an average annual rate of 52 and 91 83 lb/A respectively. These supplements were applied on average only once per crop year. The relatively low rate of soybean nutrient supplementation likely results because most soybeans are rotated after corn crops that leave sufficient nutrients to sustain the subsequent soybean crop.

Inoculants

When added to soil as an inoculant, the bacterial symbiont, *B. japonicum* can increase soybean yields by about one bushel per acre (Conley and Christmas, 2005). Historically, a nonsterile peat powder was applied to seed at planting as an inoculant carrier to the field. Improvements have since been made in inoculant manufacturing, such as using sterile carriers, adhesives to stick the inoculant to seeds, liquid carriers, concentrated frozen products, new organism strains, pre-inoculants, and inoculants containing extended biofertilizer and biopesticidal properties (Conley and Christmas, 2005). Industry has estimated that about one-third of U.S. soybean acreage was inoculated in 2009 (Seed Today, 2009).

Insecticides

Feeding on soybean foliage, seed pods and roots by several different types of insects can reduce yield (Lorenz *et al.*, 2006; Whitworth *et al.*, 2011). Nematodes are also serious pests, especially the soybean cyst nematode, because effective pesticides are not available (Nelson and Bradley, 2003). A combination of crop rotation to a non-susceptible host and the use of resistant varieties are used to manage the problem (Nelson and Bradley, 2003). However, these resistant soybean varieties often provide lower yields than other commercially available varieties.

Insecticides: Economic thresholds for soybean insect infestations are used to decide if and when to apply integrated pest management (IPM) control measures (Higgins, 1997). Thresholds are typically based on field survey data for the number of pests present and/or extent of defoliation, such as those developed for management strategic plans of the National Information System of Regional IPM Centers (USDA, 2011). Data summarizing USDA NASS chemical insecticide (active ingredient; a.i.) usage in 2017 for U.S. soybeans are included in Table 5. Based on total soybean acreage treated, the three most commonly applied insecticides were lambda-cyhalothrin, bifenthrin, and chlorpyrifos, which were applied to 8%, 5% and 3% of soybean acreage,

respectively (USDA NASS, 2017c). Some growers may use other methods to control insect infestations including crop rotation, tillage, and biological control (i.e., beneficial organisms [predators and parasites of pest species]).

Table 5. Insecticides Most Commonly Applied to Soybean Acreage* in 2017.

Insecticide (Active Ingredient)	Percent of Soybean Acreage Treated	Average Application Rate (lbs a.i./acre)	Total Applied (lbs a.i)
Lambda-cyhalothrin	8	0.03	215,000
Bifenthrin.	5	0.06	247,000
Chlorpyrifos	3	0.34	876,000
Imidacloprid	2	0.08	109,000
Zeta-cypermethrin	2	0.02	25,000
Acephate	1	0.69	861,000
Chlorantraniliprole	1	0.06	55,000
Thiamethoxam	1	0.04	44,000
Beta-Cyfluthrin	1	0.04	41,000
^a Expressed as acid equivalent		Source: (USDA NASS, 2017c)	

Fungicides: Several plant diseases can reduce soybean yields. Most are controlled by planting resistant varieties, and relatively few are treated with a pesticide. When pesticides are used, most frequently they are fungicides.

Diseases that infect soybeans are caused by bacteria, fungi and viruses (Jardine, 1997). The most serious soybean diseases include *Cercospora* foliar blight, purple seed stain, aerial blight, soybean rust, pod and stem blight, and anthracnose (Padgett *et al.*, 2011). Besides selecting varieties with resistance to the diseases prevalent in a growing region (Hershman, 1997), growers plant sterilized disease-free seed (Jardine, 1997), and use other best management practices (BMPs) such as rotating crops to prevent buildup of disease organisms in fields, and providing adequate nutrients and water for growth (Nelson, 2011). Seed treatments with various chemicals such as fungicides, promote successful seed germination (Jardine, 1997).

When other management measures fail to control diseases, soybean growers have some chemical treatment options, but most are only effective on diseases caused by fungi (Jardine, 1997; Padgett *et al.*, 2011). According to USDA NASS, the fungicides most commonly applied to soybeans in 2017 were pyraclostrobin, fluxapyroxad, azoxystrobin, propiconazole, trifloxystrobin, and picoxystrobin (applied to 5%, 5%, 4%, 3%, 2%, and 1% of U.S. soybean acreage respectively (USDA NASS, 2017c).

Herbicides: Weeds have been estimated to cause a potential yield loss of 37% in world-wide soybean production (Heatherly *et al.*, 2009). Weeds compete with soybean for light, nutrients, space and soil moisture. They also can harbor insect and soybean disease pests, and interfere with harvesting by slowing and/or damaging equipment (Loux *et al.*, 2008). Weed density and the period weeds compete with the soybean crop influence yield losses. The longer weed emergence is delayed, the lower the impact will be on yield. Soybean plants withstand early-season weed competition longer than corn because the soybean canopy closes sooner after emergence (Boerboom, 2000). The extent of canopy closure restricts the light required by weeds growing below the soybean plants. Soybean canopy closure can be accelerated by some management practices. For instance closure occurs more quickly when soybean is drilled or planted in narrow rows (Boerboom, 1999). Volunteer corn can be a serious weed in soybean crops. In some studies, it has also been observed that, depending on factors such as weed species and environmental conditions (e.g., rainfall amounts), some soybean varieties can successfully compete with weeds without any yield reduction (Krausz *et al.*, 2001). Place *et al.* (2011) have determined that larger soybean seeds produce a larger canopy more quickly and are, therefore, more successful at outcompeting weeds.

Weed management for soybeans has been done primarily with herbicides since the mid-1960s, and will continue to be an important practice for the foreseeable future. One review of aggregate data for crop yield losses and herbicide use estimated a \$16 billion (20%) U.S. crop production loss in value if herbicides were not used (Gianessi and Reigner, 2007), even if additional tillage and hand weeding labor replaced herbicides.

Growers consider several factors when selecting a weed control program including cost, potential adverse effects on the crop, residual effects that limit following crop choices in a rotation cycle, and control efficacy. All herbicides and other pesticides can only be applied legally in strict accordance with their EPA registration labels. What is allowed by the label is a primary consideration for growers. The herbicides most commonly applied to soybeans in 2017 are listed in Table 6.

Table 6. Top Five Herbicides Used to Treat U.S. Soybean Acreage in 2017.

Herbicide (Active Ingredient)	Percent of Acreage Treated	Average Application Rate (lbs a.i./acre)	Total Applied (million lbs a.i.)
Glyphosate isopropylamine salt	46	1.145 ^a	44.2 ^a
Glyphosate potassium salt	30	1.590 ^a	40.3 ^a
Sulfentrazone	22	0.179	3.3
Fomesafen sodium	19	0.240 ^a	3.9 ^a

Metribuzin	18	0.256	3.7
^a Expressed as acid equivalent		Source: USDA NASS, 2017d	

Management of Weed Herbicide Resistance

For many years, growers were able to effectively control or suppress virtually all weeds in soybean with glyphosate. However, a number of weed species have developed resistance to glyphosate, and the number of acres infested with resistant biotypes has been increasing. To date, 42 weed species resistant to glyphosate have been identified globally, 17 of which are found in the United States (Heap, 2018). Glyphosate-resistant (GR) weed biotypes in U.S. soybean fields vary by state. Each of these species is generally controlled by glufosinate except hairy fleabane, Italian ryegrass, and rigid ryegrass, which are not typically a problem in soybean fields.

Herbicide usage trends since the adoption of GE crops are the subject of much interest, research and debate. The initial assessments indicated a decline in herbicide use in the early years of HR crop production (Carpenter *et al.*, 2002). Some argue that this was followed by an increase in the volume of herbicide usage as the HR varieties became increasingly popular (Benbrook, 2009). Others report a continuing decline in herbicide use with the adoption of GE crops (Fernandez-Cornejo and Caswell, 2006), or little or no change in the amount of herbicide active ingredients applied to soybeans (Brookes and Barfoot, 2010). The contradictory findings have been attributed to the different measurement approaches used by researchers, the way data were adjusted for the effects of factors affecting pesticide use such as weather or cropping patterns, and the statistical procedures used to analyze the data (NRC, 2010).

Herbicide applications and other weed control practices exert selection pressures on weed communities. This can result in shifts in weed community structure (i.e., shifts in the types of weeds present) that favor weeds that don't respond to the herbicide or other control methods being used (Owen, 2008). In many instances, these shifts in weed communities are attributable to the presence HR weed biotypes. The development of herbicide resistance is primarily caused by natural selection for individuals with HR traits resulting from repeated sublethal exposure to one or a limited number of herbicides (Durgan and Gunsolus, 2003; Duke, 2005). HR weeds may occur in a field because of natural selection and also by the movement of HR biotypes among locations. Both the increased selection pressure resulting from the exclusive or extensive and widespread use of glyphosate herbicides on GR crops without other types of herbicides, and changes in weed management practices (i.e., conservation tillage or no-till) have resulted in weed population shifts and increased glyphosate resistance among some weed populations (Duke, 2005; Owen, 2008).

GR crops, themselves, do not influence weeds any more than non-transgenic crops. HR weed biotypes result from natural selection for those biotypes under the current weed control methods, rather than gene transfer from the crop to the weed. It is the prolonged use of the same weed control tactics by growers that causes long-term selection pressures that change weed communities and contribute to the induction of HR weeds (Owen, 2008). More details about HR weeds are reviewed in the Plant Communities section of this chapter.

The first HR biotypes were described in the 1950s, but the number of weeds resistant to herbicides increased dramatically in the 1980s and 1990s. (Heap, 2018). A recent census identified 161 weed species in the United States that are resistant to one or more herbicides, and HR weeds have been reported from 70 countries (Heap, 2018). The management of GR weeds has become a substantial challenge for U.S. agriculture especially soybean production because good alternative options are limited (Powles, 2008a; Powles, 2008b; Owen, 2011b).

Some strategies proposed to manage GR weeds (Boerboom, 1999; Beckie, 2006; Sammons *et al.*, 2007; Frisvold *et al.*, 2009), include:

- Rotating different herbicides that have different modes of action
- Site specific herbicide applications
- Use of highest labeled application rate allowed by the label (prevents sublethal dosing)
- Crop rotation
- Use of tillage for supplemental weed control
- Cleaning equipment between fields
- Controlling weed escapes
- Controlling weeds early
- Scouting for weeds before and after herbicide applications

Volunteer soybeans are not a widespread management problem, and occur most often in parts of the southern United States. In production systems where soybeans are rotated with other crops, soybeans can be a volunteer weed (Owen and Zelaya, 2005), but this is not considered difficult to manage because soybean seeds rarely remain viable the following season and any interference they may pose to subsequent crops is minimal. Furthermore, herbicides usually used for weed control in corn, the crop most often rotated with soybeans, are also effective at controlling volunteer soybean (Owen and Zelaya, 2005). Conversely, volunteer GR corn in soybean is a greater concern (Owen and Zelaya, 2005). Glyphosate had been used to control all weeds, including corn in soybean, yet, the increase in cultivation of GR corn has created problems for growers in the Midwest who manage volunteer corn with glyphosate. Growers must often include graminicides (herbicides that control weedy grasses) as part of their weed management strategy (Owen and Zelaya, 2005).

Soybean Yield Increases

Because of recent trends in farm production and land area, soybean growers will have the future challenge of expanding agricultural output by raising productivity on a stable or reduced land area (OECD-FAO, 2008). This implies that most of the projected expansion in soybean production is expected to come from increasing yield, not increasing crop acreage (OECD-FAO, 2008).

Egli (2008) reviewed historical trends in U.S. corn and soybean back to the first available data in 1924 to document soybean yield increase. Improved management practices such as mechanization, narrow-row planting, earlier planting, adoption of conservation tillage, increased weed control, and decreased harvest loss contributed to increased yields (Egli, 2008).

Agricultural biotechnology has further enhanced crop yields. For example, De Bruin and Pedersen (2009) estimate soybean cyst nematode-resistant GE soybean varieties produced yields ranging from 17% to 19% higher than comparative new non-resistant varieties.

USDA projections through 2021/2022 show an average annual rate of increased average yields of 0.45 bushels per acre for the period 2012/2013 to 2021/2022, which results in an average U.S. yield of 46.05 bushels per acre for the period (USDA-OCE, 2018). While USDA projects increasing yields, the projected rate of increase is lower than the past rate. Current and future factors that negatively affect yield increases are the expansion of soybean production into northern and western parts of the country, where yields are typically lower than in the Midwest.

3.1.3 Soybean Seed Production

Growers may plant certified soybean seed, uncertified seed, and “binrun” soybean seed (i.e., grown and stored on individual farms) (Oplinger and Amberson, 1986). Seed production differs from grain production because of additional biological, technical, and quality control factors required to maintain varietal purity. Genetic purity in the production of commercial soybean seed is regulated through a system of seed certification which ensures the desired traits in that particular seed remain within purity standards (Bradford, 2006).

The production and certification of foundation, registered, certified, or quality assurance seeds are administered by state and regional crop improvement associations, several of which are chartered under the laws of the state(s) they serve (e.g., see Mississippi Crop Improvement Association, 2008; Illinois Crop Improvement Association, 2013; SSCA, No Date-a; Virginia Crop Improvement Association, No Date). These agencies certify varietal purity and identity, while issues concerning germination and mechanical purity are governed under state and federal seed laws. Seed quality includes a variety of attributes, including genetic purity, vigor, weed seed content, seed borne diseases, and the presence of foreign material such as dirt or chaff (Bradford, 2006). The genetic purity of the seed must be maintained to maximize the value of the new variety (Sundstrom *et al.*, 2002). Some general examples of seed production practices include certification of origin and class, documentation of field cropping history, isolation from weeds and soybean grain crops, decontamination of cultivation, transportation, and storage equipment, and inspection and laboratory analysis of harvested seeds from approved fields (Mississippi Crop Improvement Association, 2008; South Dakota Crop Improvement Association, 2011; Illinois Crop Improvement Association, 2013; SSCA, No Date-a; Virginia Crop Improvement Association, No Date). There are also crop specific field, inspection, isolation, and harvested seed purity standards (e.g., percentage of pure seed, inert matter, weed seeds, other crop seeds, other variety seeds, and germination) (South Dakota Crop Improvement Association, 2011; Virginia Crop Improvement Association, 2013; SSCA, No Date-b).

The U.S. Federal Seed Act of 1939 recognizes seed certification and official certifying agencies. Implementing regulations further recognize land history, field isolation, and varietal purity standards for seed. States have developed laws to regulate the quality of seed available to farmers (Bradford, 2006). Most of the laws are similar in nature and have general guidelines for providing information on the label for the following:

- Commonly accepted names of agricultural seeds

- Approximate total percentage by weight of purity
- Approximate total percentage of weight of weed seeds
- Name and approximate number per pound of each kind of noxious weed seeds
- Approximate percentage of germination of the seed
- Month and year the seed was tested

Various seed associations have standards to help maintain the quality of soybean seed. The AOSCA (AOSCA, 2012c) defines the classes of seed as follows:

- *Breeder*: developed and used by plant breeders
- *Foundation*: progeny of Breeder or Foundation maintained to preserve specific genetic identity and purity.
- *Registered*: progeny of Breeder or Foundation maintained for satisfactory genetic identity and purity.
- *Certified*: progeny of Breeder, Foundation, or Registered handled to maintain satisfactory genetic identity and purity.

Seed certification systems differ from Identity Preservation (IP) systems for certain agricultural commodities. IP refers to a system of production, handling, and marketing practices used to maintain the integrity and purity of crop products throughout the food supply chain (Sundstrom *et al.*, 2002). IP systems are used to meet the demands for specialized grain products, including those from crops with output-specific traits (e.g., high oleic oil), without specific traits or attributes (e.g., non-GE crops), grown under specific production methods (e.g., organic crops), and requiring rigorous safeguards and confinements practices (e.g., pharmaceutical and industrial crops) (Elbehri, 2007).

Soybean is self-pollinated and propagated commercially from seed (Hoeft *et al.*, 2000; OECD, 2000). In the United States, there are no *Glycine* spp. found outside of cultivation, so the potential for outcrossing is minimal (OECD, 2000). Minimum Land, Isolation, Field, and Seed Standards (7 CFR part 201.76) specify isolation distances for the production of Foundation, Registered and Certified soybean seeds to prevent mechanical mixing from potential contaminating sources.

3.1.4 Organic Soybean Production

In the United States, only products produced using specific methods and certified under the USDA's Agricultural Marketing Service National Organic Program (NOP) can be labeled as "USDA Organic" (USDA-AMS, 2008). Organic certification is a process for validation of production practices, not certification of the end product. USDA organic certification requires that specific production methods be documented by the producer and certified by an independent auditor.

An accredited organic certifying auditor conducts an annual review of a producer's organic system plan and practices documented in records maintained on site. The auditor also makes on-site inspections to confirm accuracy of recordkeeping. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards. The

NOP regulations (7 CFR § 205.2) specifically exclude certain methods that cannot be used for the production of products labeled “USDA Organic.”

Common practices organic growers may use to exclude GE products include planting only organic seed, staggering planting earlier or later than neighboring farmers who may be using GE crops, so that the crops will flower at different times to establish adequate isolation between organic fields and neighboring fields, where non-organic crops are grown to minimize the possibility of cross-pollination (NCAT, 2003).

Although the NOP standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the NOP standards (USDA-AMS, 2008). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2008).

3.2 PHYSICAL ENVIRONMENT

3.2.1 Soil Quality

Soil consists of solids (minerals and organic matter), liquids, and gases. Inorganic and organic matter harbor a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil is characterized by its layers (USDA-NRCS, 1999b). It is further distinguished by its ability to support rooted plants in a natural environment. Soil establishes the capacity of a site’s biomass vigor and production in terms of air, water, temperature moderation, protection from toxins, and nutrient availability. Soils also determine a site’s susceptibility to erosion by wind and water, and its flood attenuation capacity.

Important soil properties include temperature, pH, soluble salts, amount of organic matter, the carbon-nitrogen ratio, numbers of microorganisms and soil fauna, and all vary seasonally, and over extended periods of time (USDA-NRCS, 1999b). Soil texture and organic matter levels directly influence its shear strength, nutrient holding capacity, and permeability. Soil taxonomy was established to classify soils according to the relationship between soils and the factors responsible for their character (USDA-NRCS, 1999b). Soils are organized into four levels of classification. Soils are differentiated based on characteristics such as particle size, texture, and color, and classified taxonomically into soil orders based on observable properties, such as organic matter content and degree of soil profile development (USDA-NRCS, 2010b). The Natural Resources Conservation Service maintains county maps for the entire United States.

Soybeans are normally grown in agricultural fields managed for crop production and are best suited to fertile, well-drained medium-textured loam soils, but can be produced in a wide range of soil types (Berglund and Helms, 2003; NSRL, No Date). Soybeans need a variety of macronutrients, such as nitrogen, phosphorus, potassium, calcium, magnesium, and sulfur, at

various levels (NSRL, No Date). They also require smaller amounts of micronutrients such as iron, zinc, copper, boron, manganese, molybdenum, cobalt, and chlorine. These micronutrients may be deficient in poor, weathered soils, sandy soils, alkaline soils, or soils excessively high in organic matter. As with proper nutrient levels, soil pH is critical for soybean development. Soybeans grow best in soil that is slightly acidic (pH 5.8 = 7.0). Soil with a pH that is too high (7.3 or greater) negatively affects yield (Cox *et al.*, 2003; NSRL, No Date). Similarly, soils that are high in clay and low in humus may impede plant emergence and development (NSRL, No Date). Soils with some clay content may increase moisture availability during periods of low precipitation (Cox *et al.*, 2003). Soybean yield is highly dependent upon soil and climatic conditions. In the United States, the soil and climatic requirements for growing soybean are very similar to corn. The soils and climate in the Midwest, portions of the Great Plains and eastern regions of the United States provide sufficient water under normal climatic conditions to produce a soybean crop. Soil texture and structure are key components in determining water availability in soils. Medium-textured soils hold more water, allowing soybean roots to penetrate deeper in medium-textured soils than in clay soils (Berglund and Helms, 2003; Cox *et al.*, 2003).

Land management practices for soybean cultivation can affect soil quality. While practices such as tillage, fertilization, the use of pesticides and other management tools can improve soil health, they can also cause substantial damage if not properly used. Several concerns relating to agricultural practices include increased erosion, soil compaction, degradation of soil structure, nutrient loss, increased salinity, change in pH, and reduced biological activity (USDA-NRCS, 2001).

Conventional and conservation tillage may be used for the cultivation of soybean. Reducing excessive tillage through practices such as conservation tillage minimizes the loss of organic matter and protects the soil surface by leaving plant residue on the surface. Management of crop residue is one of the most effective conservation methods to reduce wind and water erosion. It also benefits air and water quality and wildlife (USDA-NRCS, 2006a). Residue management that uses intensive tillage and leaves low amounts of crop residue on the surface results in greater losses of soil organic matter (SOM). Intensive tillage turns the soil over and buries the majority of the residue, stimulating microbial activity and increasing the rate of residue breakdown (USDA-NRCS, 1996). The residues left after conservation tillage increase organic matter and improve infiltration, soil stability and structure, and soil microorganism habitat (Fawcett and Caruana, 2001; USDA-NRCS, 2006b)). Organic matter is probably the most vital component in maintaining quality soil. It is instrumental in maintaining soil stability and structure, reduces the potential for erosion, provides energy for microorganisms, improves infiltration and water holding capacity, and is important in nutrient cycling, cation exchange⁴ capacity, and the degradation of pesticides (USDA-NRCS, 1996).

The residue left from conservation tillage practices increases SOM in the top three inches of the soil and protects the surface from erosion, while maintaining water-conducting pores. Soil aggregates in conservation tillage systems are more stable than that of conventional tillage because the products of SOM decomposition, and the presence of soil bacteria and fungal hyphae

⁴ Cation Exchange Capacity is the ability of soil anions (negatively charged clay, organic matter and inorganic minerals such as phosphate, sulfate, and nitrate) to adsorb and store soil cation nutrients (positively charged ions such as potassium, calcium, and ammonium).

(filamentous structures that compose the main growth) bind aggregates and soil particles together (USDA-NRCS, 1996). Although soil erosion rates are dependent on numerous local conditions such as soil texture and crops grown, a comparison of 39 studies contrasting conventional and no-till practices showed that, on average, no-till practices reduce erosion by a factor of 488 times compared to conventional tillage (Montgomery, 2007). From 1982 through 2003, erosion on U.S. cropland dropped from 3.1 billion tons per year to 1.7 billion tons per year (USDA-NRCS, 2006a). This can partially be attributed to the increased effectiveness of weed control through the use of herbicides and the corresponding reduction in the need for mechanical weed control (Carpenter *et al.*, 2002). Conservation tillage also minimizes soil compaction because it reduces, but does not eliminate the number of times a field is tilled. Other methods to improve soil quality include: careful management of fertilizers and pesticides. Use of cover crops to increase plant diversity and limit the time soil is exposed to wind and rain. Use of buffer strips, contour strips, wind breaks, crop rotations, and varying tillage practices (USDA-NRCS, 2006b). Planting cover crops is another management practice that has become recognized as a way to increase plant diversity, reduce compaction, suppress disease, control weeds, and enhance soil nutrients (Hoorman *et al.*, 2009b; USDA-NRCS, 2011a; MDA, 2012; NWF, 2012; SARE, 2012; USDA-NASS, 2012d; Corn and Soybean Digest, 2013; Lee *et al.*, No Date) in addition to suppressing erosion by limiting the time soil is exposed to wind and rain effects.

Although conservation tillage benefits soil quality in several ways, it can also have negative effects. For example, under no-till practices, soil compaction may become a problem because tillage disrupts compacted areas (USDA-NRCS, 1996). Another concern is that not all soils (such as wet and heavy clay soils) are suited for no-till. No-till practices may also increase pest abundance compared to conventional tillage (NRC, 2010).

Numerous kinds of organisms that live in soils, ranging from microorganisms to larger macroinvertebrates, such as worms and insects, affect soil quality. The microorganisms that make up the soil community include bacteria, fungi, protozoa, and nematodes. Decomposers, such as bacteria, and saprophytic fungi, degrade plant and animal remains, organic materials, and some pesticides (USDA-NRCS, 2004). Other organisms, such as protozoans, mites and nematodes, consume the decomposer microbes and release macro- and micronutrients, making them available for plant uptake.

Another important group of soil microorganisms are the mutualists. These are the mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes that have coevolved with plants, and supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004). The bacterium, *B. japonicum*, associated with soybeans fixes nitrogen in root nodules on the plants (Franzen, 1999). Since neither soybean nor *B. japonicum* is native to North America, if a field has not been planted recently with soybeans (3-5 years), either the seed or seed zone must be inoculated with *B. japonicum* prior to soybean planting (Elmore, 1984; Pedersen, 2007).

Pesticide use has the potential to affect soil quality because it can impact the soil microbial community (see the section on Microorganisms in this chapter for more details). The length of persistence of herbicides in the environment is dependent on the concentration and rate of degradation by biotic and abiotic processes (Carpenter *et al.*, 2002). Persistence is measured by the half-life, which equates to the length of time needed for the herbicide residue to degrade to half of its original concentration. The degradation of pesticides may be dependent on

mineralization by microbes in soil, photodegradation in water, and leaching (US-EPA, 2005). In soil, pesticide persistence may be strongly influenced by moisture, temperature, organic matter content and pH (FAO, 1997; Senseman, 2007).

3.2.2 Water Resources

Surface water quality is determined by the natural, physical, and chemical properties of the land that surrounds the water body. Topography, soil type, vegetative cover, minerals, and climate all influence water quality. Surface runoff is affected by meteorological factors such as rainfall intensity and duration, and physical factors such as vegetation, soil type, and topography. When land use affects one or more of these natural physical characteristics of the land, water quality is almost always impacted to some extent. These impacts may be positive or negative, depending on the type, duration and extent of land use. Agricultural practices have the potential to substantively impact water quality because of the vast amount of acreage devoted to farming nationwide and the physical and chemical demands that agricultural use has on the land. The most common types of agricultural pollutants include excess sediment, fertilizers, animal manure, and pesticides. Agricultural non-point source pollution is the leading source of impacts on rivers and lakes, the third largest source of impairment to estuaries, and a major source of impairment to groundwater and wetlands (USDA-NRCS, 2011b).

The principal law regulating pollution of the nation's water resources is the Federal Water Pollution Control Act of 1972, which is commonly referred to as the Clean Water Act (CWA). The EPA sets water quality standards, permitting requirements, and monitors water quality. The EPA sets the standards for water pollution abatement for all waters of the United States under CWA programs, but in most cases, gives qualified states the authority to issue and enforce permits. The CWA provides the authority to establish water quality standards, control discharges into surface and subsurface waters (including groundwater), develop waste treatment management plans and practices, and issue permits for discharges under the National Pollutant Discharge Elimination System. Section 303(d) of the CWA established a process for states to identify those waters within its boundaries that do not meet minimum water quality standards. Waters that do not meet clean water standards are classified under the CWA as "Impaired Waters." Impaired Waters cannot support one or more designated uses (e.g., swimming, propagation of aquatic life, drinking, and agricultural or industrial supply). Common pollutants evaluated include sediment, chemicals, fuels, biological contaminants and pathogens, and characteristics such as oxygen availability, water temperature, and water clarity. Once a waterbody or stream segment is listed as impaired, the state must complete a plan to address the issue causing the impairment. States then develop total maximum daily loads (TMDLs) for priority waters that identify the amount of a specific pollutant from various sources that may be discharged to a water body, but still ensure that water quality standards are met for that body of water. Completion of the plan is generally all that is required to remove the stream segment from the 303(d) impaired water list and does not mean that water quality has changed. Once the TMDL is completed and approved by EPA (US-EPA, 2012), the stream segment is placed on the 305(b) list of impaired streams with a completed TMDL.

Groundwater is water that flows underground and is stored in natural geologic formations called aquifers. It is ecologically important because it sustains ecosystems by releasing a constant

supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers. Currently, the largest use of groundwater in the United States is irrigation, representing approximately 67.2% of all the groundwater pumped each day (McCray, 2012).

In regions of the United States that experience low amounts of rainfall during the growing season or during drought, soybean yields benefit from proper irrigation. Soybeans require approximately 20-25 inches of water during the growing season to produce a high yield of 40-50 bushels per acre (University of Arkansas, 2006). Approximately 9% of the planted acres of soybeans in the United States are irrigated (USDA-NASS, 2010; USDA-ERS, 2011b; USDA-NASS, 2011). A majority (approximately 73%) of U.S. irrigated soybean farms occur in the Missouri and Lower Mississippi Water Resource Regions with soybean farms in the states of Nebraska, Arkansas, Mississippi, Missouri, and Kansas accounting for 85% of all irrigated soybean acres (USDA-NASS, 2010).

In the United States, approximately 47% of the population depends on groundwater for its drinking water supply. Drinking water is protected under the Safe Drinking Water Act of 1974 (SDWA) (Public Law 93-523, 42 U.S.C. 300 *et seq.*). SDWA and subsequent amendments authorize the EPA to set national health-based standards for drinking water from source water to the tap to protect against both naturally-occurring and man-made contaminants that may be found. In an effort to protect source water, the Sole Source Aquifer (SSA) Program was developed to protect drinking water supplies in areas where there are few or no alternative sources to the groundwater resource for drinking water and other needs. EPA defines an SSA as an aquifer that supplies at least 50% of the drinking water consumed in the area overlying the aquifer. There are 77 designated SSAs in the United States and its territories (US-EPA, 2011c). The designation protects an area's groundwater resource by requiring EPA to review certain proposed projects receiving federal funds or approval within the designated area to ensure that they do not endanger the water source.

Use of pesticides can introduce chemicals to water through spray drift, cleaning of pesticide equipment, soil erosion, and filtration through soil to groundwater. Solubility (whether it readily dissolves in water), its adsorptive qualities (how tightly it binds to clay and humus particles in the soil), and its degradation (how fast it breaks down into harmless components) are some of the factors that influence the degree to which residue from an herbicide can infiltrate into ground or surface water (WSU, 2010).

Approximately 94% of the soybean acreage in the United States is planted with GE HR soybean varieties (USDA-ERS, 2017). Growers who plant GE HR soybean varieties are more likely to use conservation tillage and no-till practices than growers of non-GE soybeans (Dill *et al.*, 2008; Givens *et al.*, 2009). This shift has resulted in reduced surface water runoff and soil erosion (Locke *et al.*, 2008). Reduced tillage agricultural practices result in improved soil quality having high organic material that binds nutrients within the soil (see the section on Soil Quality in this chapter for more details). An increased amount of plant residue on the soil surface reduces the effects of pesticide usage on water resources by forming a physical barrier to erosion and runoff, allowing more time for absorption into the soil, and slowing soil moisture evaporation (Locke *et al.*, 2008). The use of GE HR soybean varieties has also promoted a shift to herbicides that have lower environmental impact, such as glyphosate (Fernandez-Cornejo and McBride, 2002).

Nutrient applications to soybeans primarily include nitrogen, phosphorus (phosphate), potassium (potash), calcium, and sulfur, with other micronutrient supplements such as zinc, iron, and magnesium applied as needed (Whitney, 1997; USDA-NASS, 2007; NSRL, No Date). Runoff from cropland areas receiving manure or fertilizer contributes to increased phosphorous and nitrogen delivery to streams and lakes. Eutrophication⁵ is accelerated by phosphorus in freshwater systems because it is the limiting nutrient. Ammonium runoff into surface waters can result in the poisoning of aquatic organisms. Nitrate in runoff from fields is carried into rivers and lakes. Elevated nitrate levels in the Gulf of Mexico contribute to the hypoxia zone, an area depleted of oxygen and marine life. Conservation tillage and other management practices are used to trap and control sediment and nutrient runoff. Water quality conservation practices benefit agricultural producers by lowering input costs and enhancing the productivity of working lands (USDA-NRCS, 2012).

3.2.3 Air Quality

The Clean Air Act (CAA) requires the EPA to set National Ambient Air Quality Standards (NAAQS) for certain common and widespread pollutants. The NAAQS, developed by the EPA to protect public health, sets limits for six criteria pollutants: ozone (O₃), nitrogen dioxide (NO₂), carbon monoxide (CO), sulfur dioxide (SO₂), lead (Pb), and inhalable particulates (particulates greater than 2.5 micrometers and less than 10 micrometers in diameter are defined as coarse particulate matter [PM₁₀], and those less than 2.5 micrometers in diameter are classified as fine particulate matter [PM_{2.5}]). The CAA requires states to achieve and maintain the NAAQS within their jurisdiction. Each state may adopt requirements stricter than those of the national standard and each is also required by EPA to prepare an implementation plan with strategies to achieve and maintain the national standard for air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the criteria pollutant(s), whereas areas that comply with air quality standards are designated as attainment areas.

Primary sources of emissions associated with crop production include exhaust from motorized equipment such as tractors and irrigation equipment, soil particulates from tillage and wind-induced erosion, particulates from burning of fields, and aerosols from herbicide and pesticide applications.

More than half of the soybeans grown in the United States are rotated with corn in a two-year rotation. Soybean fields typically are tilled before planting the alternative crop rotation the following year. Because they reduce the need to till for weed control, HR soybeans have promoted the use of no-till or conservation tillage for soybean production. Longer intervals between rotating crops and minimized earth disturbance from decreased tillage reduce the use of emission-producing equipment (Table 7). Reduced tillage also causes less dust from particulates, and potentially lowers rates of wind erosion, which benefits air quality (Towery and Werblow, 2010).

⁵ Eutrophication is the process by which a body of water becomes enriched in dissolved nutrients (as phosphates) that stimulate the growth of aquatic plant life usually resulting in the depletion of dissolved oxygen.

Table 7. Examples of Estimated Annual Fuel Used for Different Tillage Methods.

Estimated Use/1,000 Acres of Soybeans Located in Urbana, Illinois	Tillage Method			
	Conventional	Mulch-till	Ridge-till	No-till
Total fuel* used	5,239	4,369	3,460	2,330
Estimated fuel saved compared to that used for conventional tillage	--	870	1,779	2,909
Percent estimated savings	--	17%	34%	56%
*Diesel fuel in gallons				

Source: USDA-NRCS (2013a)

Volatilization of fertilizers, herbicides and pesticides from soil and plant surfaces introduces these chemicals into the air. One study in the Chesapeake Bay region (USDA-ARS, 2011) determined that volatilization is highly dependent upon exposure of disturbed unconsolidated soils and variability in measured compound levels is correlated with temperature and wind conditions. Another study of volatilization of certain herbicides after application to fields found moisture in dew and soils in higher temperature regimes significantly increases volatilization rates (USDA-ARS, 2011).

Prescribed burning is a land treatment used under controlled conditions to accomplish resource management objectives. Open combustion produces particles of widely ranging size, depending to some extent on the rate of energy release of the fire (US-EPA, 2011a). The extent to which agricultural and other prescribed burning may occur is regulated by individual state implementation plans to achieve compliance with the NAAQS. Prescribed burning of fields would likely occur only as a pre-planting option for soybean production based on individual farm characteristics.

Pesticide and herbicide spraying may impact air quality from drift and diffusion. Drift is defined by EPA as “the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application” (US-EPA, 2000). Diffusion is gaseous transformation into the atmosphere (FOCUS, 2008). Factors affecting drift and diffusion include application equipment and method, weather conditions, topography, and the type of crop being sprayed (US-EPA, 2000).

Other conservation practices, as required by USDA to qualify for crop insurance and beneficial federal loans and programs (USDA-ERS, 2009a), effectively reduce crop production impacts to air quality through the use of windbreaks, shelterbelts, reduced tillage, and cover crops that promote soil protection on highly erodible lands.

3.3 BIOLOGICAL RESOURCES

3.3.1 Animal Communities

Animal communities considered in this EA include wildlife species and their habitats. Wildlife refers to both native and introduced species of mammals, birds, amphibians, reptiles, invertebrates, and fin and shellfish. Agriculture dominates human uses of land (Robertson and Swinton, 2005). In 2011, 917 million acres (approximately 47%) of the conterminous 48 states were dedicated to farming, including: crop production (about 10% [88.8 million] acres was for soybean production), pasture, rangeland, Conservation Reserve Program and Wetlands Reserve Program lands, or other government program uses (Senseman, 2007; USDA-NASS, 2012c). How these lands are maintained influences the function and integrity of the wildlife populations they support and the ecosystem services they provide.

A wide array of wildlife species occur within the 31 major soybean-producing U.S. states. During the spring and summer months, soybean fields provide browse for rabbits, deer, rodents and other mammals, birds such as upland gamebirds, and invertebrates such as insects (Palmer *et al.*, No Date). During the winter months, leftover and unharvested soybeans provide a food-source for wildlife; however, soybeans are poorly suited for meeting nutrient needs of wildlife, such as waterfowl, which require a high-energy diet (Krapu *et al.*, 2004).

A shift from conventional agricultural practices to conservation tillage and no-till practices has occurred on farms planting GE HR soybean varieties (Dill *et al.*, 2008; Givens *et al.*, 2009). This increased use of conservation tillage practices has benefitted wildlife through improved water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Brady, 2007; Sharpe, 2010). Conservation tillage practices that leave greater amounts of crop residue serve to increase the diversity and density of birds and mammals (USDA-NRCS, 1999a). Increased residue also provides habitat for insects and other arthropods, consequently increasing this food source for insect predators. Insects are important during the spring and summer brood rearing season for many upland game birds and other birds, as they provide a protein-rich diet source to fast growing young, and a nutrient-rich diet for migratory birds (USDA-NRCS, 2003).

Insects and other invertebrates can be beneficial to soybean production by cycling nutrients and preying on plant pests. Conversely, there are some insects and invertebrates that are detrimental to soybean crops, including: bean leaf beetle (*Cerotoma trifurcata*); beet armyworm (*Spodoptera exigua*); blister beetle (*Epicauta* spp.); soybean podworm (*Helicoverpa zea*); shorthorned grasshoppers (*Acrididae* spp.); green cloverworm (*Hypena scabra*); seed corn beetle (*Stenolophus lecontei*); seed corn maggot (*Delia platura*); soybean aphid (*Aphis glycines*); soybean looper (*Pseudoplusia includens*); soybean stem borer (*Dectes texanus*); spider mites (*Tetranychus urticae*); stink bugs (green [*Acrosternum hiliare*] and brown [*Euschistus* spp.]); and velvetbean caterpillar (*Anticarsia gemmatilis*) (Whitworth *et al.*, 2011; Palmer *et al.*, No Date). While insects are considered less problematic than weeds in U.S. soybean production, insect injury can impact yield, plant maturity, and seed quality. Consequently, insect pests are managed during the growth and development of soybean to enhance soybean yield (Higley and Boethel, 1994; Aref and Pike, 1998).

Under FIFRA, all pesticides including herbicides sold or distributed in the United States must be registered by the EPA (US-EPA, 2005). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to the environment, including wildlife. All pesticides registered prior to November 1, 1984 must also be reregistered to ensure that they meet the current, more stringent standards. EPA must find during its registration process (US-EPA, 2018) that a pesticide does not cause unreasonable adverse effects to the environment if used in accordance with the EPA-approved label instructions. Growers must adhere to EPA label use restrictions for herbicides and pesticides. These measures help to minimize potential impacts of their use on non-target wildlife species.

3.3.2 Plant Communities

Nearly all commercially grown U.S. soybeans are grown in 31 states (USDA-NASS, 2012b) throughout the Midwest, Mid-Atlantic, and Southeast (Figure 1), encompassing a wide range of physiographic regions, ecosystems, and climatic zones. The types of vegetation, including the variety of weeds within and adjacent to soybean fields can vary greatly, depending on the geographic area in which the field occurs. Non-crop vegetation in soybean fields is limited by the extensive cultivation and weed control programs practiced by soybean producers. Plant communities bordering soybean fields can range from forests and woodlands to grasslands, aquatic habitats, and residential areas. Adjacent crops frequently include other soybean varieties, corn, cotton, or other crops.

Weeds are classified as annuals, biennials, or perennials. Annuals and biennials are plants that complete their lifecycle within one year or two years respectively. Perennials are plants that live for more than two years. Weeds are also classified as broadleaf (dicots) or grass (monocots). Weeds can reproduce by seeds, rhizomes (underground creeping stems), or other underground parts. Annual grass and broadleaf weeds are considered the most common weed problems in soybeans (Krausz *et al.*, 2001). However, with increased rates of conservation tillage, increases in perennial, biennial, and winter annual weed species are being observed (Green and Martin, 1996; Durgan and Gunsolus, 2003). Winter perennials are particularly competitive and difficult to control, as these weeds re-grow every year from rhizomes or root systems. At least 55 weed species have been identified as commonly occurring in soybean production including: common lambsquarter (*Chenopodium album*), morning glory species (*Ipomoea* spp.), velvetleaf (*Abutilon theophrasti*), pigweed, (*Amaranthus* spp.), common cocklebur (*Xanthium strumarium*), foxtail (*Setaria* spp.), ragweed species (*Ambrosia* spp.), crabgrass (*Digitaria* spp.), barynyard grass (*Echinochloa crus-galli*), Johnsongrass (*Sorghum halepense*), and thistles (*Cirsium* spp.) (Heap, 2018).

An important concept in weed control is the seed bank, which is the reservoir of seeds that are in the soil and have the potential to germinate. Agricultural soils contain reservoirs of weed seeds ranging from 4,100 to 137,700 seeds per square meter of soil (May and Wilson, 2006). Climate, soil characteristics, cultivation, crop selection, and weed management practices affect the seed bank composition and size (May and Wilson, 2006).

Herbicide resistance is described by the Weed Science Society of America as the “inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally

lethal to the wild type” (WSSA, 2013). The first reports of weed resistance to herbicides were in the 1950s (WSSA, 2011). Individual plants within a species can exhibit different responses to the same herbicide rate. Initially, herbicide rates are set to work effectively on the majority of the weed population under normal growing conditions. Genetic variability, including herbicide resistance, is exhibited naturally in normal weed populations, although at very low frequencies. When only a single herbicide is continuously relied upon as the primary means of weed control, the number of weeds resistant to that herbicide compared to those susceptible to the herbicide may change as the surviving resistant weeds reproduce (Figure 4). With no change in weed control strategies, in time, the weed population may be composed of more and more resistant weeds (WSSA, 2011).

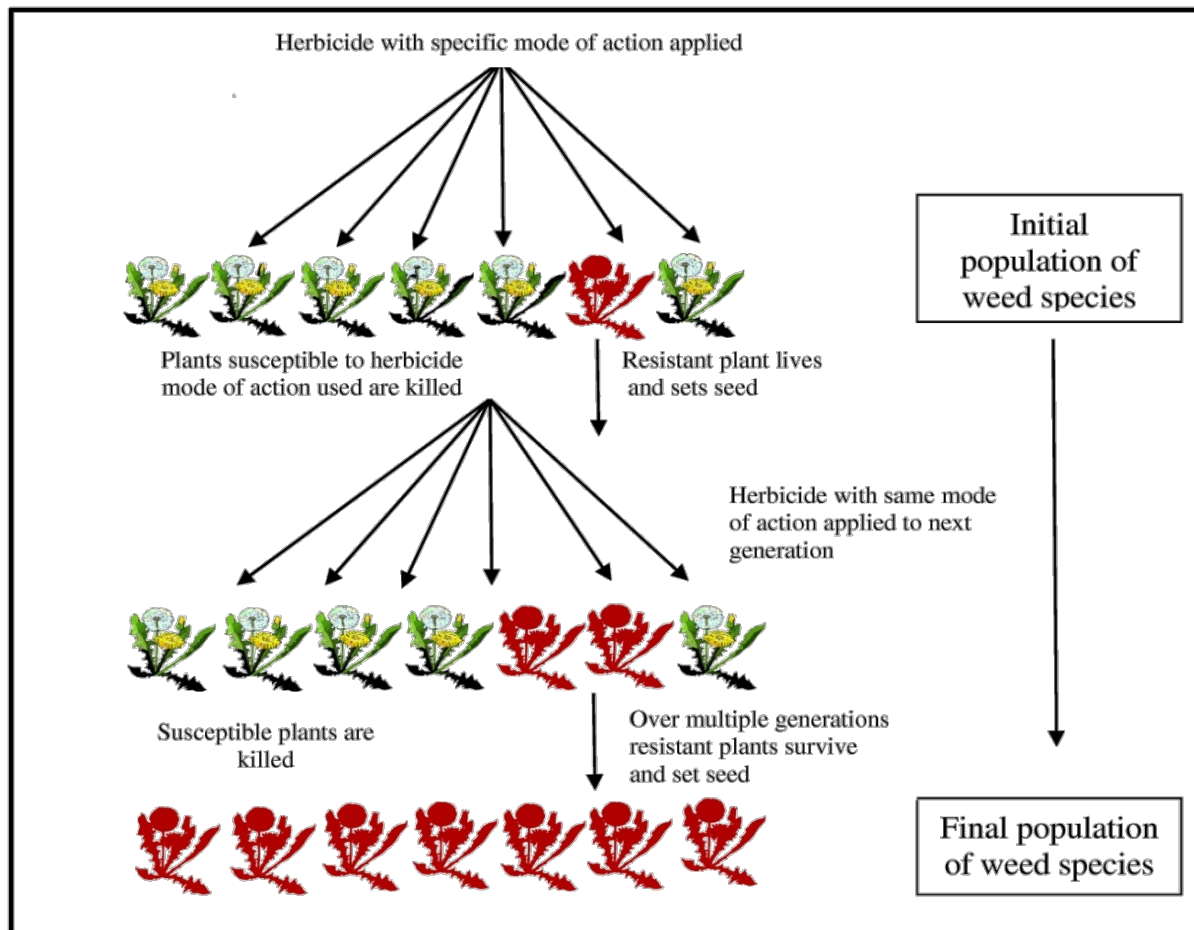


Figure 4. Schematic Diagram of the Development of Herbicide Resistance.

Source: Adapted from (Tharayil-Santhakumar, 2003)

The adoption of GR crops, including soybeans, resulted in growers changing historical weed management strategies and relying on a single herbicide, glyphosate, to control weeds in the field (Owen *et al.*, 2011; Weirich *et al.*, 2011). Reliance on a single management technique for weed control resulted in the selection for weeds resistant to that technique (Owen *et al.*, 2011; Weirich *et al.*, 2011). The development of GR weeds has necessitated a diversification of weed

management strategies by growers. GR weeds have forced growers to respond to the problem by applying herbicides with different modes of action, using tank mixes, increasing the frequency of applications, and returning to tillage and other cultivation techniques to physically control HR species, when a specific herbicide proves to be ineffective (CAST, 2012). Integrated weed management programs that use herbicides from different groups, vary cropping systems, rotate crops, and that use mechanical as well as chemical weed control methods, delay or prevent the selection of HR weed populations (Gunsolus, 2002; Sellers *et al.*, 2011).

The widespread adoption of GR GE crops has resulted in an increased use of glyphosate since 1995, and a reduction in the use of other herbicides in the United States (Weirich *et al.*, 2011). GR crops do not influence weeds any more than non-transgenic crops. The recurrent and exclusive use of glyphosate in the production of many GE crops has resulted in the selection for weed populations that are resistant to glyphosate. Glufosinate resistance in contrast has only been reported for a single subspecies of *Lolium perenne (multiflorum)* in two U.S. states (California and Oregon) (Heap, 2018).

There are currently 495 unique HR biotypes (Table 8) with herbicide resistance in 23 HRAC herbicide groups (Heap, 2018). Strategies for managing and avoiding the development of HR weed populations are well developed. In most instances, crop producers are advised to and use IWM practices to address HR weed concerns (e.g., (Wilson *et al.*, 2009; Shaw *et al.*, 2011; Vencill *et al.*, 2012). IWM consists of integrating multiple practices, including mechanical, cultural, chemical, and biological weed control tactics, into a weed management program to optimize control of a particular weed problem. IWM can include specifically timed applications of herbicides, the use of herbicides with multiple modes of action, crop rotation, cover crops, various tillage practices, weed surveillance, and hand-pulling or hoeing (Owen, 2011a; Garrison *et al.*, 2014; CLI, 2015).

Developers of GE HR varieties provide stewardship and IWM guidance to crop producers in accordance with and responsive to EPA requirements and Weed Science Society of America (WSSA) recommendations. In 2017, EPA issued PR Notice 2017-2, *Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship* (US-EPA, 2017b). Through PRN 2017-2, the EPA provides HR weed management guidance for herbicides undergoing registration review and for label registration (i.e., new herbicide active ingredients, and new uses proposed for HR crops and other case-specific registration actions). To assist growers in managing weeds, individual states track the prevalent weeds in crops in their area and provide the most effective means for their management, typically through state agricultural extension services, which work with USDA (IPM, 2015).

Table 8. Summary of World-wide HR Weeds by Herbicide Group

Herbicide Group	HRAC Group	Herbicide Example	Dicots	Monocots	Total
<u>ALS inhibitors</u>	B	<u>Chlorsulfuron</u>	98	62	160
<u>Photosystem II inhibitors</u>	C1	<u>Atrazine</u>	51	23	74
<u>ACCase inhibitors</u>	A	<u>Sethoxydim</u>	0	48	48
<u>EPSP synthase inhibitors</u>	G	<u>Glyphosate</u>	22	20	42
<u>Synthetic Auxins</u>	O	<u>2,4-D</u>	30	8	38
<u>PSI Electron Diverter</u>	D	<u>Paraquat</u>	22	10	32
<u>PSII inhibitor (Ureas and amides)</u>	C2	<u>Chlorotoluron</u>	11	18	29
<u>PPO inhibitors</u>	E	<u>Oxyfluorfen</u>	10	3	13
<u>Microtubule inhibitors</u>	K1	<u>Trifluralin</u>	2	10	12
<u>Lipid Inhibitors</u>	N	<u>Triallate</u>	0	10	10
<u>Carotenoid biosynthesis (unknown target)</u>	F3	<u>Amitrole</u>	1	5	6
<u>Long chain fatty acid inhibitors</u>	K3	<u>Butachlor</u>	0	5	5

<u>PSII inhibitors (Nitriles)</u>	C3	<u>Bromoxynil</u>	3	1	4
<u>Carotenoid biosynthesis inhibitors</u>	F1	<u>Diflufenican</u>	3	1	4
<u>Glutamine synthase inhibitors</u>	H	<u>Glufosinate-ammonium</u>	0	4	4
<u>Cellulose inhibitors</u>	L	<u>Dichlobenil</u>	0	3	3
<u>Antimicrotubule mitotic disrupter</u>	Z	<u>Flamprop-methyl</u>	0	3	3
<u>HPPD inhibitors</u>	F2	<u>Isoxaflutole</u>	2	0	2
<u>DOXP inhibitors</u>	F4	<u>Clomazone</u>	0	2	2
<u>Mitosis inhibitors</u>	K2	<u>Propham</u>	0	1	1
<u>Unknown</u>	Z	<u>Endothall</u>	0	1	1
<u>Cell elongation inhibitors</u>	Z	<u>Difenzoquat</u>	0	1	1
Total Number of Unique Herbicide Resistant Biotypes:			256	239	495

*HRAC: Herbicide Resistance Action Committee

Source: Heap (2018)

Runoff, spray drift, and volatilization of herbicides have the potential to impact non-target plant communities growing in proximity to fields in which herbicides are used. The extent of damage to non-target plants exposed to herbicides is determined by the overall vigor of the affected plant, the amount and type of herbicide to which the plant is exposed, and the growing conditions after contact (Ruhl *et al.*, 2008).

The total rainfall the first few days after herbicide applications can influence the amounts of leaching and runoff. However, it has been estimated that even after heavy rains, herbicide losses

to runoff generally do not exceed 5-10% of the total applied (Tu *et al.*, 2001; USDA-FS, 2009). Planted vegetation, such as grass buffer strips, or crop residues can effectively reduce runoff (IPPC, 2010). Volatilization typically occurs during application, but herbicide deposits on plants or soil can also volatilize.

Spray drift is a concern for non-target effects on susceptible plants growing adjacent to fields when herbicides are used in the production of soybeans. This potential impact results from off-target herbicide drift (US-EPA, 2010b). Damage from spray drift typically occurs at field edges or at shelterbelts (i.e., windbreaks), but highly volatile herbicides may drift farther into a field. The risk of off-target herbicide drift is recognized by the EPA, which has incorporated both equipment and management restrictions to address drift on the EPA-approved herbicide labels. These EPA label restrictions include requirements that the grower manage droplet size, spray boom height above the crop canopy, restrict applications to specified wind speeds and environmental conditions, and use drift control agents (US-EPA, 2010b).

Volunteer soybean is not a widespread problem. It is most common in parts of the southeastern United States. In production systems where soybean is rotated, such as with corn or cotton, it can occur as a volunteer weed, but is not considered to be as a serious problem by farmers (Owen and Zelaya, 2005). Volunteer soybean is not considered difficult to manage, as soybean seeds rarely remain viable the following season and any interference they may pose to subsequent crops are minimal. Furthermore, herbicides usually used for weed control in corn are also effective for volunteer soybeans (Owen and Zelaya, 2005). Conversely, volunteer GR corn in soybean is a greater concern (Owen and Zelaya, 2005). Glyphosate has been used to control all weeds, including volunteer corn in soybean crops rotated with corn. However, the increase in cultivation of GR corn has created problems for growers in the Midwest who must manage volunteer GR corn with alternative herbicides. Growers now often include graminicides (herbicides to control weedy grasses) as part of their weed management strategy (Owen and Zelaya, 2005).

3.3.3 Gene Flow and Weediness

Gene flow to and from an agroecosystem can occur on both spatial and temporal scales. In general, plant pollen is the most common way that genes are transmitted. The rate and success of gene flow is dependent on numerous external factors in addition to the donor and recipient plant. General external factors related to pollen-mediated gene flow include the presence, abundance, and distance of sexually-compatible plant species; overlap of flowering phenology between populations; the mechanism of pollination; the biology and amount of pollen produced; and weather conditions, including temperature, wind, and humidity (Zapiola *et al.*, 2008). Seed-mediated gene flow also depends on many factors, including the presence, and magnitude of seed dormancy, contribution and participation in various dispersal pathways, and environmental conditions and events.

Soybean is not native to the United States and there are no feral or weedy relatives. Soybean is considered a highly self-pollinated species, propagated by seed (OECD, 2000). Pollination typically takes place on the day the flower opens. The soybean flower stigma is receptive to pollen approximately 24 hours before anthesis (i.e., the period in which a flower is fully open and functional) and remains receptive for 48 hours after anthesis. Anthesis normally occurs in

late morning, depending on the environmental conditions. The pollen usually remains viable for two to four hours, and no viable pollen can be detected by late afternoon. Natural or artificial cross-pollination can only take place during the short time when the pollen is viable, and soybean's reproductive characteristics (e.g., flower orientation that reduces its exposure to wind, internal anthers, and clumping and stickiness of the pollen) decrease the dispersion ability of pollen (Yoshimura, 2011).

As a highly self-pollinated species, cross-pollination of soybean plants to adjacent plants of other soybean varieties occurs at a very low (0-6.3%) frequency (Caviness, 1966; Ray *et al.*, 2003; Yoshimura *et al.*, 2006; USDA-APHIS, 2011). A study of soybeans grown in Arkansas found that cross-pollination of soybeans in adjacent rows averaged between 0.1% and 1.6%, but may be as high as 2.5% (Ahrent and Caviness, 1994). Abud *et al.* (2007) illustrated that as distance is increased from the soybean pollination source, the chance of cross-pollination is decreased. This study found that at a distance of 1 meter, outcrossing averaged about 0.5%, at 2 meters about 0.1%, at 4 meters about 0.05%, and at 10 meters less than 0.01%.

Gene flow by seed is usually dependent on natural dispersal mechanisms, such as water, wind, or animals, or by human actions, and is favored by characteristics such as small and lightweight seed size, prolific production, seed longevity and dormancy, and long distance seed transport (Mallory-Smith and Zapiola, 2008). Soybean seeds do not possess the characteristics for efficient seed-mediated gene flow. Soybean seeds are heavy and, therefore, are not readily or naturally dispersed by wind or water (Mallory-Smith and Zapiola, 2008). Similarly, soybean seeds and seedpods do not have physical characteristics that encourage animal transport (OECD, 2000). Soybeans also lack dormancy, a characteristic that allows dispersal in time by maintaining seeds and their genes within the soil for several years (OECD, 2000; Mallory-Smith and Zapiola, 2008).

Horizontal gene transfer and expression of DNA from a plant species to bacteria is unlikely to occur (Keese, 2008). Many bacteria (or parts thereof) that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko *et al.*, 2000; Wood *et al.*, 2001; Kaneko *et al.*, 2002). There is no evidence that these organisms contain genes derived from plants. Furthermore, in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale (i.e., over millions of years) (Koonin *et al.*, 2001; Brown, 2003). The FDA has also evaluated horizontal gene transfer from the use of antibiotic resistance marker genes, and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (US-FDA, 1998).

3.3.4 Microorganisms

Soil microorganisms significantly influence soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva *et al.*, 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran *et al.*, 1996). One estimated range of the number of bacterial species in a gram of soil is between 6 and 50 thousand (Curtis *et al.*, 2002). The soil microbial community includes nitrogen-fixing microbes such as the soybean mutualist *B. japonicum*, mycorrhizal fungi, and free-living

bacteria⁶; saprophytic fungi responsible for decomposition, denitrifying bacteria and fungi, phosphorus-solubilizing bacteria and fungi, and pathogenic microbes (USDA-NRCS, 2004).

The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) and cropping history (Garbeva *et al.*, 2004; Garbeva *et al.*, 2008). Some types of soil microorganisms share metabolic pathways with plants that may be affected by herbicides. Tillage disrupts multicellular relationships among microorganisms, and crop rotation changes soil conditions in ways that favor different microbial communities.

Plant roots, including those of soybean, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere (root zone). Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva *et al.*, 2004). More information about how soybean microbes, GE crops, and herbicide use may affect soil microbial communities follows.

Soybean Microbes

An important group of soil microorganisms associated with legumes, including soybean, are the mutualists. These include mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes that have co-evolved with plants that supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004). Legumes have developed symbiotic relationships with specific nitrogen-fixing bacteria in the family *Rhizobiaceae* that induce the formation of root nodules where bacteria reduce atmospheric nitrogen to ammonia that is usable by plants (Gage, 2004). *B. japonicum* is the bacterium specifically associated with soybeans (Franzen, 1999). Since neither soybean nor *B. japonicum* are native to North America, if a field has not been planted with soybean within 3-5 years, either the seed or seed zone must be inoculated with *B. japonicum* prior to soybean planting (Berglund and Helms, 2003; Pedersen, 2007).

In addition to beneficial microorganisms, there are also several microbial pathogens that cause disease in soybean and vary somewhat depending on the region. These include fungal pathogens such as rhizoctonia stem rot (*Rhizoctonia solani*), brown stem rot (*Phialophora gregata*), sudden death syndrome (*Fusarium solani* race A), charcoal root rot (*Macrophomina phaseolina*); bacterial pathogens such as bacterial blight (*Pseudomonas syringae*) and bacterial pustule (*Xanthomonas campestris*), and viral pathogens such as soybean mosaic virus and tobacco ringspot virus (Ruhl, 2007; SSDW, No Date). The soybean cyst nematode (*Heterodera glycines*) is a microscopic parasite that infects the roots of soybeans. Management to control disease outbreaks varies by region, and pathogen/parasite, but include common practices such as crop rotation, weed control, planting resistant varieties, and proper planting and tillage practices.

GE Crop Impacts on Microbes

All soils, including agricultural soils are complex, dynamic ecosystems. Changes in agricultural practices and natural variations in season, weather, plant development stages, geographic

⁶ Organisms that are able to obtain food without the need for a host organism.

location, soil type, and plant species or varieties can impact the microbial community (Kowalchuk *et al.*, 2003; US-EPA, 2009). Direct impacts may include changes to the structure (species richness and diversity) and function of the microbial community in the rhizosphere caused by the biological activity of the inserted gene(s). Indirect impacts may result from changes in the composition of root exudates, plant litter, or agricultural practices (Kowalchuk *et al.*, 2003; US-EPA, 2009). Several reviews of the investigations into the impact of GE plants on microbial soil communities found that most of them concluded there was either minor or no detectable non-target effects (Kowalchuk *et al.*, 2003; Hart, 2006; US-EPA, 2009).

3.3.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). Loss of biodiversity can result in more costly management practices to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: (1) diversity of vegetation within and around the agroecosystem; (2) permanence of various crops within the system; (3) intensity of management; and (4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999). Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvesting limit the diversity of plants and animals (Lovett *et al.*, 2003). Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices that may be used to support biodiversity include intercropping (the planting of two or more crops simultaneously to the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and hedgerows and windbreaks (Altieri, 1999). Integrated pest management strategies include several practices that increase biodiversity such as retaining small, diverse natural plant refuges and minimal management of field borders.

A variety of federally supported programs, such as the USDA funded Sustainable Agriculture Research and Education Program, and partnership programs among the U.S. EPA and the agricultural community, support sustainable agricultural practices that are intended to protect the environment, conserve natural resources, and promote cropland biodiversity (i.e.,(US-EPA, 2017a; USDA-NIFA, 2017)).

3.4 ANIMAL FEED

Animal agriculture consumes 98% of the U.S. soybean meal produced (Soyatech, 2011) and 70% of soybeans produced worldwide (USB, 2011c). Poultry consume more than 48% of domestic soybean meal or 11.92 million MT of the U.S. soybean crop with soy oil increasingly replacing animal fats and oils in broiler diets (USB, 2011b; ASA, 2012b). Soybean can be the dominant

component of livestock diets, such as in poultry, where upwards of 66% of their protein intake is derived from soy (Waldroup and Smith, No Date). Other animals fed domestic soybean include swine (26%), beef cattle (12%), dairy cattle (9%), other (e.g., farm-raised fish 3%), and household pets (3%) (ASA, 2010a; USB, 2011a).

Although the soybean market is dominated by seed production, soybeans have a long history in the United States as a nutritious grazing forage, hay, and silage crop for livestock (Blount *et al.*, 2009). Soybean may be harvested for hay or grazed from the flowering stage to near maturity. The best soybean for forage is in the beginning pod stage (Johnson *et al.*, 2007). For silage, it should be harvested at maturity before leaf loss, and mixed with a carbohydrate source, such as corn, for optimal fermentation characteristics (Blount *et al.*, 2009). Varieties of soybean have been developed specifically for grazing and hay, but use of the standard grain varieties are recommended by some because of the whole plant feeding value (Weiderholt and Albrecht, 2003).

Similar to the regulatory oversight for direct human consumption of soybean under the FFDCa, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE soybean must comply with all applicable legal and regulatory requirements, which in turn protects human health. To help ensure compliance, GE organisms used for feed may undergo a voluntary consultation process with the FDA before release onto the market, which provides the applicant with any needed direction regarding the need for additional data or analysis, and allows for interagency discussions regarding possible issues. A developer who intends to commercialize a food derived from a GE source consults with FDA to identify and discuss relevant safety, nutritional, or other regulatory issues regarding food derived from GE crops, and then submits a summary of its scientific and regulatory assessment of the food to FDA. FDA evaluates the submission and responds to the developer by letter.

Growers must adhere to EPA label use restrictions for pesticides used to produce a soybean crop before using it as forage, hay, or silage. Under Section 408 of FFDCa, EPA regulates the levels of pesticide residues that can remain on feed from pesticide applications (US-EPA, 2010a). These tolerances are the maximum amount of pesticide residue that can legally be present in food or feed, and if pesticide residues in food or feed are found to exceed the tolerance value, it is considered adulterated and subject to seizure.

3.5 HUMAN HEALTH

This section provides a summary of the human health concerns for public health related to the human consumption of products derived from GE soybeans, and those related to occupational health and health and safety from potential exposure to agricultural hazards during crop production.

3.5.1 Public Health

Human health concerns surrounding GE soybean focus primarily on human and animal consumption. Soybeans yield both solid (meal) and liquid (oil) products. Soybean meal is high in protein and is used for products such as tofu, soymilk, meat replacements, and protein powder. It also provides a natural source of dietary fiber (USB, 2009). Nearly 98% of soybean meal

produced in the United States is used as animal feed, while less than 2% is used to produce soy flour and proteins for food use (Soyatech, 2011). Soybean liquids are used to produce salad and cooking oils, baking and frying fat, and margarine. Soybean oil is low in saturated fats, high in polyunsaturated and monounsaturated fats, and contains essential omega-3 fatty acids. Soybean oil comprises nearly 70% of the oils consumed in U.S. households (ASA, 2010b).

Non-GE soybean varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the United States for human food or animal feed safety prior to release in the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled.

GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. In a consultation, a developer who intends to commercialize a food derived from a GE source meets with the FDA representatives to identify and discuss relevant safety, nutritional, or other regulatory issues. It then submits to the FDA a summary of its scientific and regulatory assessment of the food. This process includes: (1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; (2) an assessment of the protein's potential for digestion; and (3) an evaluation of the history of safe use in food (Hammond and Jez, 2011). The FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency and the Australia and New Zealand Food Standards Agency.

Foods derived from GE sources undergo a comprehensive safety evaluation before entering the market, including reviews under the Codex Alimentarius, the European Food Safety Agency, and the World Health Organization (FAO, 2009; Hammond and Jez, 2011). Food safety reviews frequently will compare the compositional characteristics of the GE crop with non-transgenic, conventional varieties of that crop. This comparison also evaluates the composition of the modified crop under actual agronomic conditions, including various agronomic inputs (Aumaitre *et al.*, 2002; FAO, 2009). Composition characteristics evaluated in these comparative tests include moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients.

There are multiple ways in which organisms can be genetically modified through human intervention (e.g., traditional cross breeding, chemical or radiation-mediated mutagenesis, and genetic engineering using the methods of biotechnology). Unexpected and unintended compositional changes can arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004), however, no adverse health effects from genetic engineering have been documented in the human population. Reviews on the nutritional quality of GE foods have generally concluded that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky *et al.*, 2005).

Before a pesticide can be used on a food crop, the EPA must establish a tolerance, the maximum residue level of a pesticide that can remain on a crop or in foods processed from a crop, or establish an exemption for a tolerance (US-EPA, 2010a). Both the FDA and USDA monitor foods for pesticide residues and enforce tolerances (USDA-AMS, 2011). If pesticide residues in excess of a tolerance are detected on food, the food is considered adulterated and is subject to seizure. The USDA has implemented the Pesticide Data Program (PDP) to collect data on pesticides residues on food (USDA-AMS, 2016). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the FQPA. Pesticide tolerances have been established for most commodities, including soybeans, and have been published in the *Federal Register*, 40 CFR part 180, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (US-EPA, 2011b).

3.5.2 Occupational Health and Worker Safety

Agriculture is one of the most hazardous U.S. work environments. Pesticides, particularly herbicides, are used on most soybean acreage in the United States. To protect all workers, the National Institute of Occupational Safety and Health has been authorized by Congress to establish and enforce safety standards as part of a program to address high-risk issues in the work place. In response to the specific risks of poisoning and injuries among agricultural workers from pesticide exposure, the EPA has also established safeguards under its Worker Protection Standard (WPS) (40 CFR part 170) (US-EPA, 2017d). The WPS establishes protections for more than 2.5 million agricultural workers in the United States who handle pesticides at more than 560,000 workplace sites on farms, forests, nurseries, and greenhouses.

The Occupational Safety and Health Administration requires all employers to protect their employees from hazards associated with pesticides and herbicides. The EPA WPS, updated in 2015 (US-EPA, 2017), establishes specific safety procedures that employers who hire workers that handle pesticides must follow. The WPS requires pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals (reentry times) following pesticide application, decontamination supplies and practices, and access to emergency medical assistance. The EPA pesticide registration process also includes protections for worker health. Under FIFRA, all pesticides sold or distributed in the United States must be registered by the EPA (US-EPA, 2018). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. All pesticides registered prior to November 1, 1984 must also be reregistered to ensure that they meet the current, more stringent standards. During the registration decision, the EPA must find that a pesticide does not cause unreasonable adverse effects to human health or the environment if used in accordance with its approved label instructions (OSTP, 2001).

EPA labels for pesticides include use restrictions and safety measures to mitigate exposure risks. Pesticide applicators are required to use registered pesticides consistent with the instructions issued by the EPA that are listed on the label for each registered pesticide product. Worker safety precautions and use restrictions are included on pesticide registration labels. These include instructions for the levels of personal protection required for agricultural workers to safely handle and apply pesticides. Further details to achieve compliance are provided in the EPA WPS (US-EPA, 2017d). When used in accordance with the EPA registration label, pesticides do not cause any unacceptable health risk to workers.

3.6 SOCIOECONOMIC ISSUES

3.6.1 Domestic Economic Environment

In 2016, soybeans accounted for 21.9% of all crops (excluding horticultural ones) grown in the United States, and the total value of the soybeans from the 89.5 million acres (Figure 2) harvested the United States in 2017 was \$41 billion (USDA-NASS, 2017a). Ten states (Illinois, Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, Ohio, and South Dakota) had more than 5 million planted soybean acres in 2017, and total acreage for those states accounted for 77.5% of all U.S. planted soybean acreage (Figure 1).

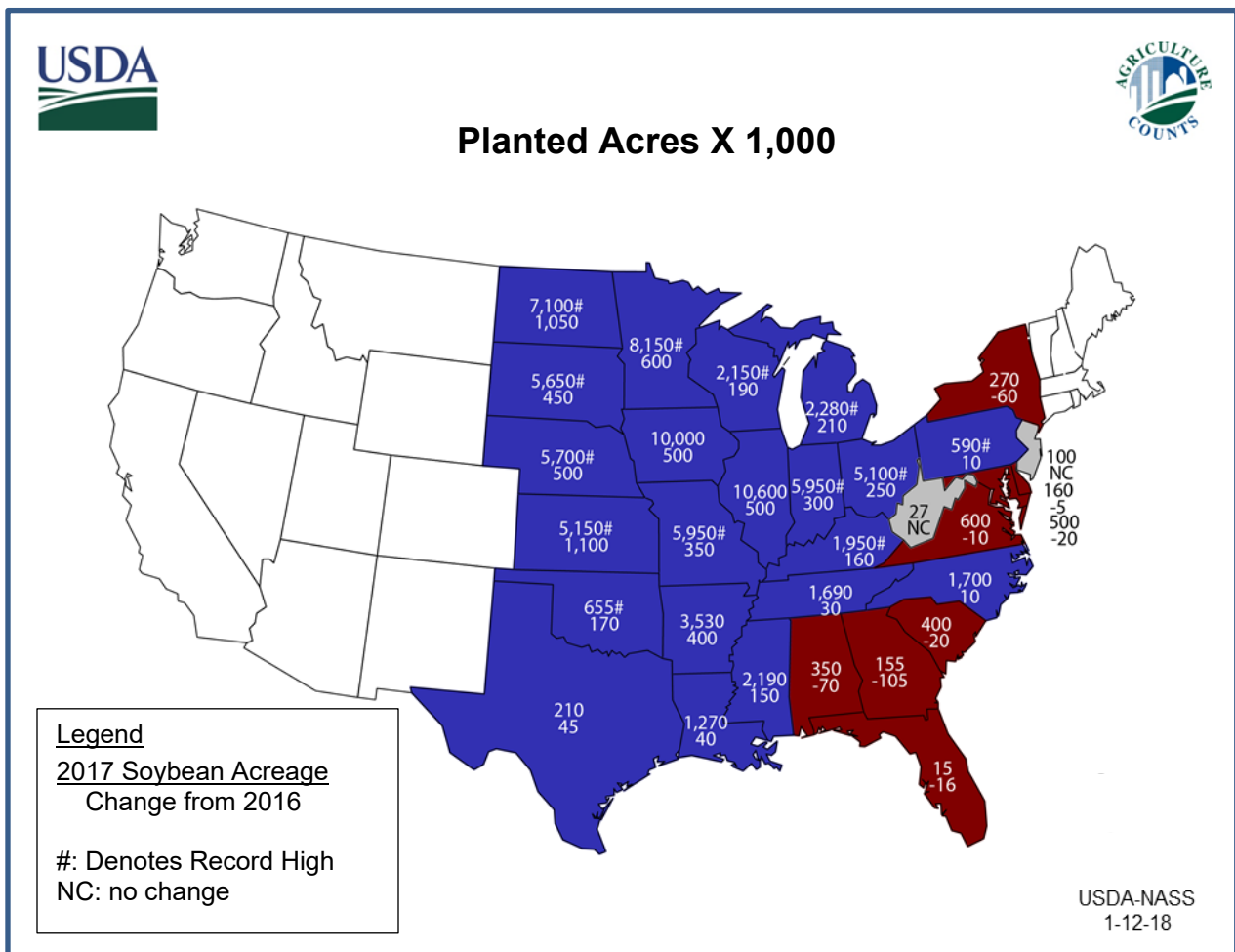


Figure 5. Soybean Planted Acreage in Major U.S. Production States in 2017.

Production cost data are compiled every 4-8 years by USDA-ERS for each commodity as part of its Agricultural Resource Management Survey. For soybeans, typical operating costs in 2011 per planted acre included purchased seed (\$55.55), fertilizer and soil amendments (\$22.84), other

chemicals (\$16.42), and irrigation water (\$0.15) (USDA-ERS, 2012f). Total 2011 operating costs were \$136.87 per planted soybean acre (USDA-ERS, 2012f). Figure 6 provides a comparison of operating costs and net crop value (excluding crop subsidies) for different growing regions of the United States.

There is consistent evidence that farmers obtain substantial financial and non-financial benefits as a result of adoption of GE crops. These benefits include increased income from off-farm labor, increased flexibility and simplicity in the application of pesticides, an ability to adopt more farming practices that have less environmental impact; increased consistency of weed control; increased human safety; equipment savings; and labor savings (Fernandez-Cornejo and McBride, 2000; Fernandez-Cornejo and McBride, 2002; Marra *et al.*, 2004; Fernandez-Cornejo *et al.*, 2005; Duke and Powles, 2009; Hurley *et al.*, 2009).

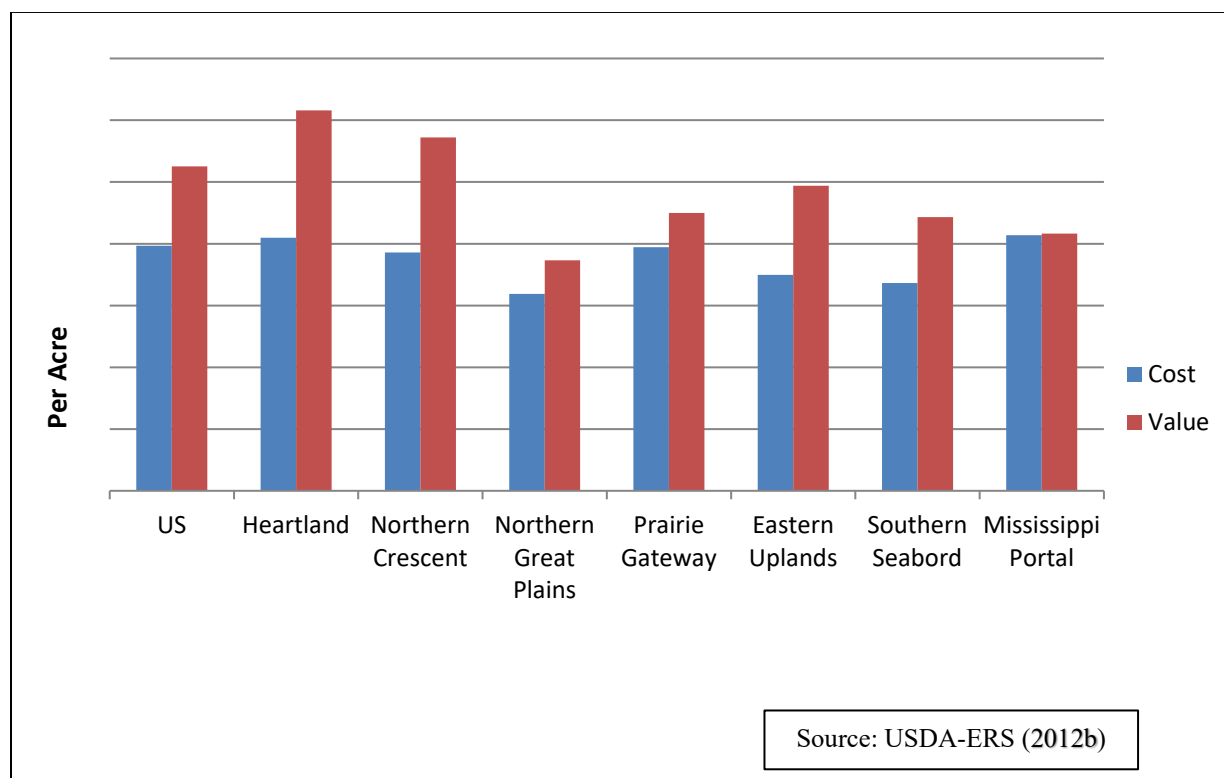


Figure 6. Estimated Soybean Crop Value by U.S. Region in 2011.
(N.B., Estimates exclude subsidies)

Most of the soybean crop is crushed to produce oil and meal. In the United States, almost all (98%) of the soybean meal is used for animal feed (Soyatech, 2011). The vast majority of the oil (79% in 2011) is used for human consumption; the balance is used for industrial products. Soybean oil represents almost 70% of the oils consumed by U.S. households. A noteworthy ongoing shift affecting soybean demand is an increased interest in using soybeans for biofuel production. From 1999 to 2009, the consumption of soybean biodiesel has increased from 0.5 to 1,070 million gallons (ASA, 2012a).

Although a miniscule portion of the U.S. soybean crop is grown organically (it accounted for 0.09% of total U.S. production, and about 0.14% of overall soybean crop value in 2011), it is profitable. According to a USDA-ERS analysis, the economic costs of organic soybean production are substantially higher than for conventional (non-GE or GE) operations. However, organic soybean production is more profitable because the premium prices paid for them more than offset higher production costs (USDA-ERS, 2009b). The USDA-ERS (2012e) reports that consumer demand for organic foods has shown double-digit growth for more than a decade, so current demand for organic soybeans is likely to show a corresponding increase.

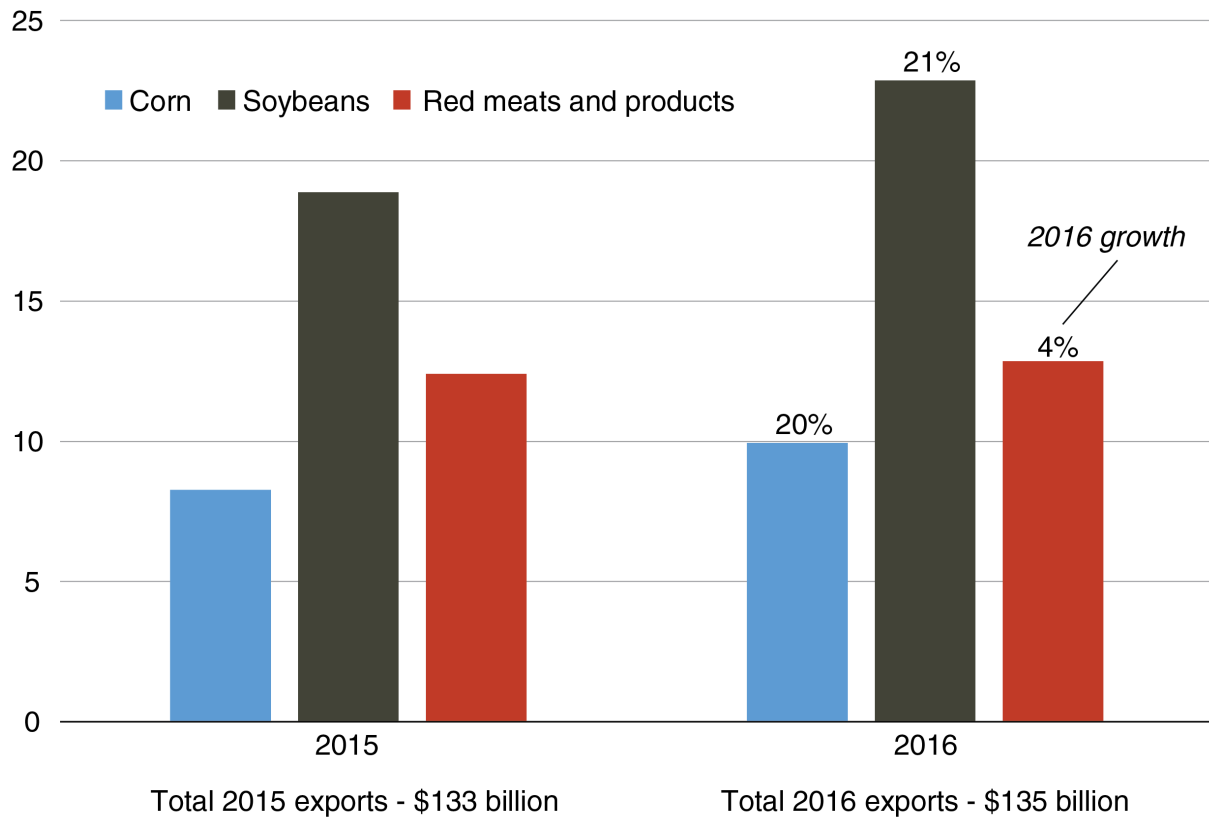
3.6.2 International Trade Economic Environment

Processed soybeans are the world's largest source of animal protein feed and the second largest source of vegetable oil. The United States is the world's leading soybean producer and the second-leading exporter. Soybeans comprise about 90% of U.S. oilseed production, while other oilseeds, including peanuts, sunflower seed, canola, and flax, make up the remainder (USDA-ERS, 2017).

The total value of U.S. agricultural exports was \$135 billion in 2016 (USDA-ERS, 2017). Of this total, \$23 billion was from soybean exports, ranking them first among all U.S. agricultural commodity exports (Figure 7). Since 2005, the percentage of U.S. soybean production that has been exported has increased from about 30% to nearly 50% (Figure 8). Despite the long-term trend in increasing export volume of U.S. soybean production, the U.S. share of the global export market has been declining (Figure 9) since 1980.

Key exports grew in 2016

Billion dollars



Source: (USDA-ERS, 2017)

Figure 7. Value of U.S. Soybean Exports and Percent Increase: 2015 and 2016.

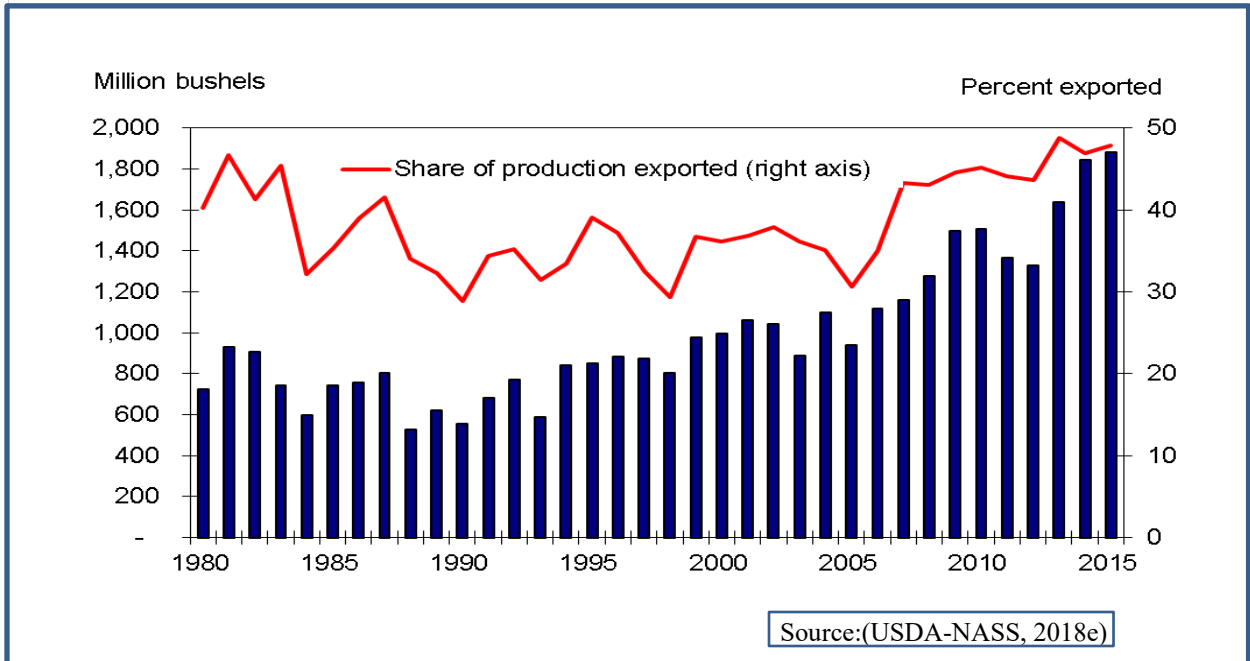


Figure 8. U.S. Soybean Export Volume and Percent Exported: 1980-2015.

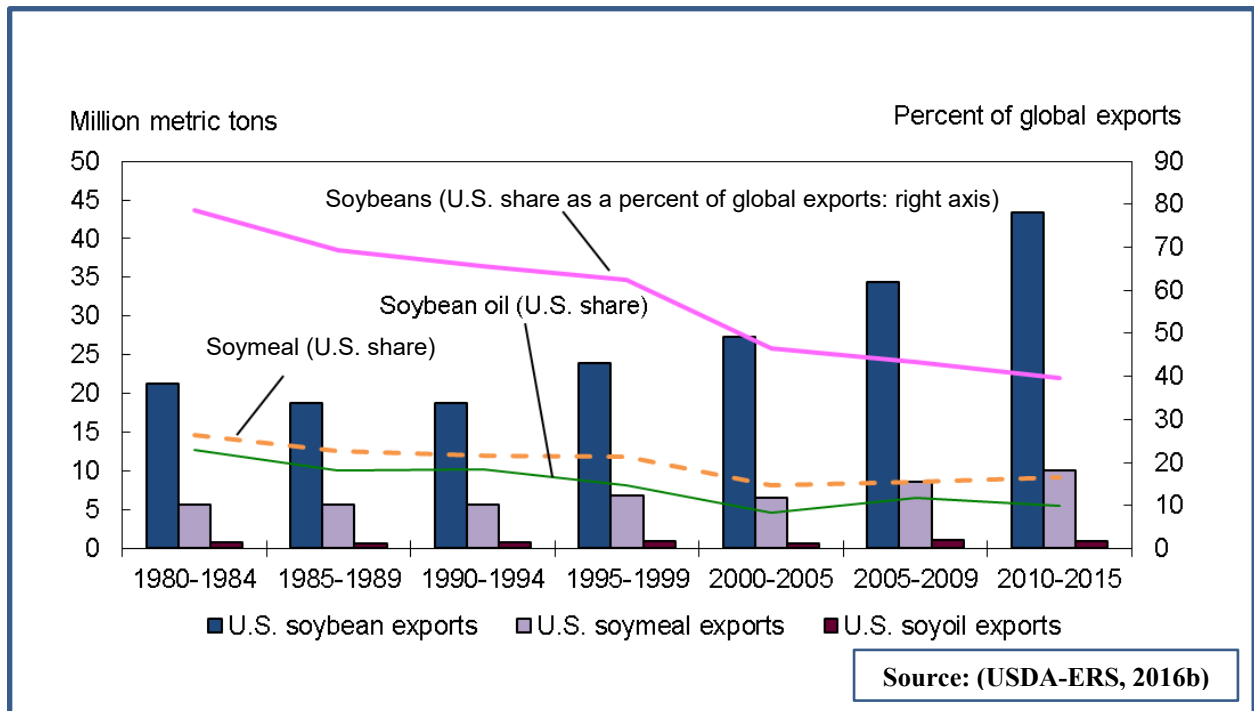


Figure 9. U.S. Soybean Export Volume and Percent of Global Market: 1980-2015.

In terms of consumption, soybeans contributed the largest share of protein meal consumed worldwide, mainly as animal feed (USDA-FAS, 2013). In the 2012/13 market year, as the world's largest source of animal protein feed, soybean meal represented 68% of the protein meal produced worldwide. As a source of oil, soybean ranked second behind palm oil in terms of worldwide vegetable oil production (USDA-FAS, 2013).

In 2011/12, the United States, Brazil, and Argentina were the major producers of soybean, producing 190.8 million metric tons (80.0%) of the world's soybeans (Table 9). The United States was responsible for 33.9% of the world's soybean production, 19.8% of world's soybean meal production, and 20.1% of the world's soybean oil production (USDA-ERS, 2012a). The United States, China, Argentina, and Brazil are the major producers of soybean meal and soybean oil in the world.

Table 9. World Soybean Production (metric tons) in 2011-2012.

Location	Soybean	Soybean Meal	Soybean Oil
Argentina	40.1	27.9	6.8
Brazil	66.5	28.6	7.1
Canada	4	ND*	ND
China	14.5	48.2	10.9
European Union	ND	9.6	2.2
India	11.0	7.7	1.7
Mexico	ND	2.8	0.6
Paraguay	4.4	ND	ND
United States	84.2	37.2	9.0
Other countries	13.8	17.2	4.0
*No Data			

Source: USDA-FAS (2013)

The United States, Brazil, Argentina, Paraguay, and Canada, account for 96.1% of the bulk soybean exported, while Argentina, Brazil, the United States, India, and Paraguay account for 90.4% of the soybean meal exported. Argentina, the European Union (EU), and Brazil are the dominant countries in terms of soybean oil exports accounting for 75.4%. China, the EU, Mexico, and Japan are the major importers of world bulk soybean, accounting for 82.9% of total imports, whereas the EU, Indonesia, Thailand, Japan and Vietnam are the largest importers of soybean meal with a world share of 55.0% (USDA-FAS, 2013). China and India are the major importers of soybean oil with a world share of 35.8% (USDA-FAS, 2013). Between 1996 and 2011, 28 countries, including the United States, adopted the use of GE crops, the largest being Brazil, Argentina, India, and Canada (Clive, 2011). Prior to exporting IND-00410-5 soybean, Verdeca would seek biotechnology regulatory approvals in all major import countries that have a functioning regulatory system to assure global compliance and support of international trade.

4 ENVIRONMENTAL CONSEQUENCES

Possible environmental impacts from selecting either the No Action Alternative or the Preferred Alternative as part of regulatory decisionmaking by APHIS for IND-00410-5 soybean were considered in this chapter. Details about how APHIS evaluated environmental impacts, results of the analyses it performed to assess whether or not they caused impacts, and the Agency's conclusions about the significance of impacts it identified are presented in this chapter. Pursuant to CEQ regulations APHIS considers the direct, indirect, and cumulative impacts of both alternatives. Potential direct and indirect impacts are discussed in this chapter, and potential cumulative impacts in Chapter 5.

4.1 ENVIRONMENTAL ANALYSIS

For this chapter, those impacts that were categorized as direct or indirect were evaluated. A direct impact was one solely caused by an Agency action without any intervening intermediate steps. An example is conversion of land use from non-agricultural to agricultural in response to an action that increases demand for a crop so much that non-agricultural land is converted to agricultural use to meet production demand. An indirect impact is one related to, but removed from the Agency's decision in space and time. An example is increased runoff of sediment from soil erosion that increased degradation of surface water quality because an action resulted in an increase in crop acreage that caused conversion of non-agricultural land to agricultural use.

4.2 SCOPE OF THE ENVIRONMENTAL ANALYSIS

Those resource areas listed in Chapter 1 (see Issues Considered) that may be affected by selecting either the No Action Alternative or the Preferred Alternative were considered for this EA. Impacts were defined as those effects likely to result in permanent changes to the environment. Impacts were evaluated for significance by analyzing the positive or negative changes from the existing (baseline) conditions described in Chapter 3 (Affected Environment). Wherever possible, APHIS used data that supported a quantitative analysis of the impacts of selecting either the No Action Alternative or the Preferred Alternative. When data were not available or were insufficient to support a quantitative assessment, APHIS made qualitative assessments of the impacts of an Agency regulatory decision for IND-00410-5 soybean.

APHIS limited its environmental analyses to the geographic areas that currently support U.S. soybean production. These analyses were also made under the assumption that most U.S. farmers who produce soybeans rely on widely accepted BMPs. It was also assumed that if IND-00410-5 soybean was no longer regulated by APHIS and became widely planted, farmers would use the same BMPs that are currently used for soybean production in the United States.

The *bar* gene inserted into the genome of IND-00410-5 soybean codes for expression of phosphinothricin-N-acetyl transferase (PAT), a protein that degrades the herbicide active ingredient, glufosinate (Verdeca, 2017). When a sufficient number of multiple copies of the *bar* gene are inserted into a plant's genome, the variety that results has resistance to herbicide applications containing glufosinate as the active ingredient because the PAT protein degrades it (Block et al. 1987, Thompson et al. 1987, White et al. 1990). Production of the PAT protein in

GE crops have been evaluated previously in EISs and EAs⁷ by APHIS. Several of these were for soybean varieties that contained the *bar* gene that expressed the PAT protein, which demonstrated an established history of safety (USDA-APHIS, 1998; 2014a; 2014b). Since these assessments did not identify any significant impacts associated with the *bar* gene or the PAT protein, they have been incorporated into this EA by reference, so no further analysis of the *bar* gene or the PAT protein was performed for this EA.

It should be noted that APHIS has regulatory authority over IND-00410-5 soybean plants, but EPA has regulatory authority over herbicides that are applied to the crop. The scope of this EA covers the possible direct and indirect impacts that would result primarily from the cultivation and use of the plant. EPA is considering any direct and indirect impacts from the use of glufosinate on IND-00410-5 soybean plants as part of its registration process. USDA is relying on EPA's authoritative assessments and will not duplicate the assessment prepared by EPA. The EA will provide informative assessments, but not the determinative document for any impacts of herbicide usage, since that analysis will have been completed by EPA under its regulatory authority.

4.3 AGRICULTURAL PRODUCTION OF SOYBEAN

4.3.1 Acreage and Regional Distribution (Locations) of Soybean Production

No Action Alternative: Acreage and Locations of Soybean Production

Under the No Action Alternative, IND-00410-5 soybean would remain regulated and would not be commercially available for production. Most commercial U.S. GE soybean production is expected to continue unchanged in the major soybean producing states listed previously in Chapter 3 (Table 2). U.S. soybean acreage is concentrated primarily in the Midwest (Figure 1), where yields are highest (USDA-NASS, 2016b). Soybean acreage has expanded recently to the northern and western parts of the country. This has resulted because of stagnant wheat yields and the availability of newer improved soybean varieties better adapted to provide higher yields under the short-season climatic conditions of those areas (USDA-ERS, 2010b). This has been a major factor contributing to a 31% increase in total U.S. soybean acreage from 1992 to 2012. Since then, U.S. soybean acreage has increased to nearly 90 million acres (USDA-NASS, 2018).

GE soybeans were introduced in the United States in 1996 (Fernandez-Cornejo and Caswell, 2006; USDA-ERS, 2011a). By 2017, 94% of U.S. soybean acreage was planted in a GE variety (USDA-NASS, 2018b). Most of this shift by growers to GE soybeans resulted because of the cost-effective benefits gained from improved weed control with HR varieties. The trend of planting primarily GE soybeans in the United States will likely continue under the No Action Alternative as new varieties are developed with new traits or that combine different traits desired by growers and consumers. For example, during the past decade, APHIS has considered petitions for nonregulated status for GE soybean varieties that combine resistance to multiple herbicides, provide insect resistance, or modify nutritional properties of the oil derived from

soybeans. Although these current trends for development of new GE soybean varieties are expected to continue, U.S. soybean acreage and production is not expected to change in the foreseeable future, and selection of the No Action Alternative is unlikely to alter this projection.

Preferred Alternative: Acreage and Locations of Soybean Production

Verdeca conducted phenotypic, agronomic, and environmental interaction trials with IND-00410-5 soybean and its non-transgenic soybean control parental line having a genetic background similar to IND-00410-5 soybean. The results of the combined trials demonstrated that there were no substantial agronomic or phenotypic differences between IND-00410-5 soybean and its comparator control or other commercial soybean varieties.

The increased yield of IND-00410-5 soybean is similar to and within the range of variability of other conventionally high-yield varieties described in Chapter 3 (Agronomic Practices). No meaningful phenotypic, agronomic, or environmental interaction differences between IND-00410-5 soybean and other commercial varieties were identified from test results (Verdeca, 2017); Verdeca, 2018). Therefore, no changes to the areas of U.S. soybean production are expected if a decision to not regulate IND-00410-5 soybean is made.

Because IND-00410-5 soybean is anticipated to increase yields, it might be expected to replace other varieties of soybean currently grown. Since the middle of the last century, changes in soybean varieties have contributed to increased yields, as have improved management practices. From 1991 to 2011, average soybean yield increased approximately 17.6% from 34.2 bushels per acre in 1991 to 41.5 bushels per acre in 2011, then declined slightly in 2012 to 39.3 (USDA-NASS, 2012f). Since 1991, U.S. soybean production acreage has increased 31% and reached 53.1 bushels per acre in 2017 (USDA-NASS, 2018b).

Between 1949 and 2007 total U.S. cropland has changed little, ranging between 478 million acres at the beginning of the period and 408 million acres in 2007, the lowest point of this period (USDA-ERS, 2011c). As explained in Chapter 3 (Acreage and Regional Distribution of Soybean Production), the decline in soybean acreage in 2007 is partially attributable to a change in the land use classification system used by USDA for the 2007 Agricultural Census (USDA-ERS, 2011c). Based on available data, most of the historic increase in soybean acreage reflects replacement of other crops with soybeans on existing cropland and more reliance on double-cropping with soybeans rather than conversion of non-crop land to new soybean production.

As described for the No Action Alternative, the USDA has projected that soybean acreage will remain relatively steady at approximately 91.5 million acres during the next decade (USDA-OCE, 2018). Although the yield potential of IND-00410-5 soybean is higher than its comparator, it is within the range of variation of many commercially available conventional varieties such as non-GE high-yield varieties that have been conventionally crossed with GE HR varieties (see “Soybean Yield” in Chapter 3 for more details). Based upon its phenotypic and agronomic similarity to other soybean varieties, IND-00410-5 soybean is also subject to the same variables affecting yield in other soybean varieties, such as management practices and weather (see “Agronomic Inputs” in Chapter 3 for more details). It is unlikely that a significant change in U.S. soybean production acreage would result from a determination of nonregulated status of

IND-00410-5 soybean. Therefore, effects on soybean production acreage under the Preferred Alternative would be the same as for the No Action Alternative and would not differ from current baseline conditions reviewed in Chapter 3, so no significant impacts are anticipated.

4.3.2 Agronomic Practices

No Action Alternative: Agronomic Practices

Under the No Action Alternative, IND-00410-5 soybean would continue to be subject to the regulatory requirements of 7 CFR part 340 and plant pest provisions of the PPA. However, growers would still have access to the many non-GE and the nonregulated GE soybean varieties currently available. The potential environmental impacts associated with the agronomic practices and inputs used for the production of GE and non-GE soybean varieties such as conventional and conservation tillage, soil and foliar fertilization, crop rotation, irrigation, pest (insects and weeds) and disease management with herbicides, pesticides, and fungicides, and crop residue management would be unaffected by continued regulation of IND-00410-5 soybean. EPA approves and labels uses of pesticides on soybeans. Commercial soybean growers would continue to use the same pesticides for soybean insect pest and weed as are currently used.

Preferred Alternative: Agronomic Practices

A determination of nonregulated status of IND-00410-5 soybean is not expected to result in changes to current soybean cropping practices. Verdeca's studies demonstrated that IND-00410-5 soybean is essentially the same as other commercial soybean varieties in terms of agronomic characteristics and cultivation practices, except for the potential added availability for use of glufosinate on IND-00410-5 soybean (Verdeca, 2017; 2018), so soybean growing practices would not change under the Preferred Alternative.

Producing higher grain crop yields often requires additional fertilization to be applied to replace the nutrients removed from the soil by the crop, whether or not the variety grown is bred to be high yielding. In two-year rotations of corn and soybean, a common practice is to fertilize the previous year's corn crop with enough phosphorus and potassium to allow for the subsequent soybean crop to be grown with no supplemental fertilizer as it is more economical than two separate applications (Franzen, 1999; Berglund and Helms, 2003; Ebelhar *et al.*, 2004). About two-thirds of U.S. soybean is grown in rotation with corn. However, annual supplementation of nutrients is common in soybean to soybean rotations in the southern United States. Levels of these nutrients may need to be checked and corrected if needed if IND-00410-5 soybean is planted. Regular testing of soil fertility levels and supplementation if needed is already widely recommended in soybean production for achieving optimal yields. Current practices in soybean include 41% of soybean acreage annually supplemented with phosphate (phosphorous) and 42% annually supplemented with potash (potassium) (USDA-NASS, 2018a). As soybean yields have been steadily increasing since the 1920s (Egli, 2008), and variations of yields are experienced field-to-field and year-to-year in GE and non-GE soybean production (USDA-NASS, 2012f; 2012e), growers are accustomed to managing for increased yields.

EPA's regulatory oversight of pesticides would not change. IND-00410-5 soybean is susceptible to the same insect and other invertebrate pests that affect other commercially available

conventional and GE soybean varieties, so pest management practices would not change from the No Action Alternative. Growers with weeds resistant to herbicides with other modes of action (MOAs) may choose glufosinate for weed management.

A determination of nonregulated status for IND-00410-5 soybean would make available to growers a soybean variety with glufosinate resistance. IND-00410-5 soybean would offer growers an additional HR soybean variety that may provide more flexibility in weed management programs. Growers would adopt and continue use of this soybean variety to the extent it provided optimal crop yields, product quality, and net returns.

IND-00410-5 soybean would only replace other glufosinate resistant varieties. Since there is no anticipated increase in U.S. soybean acreage in the foreseeable future, and no anticipated change in the acreage of glufosinate-resistant soybeans if IND-00410-5 soybean were no longer regulated, total glufosinate use is unlikely to change because current EPA-labeled uses of glufosinate are expected to remain the same.

Because the agronomic practices and inputs used to grow IND-00410-5 soybean are similar to existing soybean cultivation practices as described in Chapter 3, the potential impacts on agronomic practices under the Preferred Alternative would be the same as for the No Action Alternative.

4.3.3 Soybean Seed Production

No Action Alternative: Soybean Seed Production

Under the No Action Alternative, current soybean seed production practices are not expected to change. Several factors influence optimal planting rate for soybean such as row spacing, seed germination rate, soil conditions, climate, disease and pest pressure, past tillage practices and crop rotation (Robinson and Conley, 2007). Seeding rate is also determined by the plant population desired by the grower. Growers may plant certified soybean seed, uncertified seed, and binrun soybean seed that is grown and stored on individual farms (Oplinger and Amberson, 1986).

The production of the soybean seed crop for foundation, registered, certified, or quality control seed requires biological, technical, and quality control practices to maintain varietal purity greater than that for soybean grain production. The production and certification of soybean seed is regulated by state or regional crop improvement agencies that are chartered under the laws of the state(s) they serve (e.g., see Mississippi Crop Improvement Association, 2008; Illinois Crop Improvement Association, 2013; SSCA, No Date-a; Virginia Crop Improvement Association, No Date). The procedures followed by certified seed producers to ensure varietal purity and identity during the cultivation, harvest, storage, and transportation of soybean seed are not expected to change under the No Action Alternative.

Seed genetic purity is maintained to maximize the value of a new variety (Sundstrom *et al.*, 2002), of which a seed certification process ensures that the desired traits remain within purity standards (Bradford, 2006) (for more details see Chapter 3: Soybean Seed Production). Seed producers routinely submit applications to the AOSCA National Variety Review Boards for review and recommendation for inclusion into seed certification programs. For example, in

September 2012, AOSCA recommended the inclusion of 60 varieties of soybean expressing high yield traits by three seed producing companies for certification (AOSCA, 2012a; 2012b). It is expected that soybean seed producers would continue to implement measures to preserve the identity of their seed varieties if the No Action Alternative is selected.

Preferred Alternative: Soybean Seed Production

Field trials conducted by Verdeca have not demonstrated any agronomic or phenotypic differences between IND-00410-5 soybean and conventional soybean varieties that would require changes to soybean seed production practices (Verdeca, 2017). Based on the data provided by Verdeca, APHIS has concluded that the availability of IND-00410-5 soybean under the Preferred Alternative would not alter the agronomic practices, cultivation locations, seed production practices or quality characteristics of conventional and non-GE soybean seed production (USDA-APHIS, 2018e). Verdeca has also indicated IND-00410-5 soybean will be adopted into existing maturation groups to match the area in which it would be cultivated. Therefore, its adoption would not alter planting practices of soybean grown for seed. Various state agencies affiliated with AOSCA provide seed certification services. Verdeca has indicated that tests would be available and easily accomplished to determine the presence of the *HAHB4v* gene in seed stock. Based on this information, soybean seed production associated with the Preferred Alternative would not be any different than practices under the No Action Alternative.

4.3.4 Organic and Non-GE Soybean Production

No Action Alternative: Organic and Non-GE Soybean Production

Under the No Action Alternative, IND-00410-5 soybean would remain subject to the regulatory requirements of 7 CFR part 340 and the plant pest provisions of the PPA. GE, non-GE and organic soybean seed availability would not change as a result of the continued regulation of IND-00410-5 soybean. Organic and non-GE soybean growers would continue to use the same methods they currently use to manage crop identity, preserve the integrity of their production systems, and maintain organic certification. As described in Chapter 3 (Affected Environment: Organic Soybean Production), organic and non-GE soybean production is a very small portion of the soybean market., fluctuating between 96,080 to 126,000 acres between 2005 and 2011 (USDA-ERS, 2010a; USDA-NASS, 2012a). It would not be expected to change under the No Action Alternative

Preferred Alternative: Organic and Non-GE Soybean Production

GE soybean lines are already extensively used by farmers, while organic (less than 1.0%) and non-GE (less than 10.0%) soybean production represents a small percentage of the total U.S. soybean acreage (USDA-NASS, 2012a) . Organic and non-GE soybean acreage is unlikely to change significantly, regardless of whether new non-GE or GE soybean varieties, such as IND-00410-5 soybean, become available for commercial production.

When compared to other GE varieties of soybean, IND-00410-5 soybean does not present any new or different issues or potential impacts for organic and other specialty soybean producers and consumers. Organic producers employ a variety of measures to manage, identify and preserve the integrity of organic production systems (NCAT, 2003). Agronomic tests conducted

by Verdeca found that IND-00410-5 soybean is substantially equivalent to non-GE soybeans (Verdeca, 2017). Pollination characteristics are similar to other soybean varieties currently available to growers. Since soybeans exhibit limited pollen movement and are mostly self-pollinating (Caviness, 1966; OECD, 2000; Ray *et al.*, 2003; Abud *et al.*, 2007; Yoshimura, 2011), there is no indication that organic and non-GE soybean crops will be affected by a determination of nonregulated status for IND-00410-5 soybean if they continue to be produced in accordance with current agronomic practices to meet organic standards such as those of the NOP.

The trend in the cultivation of GE, non-GE, and organic soybean varieties, and the corresponding production systems to maintain varietal integrity are likely to remain the same as those for the No Action Alternative. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. Therefore, impacts on organic and non-GE soybean growers if a determination of nonregulated status for IND-00410-5 soybean is made (selection of the Preferred Alternative) would be the same as or similar to the No Action Alternative.

4.4 PHYSICAL ENVIRONMENT

4.4.1 Soil Quality

No Action Alternative: Soil Quality

Under the No Action Alternative, current soybean soil management practices that effect soil quality, including the use of cover crops to limit the time soil is exposed to wind and rain, tillage methods to reduce erosion and compaction, control weeds, and enhance nutrients, careful management of fertilizers and pesticides, crop rotation, establishing windbreaks and contour plowing (for more details see Chapter 3: Agronomic Practices) would be expected to continue. Growers would continue to choose management techniques based on weed, insect, and disease pressure, as well as the costs of seed and other inputs as they currently practice.

Preferred Alternative: Soil Quality

A determination of nonregulated status for IND-00410-5 soybean is not expected to result in changes to current soybean cropping practices that may impact soil quality. Studies conducted by Verdeca demonstrated that IND-00410-5 soybean is essentially indistinguishable from non-GE and other GE soybean varieties in terms of agronomic characteristics and cultivation practices (Verdeca, 2017). With regard to fertilization, IND-00410-5 soybean would not remove phosphorous and potassium from soil at a higher rate than other high-yield varieties, so applications to replace these nutrients, which is a common practice to maintain soil fertility (USDA-NASS, 2007), are unlikely to change if the Preferred Alternative were selected.

Use of glufosinate would likely offset the need to change tillage practices to control HR weeds, which would prevent soil quality losses from erosion. Application of EPA-registered glufosinate formulations would prevent unacceptable risks to current soil quality conditions.

The *HaHb4v* gene derived from sunflower (*Helianthus annuus*) that has been inserted into the IND-00410-5 soybean genome (Verdeca, 2017) mediates production of the HAHB4v protein, and it is not expected to cause an impact to the physicochemical characteristics of the soil. The HAHB4 protein allows for greater plant nutrient assimilation and utilization to drive yield improvement. Soil quality may be impacted by a soybean crop through direct interaction with soil fauna at the root system and by the degradation of remaining plant tissue after harvest. Compositional analysis of IND-00410-5 soybean forage tissue (i.e., stems and leaves) revealed no significant or consistent differences between it and the conventional control variety (Verdeca, 2017). There also were no differences between IND-00410-5 soybean and the conventional control variety with respect to plant-environment interactions or plant-symbiont interactions (Verdeca, 2017). Because of the compositional similarities between IND-00410-5 soybean and conventional soybeans, and the examined safety of the IND-00410-5 soybean gene products, it is not anticipated that IND-00410-5 soybean interactions with soil fauna or the impact of degradation of its stubble remaining in fields following harvest would be significantly different from that of conventional soybean. Based on the Agency's analyses of this information, overall impacts to soil under the Preferred Alternative is not expected to differ significantly from those of the No Action Alternative.

4.4.2 Water Resources

No Action Alternative: Water Resources

Current soybean management practices, including irrigation, and pesticide and fertilizer applications, would be expected to continue unchanged under the No Action Alternative. Under the authority of FIFRA, environmental risks of pesticide use are assessed during the registration processes of the EPA, and are regularly reevaluated to ensure that registered uses continue to pose no unreasonable risks to humans or the environment, including risks to water resources.

The trend towards conservation tillage or no-tillage practices since the adoption of GE HR soybean varieties is expected to continue, resulting in reduced surface water run-off and soil erosion (Dill *et al.*, 2008; Givens *et al.*, 2009). Conservation tillage and other management practices are used to trap and control sediment and nutrient runoff. Water quality conservation practices benefit agricultural producers by lowering input costs and enhancing the productivity of working lands (USDA-NRCS, 2012).

As of 2018, nitrogen, potassium, and phosphorous were applied to 18%, 25%, and 23% respectively of soybean acreage in 19 states surveyed (USDA-NASS, 2018d). High yield production practices for any soybean variety including those bred specifically for high yield, remove more nutrients from soils (Pedersen, 2008) than less intensive methods. Regular testing of soil fertility is required and applications of nutrients are not uncommon in soybean production (USDA-NASS, 2018a). As described in Chapter 3 (Cultivation), nitrogen is not usually applied to soybeans because they fix nitrogen in the soil through their symbiotic relationship with rhizomatous bacteria (CAST, 2009).

Preferred Alternative: Water Resources

No differences in morphological characteristics and agronomic requirements were found between IND-00410-5 soybean and its parent Williams 82 (Verdeca, 2017). Therefore, cultivation of IND-00410-5 soybean would not necessitate changes in current agronomic practices for soybean production, so current impacts of soybean cultivation on water quality would not change if IND-00410-5 soybean were no longer regulated under 7 CFR part 340. Verdeca evaluated on a site-specific basis abiotic stressors such as drought and flood, and found no difference between IND-00410-5 soybean and its comparator (Verdeca, 2017). As described previously in detail in this chapter (under Acreage and Regional Distribution of Soybean Production), if IND-00410-5 soybean is no longer regulated under 7 CFR 340, neither total U.S. soybean acreage nor its locations would change, so there would be no shifts in how or where water quality impacts related to soybean cultivation would occur in the United States. For these reasons, a determination of nonregulated status of IND-00410-5 soybean is unlikely to change the current irrigation practices in commercial soybean production.

Runoff from cropland areas receiving manure or fertilizer contributes to increased phosphorous and nitrogen in streams and lakes. In fresh water systems, phosphorus is the limiting factor causing eutrophication (see Chapter 3, Water Resources, for more details). Up to 41% of soybean acreage has been annually supplemented with phosphorous (USDA-NASS, 2018a). Since IND-00410-5 soybean is unlikely to change total U.S. soybean acreage or where soybeans are grown in the United States, impacts to water resources from fertilization are unlikely to change if the Preferred Alternative is selected.

Adoption of HR crops is associated with increased use of no-till and reduced till practices that benefit water quality by reducing runoff loads from soil erosion (Dill *et al.*, 2008; Givens *et al.*, 2009). The adoption rate of HR soybeans has steadily increased since their introduction in 1996. Today, more than 90% of U.S. commercially grown soybeans are herbicide resistant (USDA-NASS, 2018b) (see Chapter 3, “Area and Acreage” for more details). This trend is unlikely to change if IND-00410-5 soybean were to become commercially available.

Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. Application of glufosinate in accordance with EPA registration label requirements would prevent unacceptable risks to water quality from runoff.

Because IND-00410-5 soybean is expected to simply replace soybean varieties already in use and no changes to agronomic practices are required for its cultivation, the impacts of the Preferred Alternative on water use and water quality would be the same as those for the No Action Alternative.

4.4.3 Air Quality

No Action Alternative: Air Quality

Under the No Action Alternative, current air quality impacts from the soybean agronomic practices described in Chapter 3 such as tillage, cultivation, and agrochemical applications would continue unchanged. Applications of EPA-registered pesticides would continue unchanged, as would any associated environmental impacts because as part of its reregistration process, the EPA regularly reevaluates registered pesticides to ensure that they continue to pose no unacceptable risks. Of particular relevance to air quality, this process includes identifying methods to reduce pesticide drift, which are included on pesticide labels and approved by the EPA. Under the No Action Alternative use of pesticides according to EPA-approved labels would not pose unreasonable risk to air quality. The trend towards conservation tillage and no-till practices associated with cultivating HR soybean varieties, which reduces exhaust emissions from agricultural equipment and airborne dust from soil disturbance is also likely to continue (Dill *et al.*, 2008; Givens *et al.*, 2009).

Preferred Alternative: Air Quality

No differences in morphological characteristics and agronomic requirements were found between IND-00410-5 soybean and its comparator parent, Williams 82 soybean (Verdeca, 2017). Therefore, if the Preferred Alternative is selected, cultivation of IND-00410-5 soybean would not require changes to current soybean agronomic practices and no changes to emission sources (i.e., tillage, fossil fuel burning equipment, the application of fertilizers and pesticides) are expected. As discussed previously in this Chapter (under “Acreage and Regional Distribution of Soybean Production), commercial use of IND-00410-5 soybean would neither increase the total U.S. soybean acreage nor modify the existing U.S. soybean production range. Since no changes to agronomic practices for the cultivation of IND-00410-5 soybean and no increase in area or acreage are expected if the Preferred Alternative is selected, impacts to air quality are expected to be the same as the No Action Alternative.

Use of glufosinate would likely offset the need to change tillage practices to control HR weeds, so soil erosion impacts on air quality from soybean production would not change significantly from that of the No Action alternative. Application of EPA-registered glufosinate formulations would prevent unacceptable risks to air quality. Therefore, the impacts on air quality from selecting the Preferred Alternative are expected to be the same as or similar to those related to the No Action Alternative.

4.5 BIOLOGICAL RESOURCES

4.5.1 Animal Communities

No Action Alternative: Animal Communities

Under the No Action Alternative, animal species would continue to be affected by agronomic practices associated with soybean production, such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment (USDA-NRCS, 1999a; Brady, 2007; Sharpe, 2010; Palmer *et al.*, No Date) no differently than they are currently. Some of these current practices have potential to impact animal communities. For example, if tillage rates were to increase as a means of weed suppression, it could possibly diminish benefits to wildlife from conservation tillage practices. Some pesticides for weed, insect, and disease control may also

impact animal communities. However, environmental risks of pesticides to wildlife and their habitats are assessed by the EPA in its registration process and are regularly reevaluated to establish uses that have a reasonable certainty of not causing harm to non-target animals and their habitats.

Preferred Alternative: Animal Communities

A determination of nonregulated status of IND-00410-5 soybean is not expected to result in changes to current soybean cropping practices. Verdeca's studies demonstrated IND-00410-5 soybean is the same as other soybean varieties in terms of agronomic characteristics and cultivation practices (USDA-APHIS, 2018e; 2018f). IND-00410-5 soybean improves the potential for increased yield. If available, it would be another option to growers to improve yields. Because IND-00410-5 soybean is the same as other GE and non-GE soybeans in terms of agronomic practices (e.g., crop rotation; weed management; cultivation), no impacts to wildlife that use soybean fields for cover and forage (as described in Chapter 3 in "Animal Communities") are likely. Field trials showed that IND-00410-5 soybean does not confer any biologically significant differences to susceptibility or tolerance to insect pests, indicating that it would not impact wildlife (Verdeca, 2017).

USDA-APHIS (2018f) has evaluated the potential allergenicity and toxicity of the HAHB4 protein following Codex Alimentarius Commission guidelines to assess potential adverse effects to animals from feeding on IND-00410-5 soybean. These evaluations determined that the HAHB4 protein does not share any amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins. They also show that the HAHB4 protein is degraded rapidly and completely. The results presented by Verdeca indicated that the HAHB4 protein is unlikely to be toxic in animal diets. As part of its regulatory compliance process, Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4 protein produced by IND-00410-5 soybean ((FDA, 2015); NPC 000016; HAHB4). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017 (US-FDA, 2017b; 2017a). Copies of each document may be viewed on the FDA web site at: <http://www.fda.gov/bioconinventory>

The EPA considers non-target animal exposure in the registration and review of pesticides under FIFRA, including glufosinate (US-EPA, 2017c). The use of EPA-registered glufosinate formulations in accordance with EPA-approved label recommendations and restrictions would ensure that glufosinate poses only minimal risks to animals or animal communities.

Based on the above information, there are no expected hazards associated with the consumption of IND-00410-5 soybean and therefore it is unlikely to pose a hazard to wildlife species. More information about the Agency's analysis of the potential for impacts from the consumption of IND-00410-5 soybean is included in the section entitled "Animal Feed."

4.5.2 Plant Communities

No Action Alternative: Plant Communities

Under the No Action Alternative, IND-00410-5 soybean would remain under APHIS regulation. Soybean production would likely continue as it does today. Growers would likely continue to select the agronomic practices such as tillage, irrigation, row spacing, timing of planting, and weed management that optimize soybean yield and efficiency.

Plant species that typically compete with soybean production would be managed through the use of mechanical, cultural, and chemical control methods. Multiple herbicides would likely continue to be used for weed control in soybean fields. Runoff, spray drift, and volatilization of herbicides have the potential to impact non-target plant communities growing in proximity to fields in which herbicides are used. The environmental impacts of pesticide use are assessed by the EPA in the pesticide registration process and are regularly reevaluated by the EPA in its reregistration process under FIFRA. In this process, where appropriate, steps to reduce pesticide drift and volatilization are included on a pesticide's label approved by the EPA to minimize off-target effects

Preferred Alternative: Plant Communities

A determination of nonregulated status of IND-00410-5 soybean is not expected to result in changes to current soybean cropping practices. Field trials and laboratory analyses conducted by Verdeca showed no evidence of differences between IND-00410-5 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases (Verdeca, 2017). The expression of the HAHB4 protein in IND-00410-5 soybean is not expected to cause plant disease or increase susceptibility of IND-00410-5 soybean or its progeny to diseases or other pests (USDA-APHIS, 2018g).

Similar to the No Action Alternative, weeds within fields of IND-00410-5 soybean could be managed using mechanical, cultural, and chemical control. There are no differences expected in the use of herbicides or other pesticides in the production of IND-00410-5 soybean, when compared to other GE and non-GE soybean varieties (USDA-APHIS, 2018e). Except for the option to substitute glufosinate for other herbicides used, agronomic practices to cultivate IND-00410-5 soybean would not differ from the No Action Alternative. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. As with other herbicides used for soybean cultivation, glufosinate used in accordance with EPA registration requirements would continue to ensure that no unacceptable risks to non-target plants and plant communities would occur.

Based on the above information, APHIS has determined that the impacts to plant communities from a determination of nonregulated status of IND-00410-5 soybean are the same as or similar to those under the No Action Alternative.

4.5.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative, IND-00410-5 soybean would remain under APHIS regulation. The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of IND-00410-5 soybean. Because soybean is mostly self-pollinated and its cross-pollination rate significantly decreases with distance, introgression of soybean pollen to wild or weedy species is virtually impossible. This conclusion is further supported by several other characteristics of soybeans. Of greatest significance, is that no near relatives of soybeans that could be cross-pollinated occur in the United States. In addition, volunteer soybeans are typically not a major problem in agroecosystems, and regionally where volunteer soybean populations can develop, the volunteer plants are manageable and do not represent a serious weed threat (York *et al.*, 2005).

Preferred Alternative: Gene Flow and Weediness

A determination of nonregulated status of IND-00410-5 soybean is not expected to pose greater pollen- or seed-mediated gene flow, or increased potential for weediness than that of currently cultivated soybean varieties. There were no significant differences between the parental variety, Williams 82 and IND-00410-5 soybean that would increase the potential for gene flow from IND-00410-5 soybean or otherwise increase its weediness.

The *HaHb4* gene derived from the sunflower, *H. annuus*, was inserted into the IND-00410-5 soybean gene sequence as a variant (*HaHb4v*) and interacts with one or more endogenous transcription factors to increase plant nutrient assimilation (Verdeca, 2017). APHIS evaluated information in its PPRA (USDA-APHIS, 2018e) on the inserted genetic material, the potential for vertical and horizontal gene transfer, and weedy characteristics of IND-00410-5 soybean and concluded it would not represent any plant pest risk. Field trials and laboratory data for IND-00410-5 soybean indicate no plant pathogenic properties or weediness characteristics. Based on agronomic data and compositional analyses, IND-00410-5 soybean was found to be substantially equivalent to conventional soybeans and would no more likely become a plant pest than conventional soybeans. The reproductive characteristics of IND-00410-5 soybean are essentially equivalent to other GE and non-GE soybean varieties (Verdeca, 2017). IND-00410-5 soybean would not persist in unmanaged environments and does not demonstrate a competitive advantage compared to conventional soybeans. The trait for increased yield is not expected to contribute to increased weediness without changes in a combination of other characteristics associated with weediness, such as hard seed and increased lodging, among other characteristics. Given the reproductive nature of soybean, the potential for cross-pollination of IND-00410-5 soybean with other soybean varieties is highly unlikely.

Studies have indicated horizontal gene transfer and expression of DNA from a plant species to bacteria is unlikely to occur (Keese, 2008). Furthermore, there is no evidence that bacteria closely associated with plants and/or their constituent parts contain genes derived from plants (Kaneko *et al.*, 2000; Wood *et al.*, 2001; Kaneko *et al.*, 2002) and when horizontal gene transfer has been found to occur, it has been on an evolutionary time scale of millions of years (Koonin *et al.*, 2001; Brown, 2003). Finally, the FDA has determined the chance of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (US-FDA, 1998). Based on this information, APHIS has concluded that horizontal gene flow from IND-00410-5 soybean to other unrelated

organisms would be highly unlikely (USDA-APHIS, 2018e).

If a determination of nonregulated status is made for IND-00410-5 soybean, the risks to wild plants and agricultural productivity from weedy IND-00410-5 soybean populations are negligible, as volunteer soybean populations can be easily managed and there are no feral or weedy relatives in the United States (Carpenter *et al.*, 2002). If present as volunteer soybean, IND-00410-5 soybean would not be considered difficult to control, as soybean seeds rarely remain viable the following season and are easily managed with cultivation, hand weeding, or the application of herbicides. In addition, since no feral or weedy species of soybean exist in the United States (Ellstrand *et al.*, 1999; OECD, 2000), IND-00410-5 soybean poses no potential for either naturally occurring, pollen-mediated gene flow or transgene introgression (USDA-APHIS, 2018e). Based on the above information, APHIS has determined that the effects on other vegetation in and around soybean fields from a determination of nonregulated status for IND-00410-5 soybean are identical to or similar to those under the No Action Alternative. Therefore, selection of the Preferred Alternative would not result in any new significant impacts related to gene flow or weediness.

4.5.4 Microorganisms

No Action Alternative: Microorganisms

Under the No Action Alternative, IND-00410-5 soybean would remain under APHIS regulation. The availability of GE, non-GE, and organic soybeans would not change as a result of the continued regulation of IND-00410-5 soybean. Agronomic practices used for soybean production, such as soil inoculation, tillage, and the application of agricultural chemicals (pesticides and fertilizers) that potentially impact microorganisms, would continue.

Preferred Alternative: Microorganisms

A determination of nonregulated status of IND-00410-5 soybean is not expected to change current soybean cropping practices that may affect microorganisms. Possible direct and indirect impacts of IND-00410-5 soybean on microbial communities would be identical or similar to those for non-GE soybeans and other GE varieties. IND-00410-5 soybean could have some effect on the structure of the soil microbial community in which it is planted, which could include nitrogen-fixing bacteria and mycorrhizal fungi; bacteria, actinomycetes (filamentous bacteria), and saprophytic fungi responsible for decomposition; denitrifying bacteria and fungi; phosphorus-solubilizing bacteria and fungi; as well as pathogenic and parasitic microbes (see Subsection 3.3.4, Microorganisms) (USDA-NRCS, 2004). Testing by Verdeca revealed no significant differences found in the parameters measured to assess the relationship of the legume and its associated symbiont between IND-00410-5 soybean and the conventional control Williams 82 (Verdeca, 2017).

Like other high yielding soybean varieties and high yield soybean production systems, cultivation of IND-00410-5 soybean may remove more nutrients, particularly phosphorus and potassium, than other varieties, necessitating testing and possibly increased soil nutrient amendments. Soil organisms require varying amounts of both macronutrients, including phosphorus, and micronutrients (USDA-NRCS, 2004). Several studies have demonstrated *B.*

japonicum activity, root nodulation, and nitrogen fixation are positively correlated with phosphorus levels (Cassman *et al.*, 1980; Beck and Munns, 1984; Israel, 1987; Mullen *et al.*, 1988; Sa and Israel, 1991; Tsvetkova and Georgiev, 2003). Likewise, potassium is necessary for nodule formation and bacteria-mediated nitrogen fixation in soybean and other nitrogen-fixing legumes (Mengel *et al.*, 1974; IPNI, 1998). As reviewed in the section entitled “Agronomic Practices” in Chapter 3, the application of these nutrients to soybean is not an uncommon practice and is widely recommended to sustain the yields of all soybean varieties.

Field and greenhouse tests show no significant differences from other nonregulated soybean varieties in the parameters measured to assess the relationship of IND-00410-5 soybean with its symbionts (Verdeca, 2017). IND-00410-5 soybean would not result in any significant changes to current soybean cropping practices that may impact microorganisms except that glufosinate may be substituted for other herbicides, where HR weeds are a problem. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. As with other herbicides used for soybean cultivation, glufosinate used in accordance with EPA registration requirements would continue to ensure that no unacceptable risks to non-target microorganisms would occur.

Based on the above information, overall impacts to microorganisms under the Preferred Alternative are expected to be the same as or similar to the No Action Alternative. Therefore, there are no indications that the effects of commercially growing IND00410-5 soybean would cause significant impacts to microorganisms if the Preferred Alternative were selected.

4.5.5 Biodiversity

No Action Alternative: Biodiversity

Under the No Action Alternative, IND-00410-5 soybean would remain under APHIS regulation. The availability of GE, non-GE and organic soybeans would not change. Agronomic practices used for soybean production and yield optimization, such as tillage, the application of agricultural chemicals (pesticides and fertilizers), timing of planting, row spacing, and scouting for pest infestations would be expected to continue unchanged. Agronomic practices that benefit biodiversity both on cropland (e.g., intercropping, agroforestry, crop rotations, cover crops, and no-tillage) and on adjacent non-cropland (e.g., woodlots, fencerows, hedgerows, and wetlands) would also remain the same.

Preferred Alternative: Biodiversity

A determination of nonregulated status of IND-00410-5 soybean is not expected to result in changes in current soybean cropping practices that may impact biodiversity. Trials conducted by Verdeca showed no differences between IND-00410-5 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases (Verdeca, 2017). Similar to the No Action Alternative, weeds within fields of IND-00410-5 soybean could be managed using mechanical, cultural, and chemical control. Growers would determine the best method necessary to manage pests based on individual needs. The environmental risks of

pesticide use are assessed by the EPA in the pesticide registration process and are regularly reevaluated by the EPA as part of its reregistration process under FIFRA. Pesticide use in accordance with label instructions established by the EPA would not result in unreasonable risks to the environment. Under the Preferred Alternative, potential impacts to biodiversity from runoff, spray drift, and volatilization of agricultural chemicals such as pesticides, herbicides, and fungicides are not expected to be substantially different from those associated with the No Action Alternative.

Possible risks to biodiversity from the production of GE crops include the disturbance of biosystems, including the agroecosystem, and permanent loss or changes in species diversity or the genetic diversity within a species (Snow *et al.*, 2005). As discussed in Chapter 3 in the section, “Biodiversity,” the intensive farming practices associated with agricultural lands limit the diversity of plants and animals (Lovett *et al.*, 2003). Diversity in adjacent natural areas, and those areas established to promote biodiversity (e.g., woodlots, fencerows, hedgerows, and wetlands) tend to have greater biodiversity. Agronomic practices for the production of IND-00410-5 soybean are not expected to change from those currently used for other commercially available GE and non-GE soybean varieties. Therefore, impacts on species diversity would be the same as or similar to those of the No Action Alternative. Agronomic practices commonly used to increase farm-scale biodiversity (see Chapter 3: “Biodiversity”) are also unlikely to change. As described in this chapter in the section entitled “Gene Flow and Weediness,” IND-00410-5 soybean has no potential to produce naturally occurring, pollen-mediated gene flow and transgene introgression, so is not expected to affect genetic diversity.

A determination of nonregulated status of IND-00410-5 soybean is anticipated to have similar impacts on crop, farm, or landscape level biodiversity as the No Action Alternative. Therefore, the impacts on biodiversity if the Preferred Alternative is selected would be the same as or similar to those for the No Action Alternative

4.6 ANIMAL FEED

4.6.1 Animal Feed

No Action Alternative: Animal Feed

Under the No Action Alternative, IND-00410-5 soybean would continue to be regulated. Soybean-based animal feed derived from both non-GE and those GE varieties that are not regulated under 7 CFR part 340 would continue to be available. Nonregulated GE soybean varieties used as animal feed have been previously determined to not pose any risk to animal health.

Preferred Alternative: Animal Feed

Results of studies conducted by Verdeca confirmed that there are no differences in the quality of animal feed produced from IND-00410-5 soybean compared to feed derived from both non-GE and those GE varieties that are not regulated under 7 CFR part 340 (Verdeca, 2017). APHIS critically reviewed data provided by and information in the scientific literature cited by (Verdeca,

2017), and concluded that a determination of nonregulated status of IND-00410-5 soybean would not alter the nutritional quality of animal feed derived from it.

Possible impacts to livestock from a determination of nonregulated status for IND-00410-5 soybean are related to potential health impacts on animals from consuming soybean products derived from soybeans containing the *HaHb4v* gene and HAHB4v protein it expresses or the *bar* gene or PAT protein it expresses. Safety evaluations conducted by Verdeca followed Codex Alimentarius Commission procedures recommended to assess potential adverse impacts to animals and humans. These safety studies included: (1) characterization of the physicochemical and functional properties of the HAHB4v protein; (2) quantification of the HAHB4v protein levels in plant tissues; (3) comparison of the amino acid sequence of the HAHB4v protein in IND-00410-5 soybean to known allergens, gliadins, glutenins, toxins, and other biologically-active proteins known to have adverse effects on mammals; (4) evaluation of the digestibility of the HAHB4v protein in simulated gastric and intestinal fluids; (5) documentation of the presence of related proteins in several plant species currently consumed; and (6) investigation of the potential mammalian toxicity through an oral gavage assay. The HAHB4v protein was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid.

As part of its regulatory compliance process, Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4v protein produced by IND-00410-5 soybean ((FDA, 2015); NPC 000016; HAHB4). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (FDA, 2017). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017 (US-FDA, 2017b; 2017a). Copies of each document may be viewed on the FDA web site at: <http://www.fda.gov/bioconinventory>

The *bar* gene that expresses the PAT protein that degrades glufosinate has been evaluated previously in EAs conducted by APHIS and has an established history of safety in conjunction with GE crop varieties expressing it that are no longer regulated. Results provided by Verdeca confirmed that there are no differences in the *bar* gene inserted into the genome of IND-00410-5 soybean or the PAT protein expressed in IND-00410-5 soybean plants compared to other GE glufosinate-resistant soybean varieties (Verdeca, 2017). On May 22, 2018, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for the PAT protein expressed by IND-00410-5 soybean. The FDA response is pending. Pesticide residue tolerances for pesticides listed in 40 CFR § 180 establish residue limits for soybean forage, hay, hulls, and seed (US-EPA, 2010a) that are protective of livestock and human health. The EPA has established an exemption for a tolerance for the PAT protein when it is a plant-incorporated protectant (CFR 174.522).

Based on the above information, there are no expected hazards associated with the consumption of IND-00410-5 soybean by animals, so it is unlikely to pose a hazard to any livestock species. The results of studies conducted by Verdeca confirmed that the crops containing these proteins can be safely used as animal feed (Verdeca, 2017). There are no differences in feed safety between the IND-00410-5 soybean and other varieties currently available under the No Action

Alternative. Based on this information, APHIS has concluded that a determination of nonregulated status of IND-00410-5 soybean would have no adverse impacts on animal feed or the health of livestock that consume it. Overall impacts of selecting the Preferred alternative would be the same as or similar to those of the No Action Alternative.

4.7 HUMAN HEALTH

4.7.1 Public Health

No Action Alternative: Public Health

Under the No Action Alternative, IND-00410-5 soybean would remain under APHIS regulation. Human exposure to existing GE and non-GE soybean varieties would not change under this alternative. A variety of EPA-registered pesticides would continue to be used for pest management in both GE and non-GE soybean cultivation. The environmental risks of pesticide use are assessed by the EPA in its pesticide registration process and are regularly reevaluated under its reregistration process to ensure that pesticides do not cause unreasonable adverse effects on human health or the environment.

The EPA also establishes maximum residue limits for pesticides that are referred to as tolerances (US-EPA, 2010a). Tolerances represent the maximum amount of pesticide residues that can remain on or in food or feed. These levels have been carefully determined using scientific data to establish exposure levels that will not cause adverse health effects. The EPA sets tolerances for pesticides to meet FQPA safety standards for the U.S. population and designated sensitive populations (i.e., infants and children) to ensure that there is a reasonable certainty of no harm to the general population and any subgroup. Food or feed may not be distributed for consumption if it contains residues of one or more pesticides that exceed a tolerance. Food and feed with pesticide residues that exceed a tolerance are considered adulterated and may be seized. The FDA and USDA monitor foods for pesticide residues and enforce tolerances (USDA-AMS, 2011). Refer to the section in Chapter 3 entitled “Human Health” for further details about tolerances or go to the EPA web site at: <http://www.epa.gov/pesticides/bluebook/chapter11.html>

Preferred Alternative: Public Health

The protein in IND-00410-5 soybean that promotes potential increased yield is derived from the *HaHB4* gene from the sunflower, *H. annuus*. Verdeca conducted safety evaluations using Codex Alimentarius Commission procedures to assess any potential adverse impacts to humans or animals resulting from environmental releases and consumption of IND-00410-5 soybean (Verdeca, 2017). The HAHB4v protein expressed by the *HaHB4v* gene in IND-00410-5 soybean was determined to have no amino acid sequences similar to known allergens and lacked toxic potential to mammals. As part of its regulatory compliance process, Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4 protein produced by IND-00410-5 soybean (FDA, 2015). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF No. 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017. Copies of each document may be viewed on the FDA web site at: <http://www.fda.gov/bioconinventory>

The *bar* gene that expresses the PAT protein that degrades glufosinate has been evaluated previously in EAs conducted by APHIS and has an established history of safety in conjunction with GE crop varieties expressing it that are no longer regulated (USDA-APHIS, 1998; 2014a; 2014b). Results provided by Verdeca (Verdeca, 2017; Verdeca, 2018) confirmed that there are no differences in the *bar* gene inserted into the genome of IND-00410-5 soybean or the PAT protein expressed in IND-00410-5 soybean plants compared to those soybean varieties previously evaluated by APHIS. On May 22, 2018, Verdeca initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean. The FDA response is pending.

Based on this information, including field and laboratory data and scientific literature provided by USDA-APHIS (2018f) and safety data for other GE soybeans, APHIS concluded that there would not be any adverse human health effects from a determination of nonregulated status of IND-00410-5 soybean. Human consumption of food products derived from IND-00410-5 soybean would not be different from those derived from non-GE or GE soybean varieties that are not regulated under 7 CFR part 340. Likewise, human consumption of food products derived from livestock feed derived from IND-00410-5 soybean would not be different from products from livestock feed from non-GE or GE soybean varieties that are not regulated under 7 CFR part 340 because no significant impacts on animal health were identified for IND-00410-5 soybean (see the preceding section, “Animal Feed,” for further details). Any impacts associated with choosing the Preferred Alternative would be the same as or similar to those for the No Action Alternative, and not have significant impacts on human health.

4.7.2 Worker Safety

No Action Alternative: Worker Safety

The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of IND-00410-5 soybean. Agronomic practices used for soybean production, such as the application of agricultural chemicals (pesticides and fertilizers), would be expected to continue unchanged. Growers will continue to choose agronomic practices based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006). Worker safety is taken into consideration by the EPA in the pesticide registration and reregistration processes. Pesticides are regularly reevaluated by the EPA for each pesticide to maintain its registered status under FIFRA. Occupational Safety and Health Administration requires all employers to protect their employees from hazards associated with pesticides and herbicides. When used according to label directions, pesticides can be used with a reasonable certainty of no harm to human health and no unreasonable risks to the environment.

The EPA Worker Protection Standards (WPS) (40 CFR Part 170) implement protections for agricultural workers, handlers, and their families. These WPS requirements were revised in 2015 to implement even stronger standards that became effective on January 2, 2017, with further revisions implemented as of January 2, 2018. The EPA has also issued guidance for farm managers about how to implement the new standards (US-EPA, 2017d).

Preferred Alternative: Worker Safety

A determination of nonregulated status of IND-00410-5 soybean is not expected to result in changes in current soybean cropping practices. Similar to the No Action Alternative, it is expected that EPA-registered pesticides, fertilizers, and other chemicals that are currently used for soybean production would continue to be used by growers. The EPA's core pesticide risk assessment and regulatory processes ensure that each registered pesticide continues to meet the highest standards of safety including all populations of non-target species and humans, and if used in accordance with the label, can be demonstrated to pose a reasonable certainty of no harm to humans, including those employed in agricultural and farm-related occupations, and no unreasonable adverse effects to the environment. The EPA WPS (40 CFR Part 170) would be the same as that described for the No Action Alternative. Growers are required to use pesticides in accordance with the application instructions provided on the EPA registration label for each pesticide product label, and follow the additional guidance (US-EPA, 2017d) issued by the EPA to ensure farm worker safety. These label restrictions are legally enforceable and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful Acts).

Exposure to IND-00410-5 soybean under the Preferred Alternative is not expected to pose any changes to existing human health risks. Based on the above information, occupational health and safety risks under the Preferred Alternative are expected to be the same as or similar to those associated with the No Action Alternative. Neither the No Action Alternative nor the Preferred Alternative are likely to have impacts that cause harm to workers in farm-related agricultural occupations.

4.8 SOCIOECONOMIC IMPACTS

4.8.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, IND-00410-5 soybean would remain under APHIS regulation. Growers and other parties who are involved in production, handling, processing, or consumption of soybeans would continue to have access to other nonregulated GE and non-GE soybean varieties. Domestic growers would continue to utilize GE and non-GE soybean varieties based upon availability and market demand. Current production practices (see Chapter 3, "Agronomic Practices" for more details), using GE HR and IR varieties to optimize yield and reduce production costs would not change if the No Action Alternative is selected. Grower net returns are estimated to increase approximately 24% from \$303 to \$375 per acre by the end of the period, 2013/2014 to 2021/2022, despite an estimated 3% rise in seed and residual costs, and 10.3% rise in overall per acre cost of production (USDA-OCE, 2012).

Preferred Alternative: Domestic Economic Environment

In field tests conducted by Verdeca, the performance and composition of IND-00410-5 soybean was determined not to be substantially different from that of the non-GE comparator Williams 82

(Verdeca, 2017). If no longer regulated, IND-00410-5 soybean would be subject to the same variables that affect yield of other GE and non-GE soybean varieties such as weather, timing and density of planting, and soil nutrients (see Chapter 3, “Agronomic Practices” for more details). Growers are familiar with yield improvements using increased yield varieties obtained through traditional breeding techniques, and more recently, increased yields from better weed control and disease resistance in GE soybean varieties. As noted previously, soybean yields have increased steadily since 1924 (USDA-NASS, 2012f).

IND-00410-5 soybean would be expected to be adopted by some growers who are already growing GE soybeans. The rate of adoption would depend on anticipated yield increase, and how this equates to increased profitability after seed and production costs of growing the IND-00410-5 soybean variety are considered. It is unlikely the availability of IND-00410-5 soybean would significantly impact the domestic economic environment. As described under the No Action Alternative, past and recent increases in U.S. soybean acreage have occurred as growers replaced other crops with soybeans; not by bringing new lands into production. U.S. total cropland has remained relatively stable since the mid-20th century. Since 94% of U.S. soybean acreage is planted with GE soybean varieties (USDA-NASS, 2018b), it is likely that IND-00410-5 soybean would only replace other varieties of GE soybean grown on existing cropland. Historically, soybean yields have been increasing for decades. In more recent times, this has resulted from conventional cross-breeding of high yielding varieties with GE HR and IR varieties, and applying improved management practices.

GE seed is generally more expensive than conventional seed. Producers using IND-00410-5 soybean would likely be charged a technology fee as part of the seed purchase price (NRC, 2010). Technology fees are charged by the product developer to cover research and development, production, marketing and distribution expenses. The amount of the fee is determined by the willingness of producers to purchase the seed, the competitiveness of the seed market, and the pricing behavior of firms that hold large shares of the market (NRC, 2010). APHIS has no control over the establishment of technology fees, but assumes that the fee for IND-00410-5 soybean would be comparable to those for other GE crops. Growers would have to make an independent assessment as to whether the benefits of IND-00410-5 soybean would offset higher seed cost.

Only a small portion of the U.S. soybean market is organic. In 2016, organic soybeans were produced on 124,591 acres in the United States, compared to 94,841 in 2015. Iowa reported the largest number of acres planted to certified organic soybeans that year: 20,547. That same year, Minnesota had 13,893 acres planted in organic soybeans, and Michigan had 10,815 acres. Frequently, the organic market specifies 'Vinton' and other varieties of food-grade soybeans. These varieties are used primarily in the production of tofu, tempeh, soya nuts and a host of other products and are generally grown under contract (USDA-AMS, 2017). If IND-00410-5 soybean were available as another option for farmers to pursue increased productivity, this would not be expected to influence changes in decisions made by growers of organic soybean production.

Based upon the preceding information, the potential domestic economic impacts from a determination of nonregulated status for IND-00410-5 soybean would be similar to or no different than those under the No Action Alternative.

4.8.2 International Trade Economic Environment

No Action Alternative: International Trade Economic Environment

If the No Action Alternative is selected, IND-00410-5 soybean would continue to be regulated by APHIS. It is unlikely the current soybean market trade trends described in Chapter 3 would change if IND-00410-5 soybean remained a regulated article. U.S. soybeans will continue to be a major contributor to global soybean production, and the United States will continue to be major exporter and supplier in the international market (USDA-NASS, 2016d).

Preferred Alternative: International Trade Economic Environment

As reviewed in Chapter 3 (International Trade Economic Environment), there are several factors that influence worldwide prices for oilseed, including soybean and its products. These include energy costs, fluctuations in currency exchange rates, government policies, national population size, per capita income, global market conditions, and trends and practices in market trading and speculation (Trostle, 2008b; Trostle, 2008a; Irwin and Good, 2009). These factors influence the value derived from soybeans. If this value increases, it gets distributed between consumers in the form of lower product prices and growers and distributors as increased profits.

As described previously in this chapter (under “Acreage and Locations of Soybean Production”), projections from current trends in U.S. production indicate that it is unlikely that U.S. soybean acreage will increase significantly, so if it became commercially available, IND-00410-5 soybean, would likely replace other high yield GE soybean varieties. Any impact on soybean market prices from the potential increased yield from IND-00410-5 soybean production would likely be negligible because it is similar to other high yielding soybean varieties already commercially available. Therefore, it would not alter the value currently derived from U.S. soybean production, so would not have any significant impact on the international trade environment for U.S. exports of soybean products.

USDA projects that from 2013/2014 to 2021/2022, the national annual average of U.S. soybean yield is expected to increase approximately 8% without expanding acreage (USDA-NASS, 2016d), but the U.S. average farm price per bushel of soybean is predicted to vary only between \$10.30 and \$11.35. Grower annual net returns per acre are estimated to increase on average approximately 24% over the same period, despite an estimated approximately 3% rise in seed and residual costs, and 10.3% rise in overall per acre cost of production (USDA-OCE, 2012). Adoption of IND-00410-5 soybean would likely be gradual at a pace equal to the extent growers find value in another higher than average yielding soybean variety.

It is not expected that if available, IND-00410-5 soybean would affect world attitudes towards GE crops. While 28 other countries have adopted the use of GE crops (Clive, 2011), consumers in many countries, including some EU countries view the potential risks from GE crops as greater than the benefits (Costa-Font *et al.*, 2008). However, the EU has approved soybean food and feed products derived from varieties containing traits conferring resistance to glufosinate, glyphosate, and ALS-inhibiting herbicides and certain lepidopteran pests (European

Commission, 2013). Therefore it is likely that food and feed derived from IND-00410-5 soybean would also be approved by the EU, since it has been genetically modified for increased yield using a plant gene from the sunflower, *H. annuus*, which is also a source of food for human consumption, and has also been genetically engineered for glufosinate resistance. The adventitious presence of GE products in other food or feed continues to be a concern of internationally traded grain (Demeke *et al.*, 2005). Buyers, foreign governments, nongovernmental organizations, and consumer groups may use private testing firms to mitigate against the potential for adventitious presence of GE traits in food or feed products.

In conclusion, the potential impacts to the trade economic environment from a determination of nonregulated status of IND-00410-5 soybean would be similar to or no different than those currently observed for other high yield soybean varieties under the No Action Alternative. Therefore, a determination of nonregulated status of IND-00410-5 soybean is not expected to have any significant impact on total annual U.S. soybean production, and no significant impacts on the international trade economic environment affecting U.S. soybean exports.

5 CUMULATIVE IMPACTS

The CEQ regulations define a cumulative impact 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 other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time” (40 CFR part 1508, Section 1508.7, Cumulative impact).

In Chapter 4, APHIS analyzed individually the environmental consequences that may derive from denial and approval of the petition. As part of that analysis, APHIS considered the potential direct and indirect impacts on those aspects of the human environment related to the petition, and any subsequent commercial production of IND-00410-5 soybean. In this chapter, APHIS considers the potential cumulative impacts that could derive from APHIS’ decision on the petition.

5.1 METHODOLOGY AND ASSUMPTIONS

For its analysis, APHIS assumed that if no direct or indirect impacts on a resource area were identified as part of its analyses of impacts from a regulatory decision for IND-00410-5 soybean under Environmental Consequences (Chapter 4), then there cannot be any cumulative impacts on that resource area. When possible, effects were quantified for the analysis to measure the potential to cause significant impacts; otherwise qualitative assessments were made.

APHIS limited its cumulative impacts analysis to the areas in the United States where soybeans are commercially grown. The potential for significant impacts from effects identified by the Agency as being reasonably foreseeable cumulative impacts were analyzed under the assumption that farmers, who grow non-GE or other GE soybeans conventionally or organically would continue to use the same BMPs they currently use if IND-00410-5 soybean were no longer regulated.

GE soybeans grown in the United States are frequently produced from varieties that have multiple GE traits. Such varieties are referred to as “stacked” hybrids, and some have been developed using the same recombinant DNA techniques used to produce single-trait GE varieties. These are subject to APHIS regulation under 7 CFR part 340 until a determination of nonregulated status is made. However, stacked hybrids can also be developed using traditional cross-breeding to combine GE traits from different GE varieties, including those that have previously been evaluated individually by APHIS and have been determined to have nonregulated status. Therefore, if APHIS makes a determination of nonregulated status for IND-00410-5 soybean, it is possible that it will be combined with non-GE and other GE soybean varieties that are not regulated by the Agency.

If it is no longer regulated, traditional plant breeding methods could be used to develop stacked trait hybrids between IND-00410-5 soybean and other GE soybean varieties that have previously been determined to have nonregulated status. These include, for example, varieties that are resistant to herbicides and certain insect pests, and those expressing modified nutritional profiles.

If IND-00410-5 soybean were no longer regulated, cross-breeding it with other GE soybean varieties to produce stacked trait varieties is a reasonably foreseeable action that might occur.

5.2 Cumulative Impacts: Agricultural Production of Soybean

Except for its enhanced yield potential and glufosinate resistance, IND-00410-5 soybean is agronomically and compositionally similar to its non-GE comparator, Williams 82 and other GE and non-GE soybean varieties (Verdeca, 2017). Although IND-00410-5 soybean yielded more than its comparator variety in field studies, its yield was within the range of other high yield conventional soybeans (Verdeca, 2017)

Neither the No Action Alternative nor the Preferred Alternative are expected to change total U.S. soybean acreage or cause any shift in the regions where soybean crops are currently grown for grain or seed (see Chapter 4: Acreage and Regional Distribution Area of Soybean Production and Soybean Seed Production for more details). Total U.S. cropland has remained relatively steady since the middle of the last century. Increases in soybean acreage have occurred during this period, but this is the result of replacing other crops on existing cropland (USDA-ERS, 2011c). Future increases in soybean production will likely be from improved soybean varieties and production methods that increase yield rather than expand production area (OECD-FAO, 2008). Most soybeans currently grown in the United States are GE HR varieties (USDA-ERS, 2012c). Long-term projections indicate that soybean acreage will remain level at about 76 million acres until 2028 (USDA-OCE, 2018). If it were no longer regulated, it is expected that IND-00410-5 soybean would replace other similar GE soybean varieties and would not increase current total U.S. acreage or change the areas where soybeans are grown. Therefore, there would be no difference in the environmental impacts of selecting either the Preferred Alternative or the No Action Alternative on total U.S. soybean acreage or the locations where soybeans are grown for seed or grain, so there would not be any associated cumulative impacts.

Based upon past and current trends, the addition of another GE soybean variety would not have any impacts on the ability of organic soybean producers to maintain their current market share (see Organic Soybean Production in Chapter 3 for more details). U.S. organic soybean production acreage has fluctuated somewhat from year to year between 82,143 and 126,000 acres during the period, 1997-2011 (USDA-ERS, 2010a; USDA-NASS, 2012a). This represented about 0.09% of total U.S. soybean acreage in 2011 (USDA-NASS, 2012a). The most recent data puts U.S. organic soybean acreage at 124,591 in 2016, compared to 94,841 in 2015 (USDA-AMS, 2017), which indicates little fluctuation from the previously reported trends. Availability of another GE soybean variety, such as IND-00410-5 soybean would not be expected to alter any impacts that GE soybeans currently have on organic soybean production, so no cumulative impacts will be associated with selecting either the No Action Alternative or the Preferred Alternative.

Studies conducted by Verdeca demonstrated that, in terms of agronomic characteristics and cultivation practices such as tillage, fertilization, irrigation, pest and disease control measures, crop rotation, and irrigation, IND-00410-5 soybean is similar to other high yield soybean varieties currently grown (Verdeca, 2017). Therefore, IND-00410-5 soybean production is likely to require the same fertilizer inputs as other high yield soybean systems utilizing conventional or GE soybean varieties. As described in Chapter 3 (Agronomic Inputs), supplementing soybean

crops with nutrients is not uncommon (USDA-NASS, 2018d), and BMPs that include soil fertility testing and supplementation recommendations to optimize nutrient replacement and maximize yield potential are widely used (Snyder, 2000; Specht *et al.*, 2006; Pedersen, 2008; CAST, 2009; Mallarino *et al.*, 2011; Silva, 2011).

If IND-00410-5 soybean were no longer regulated, it would be grown in rotation with other crops such as corn or wheat, no differently than any other high yield soybean varieties. In two-year corn-soybean rotations, enough potassium and phosphorus amendments are commonly applied to the corn crop to sustain the soybean crop the following year without additional supplementation (Bender *et al.*, 2013). However, recent research has shown higher yielding corn varieties may remove more phosphorus than is applied on average, and soil fertility testing prior to soybean planting is recommended (Bender *et al.*, 2013). Potassium and phosphorus are commonly applied annually where soybeans are not rotated, which is the predominant practice in the South (Heatherly, 2012). Testing soil fertility and supplementing nutrients is widely recommended and used in soybean production to achieve optimal yield potential (Snyder, 2000; Specht *et al.*, 2006; Pedersen, 2008; CAST, 2009; Mallarino *et al.*, 2011; Silva, 2011). There is no evidence that cultivation of IND-00410-5 soybean would require changes to any of these fertilization practices in soybean production.

Since the agronomic requirements and cultivation practices for IND-00410-5 soybean are the same as those for other high yield conventional and GE soybean varieties currently grown in the United States, any environmental impacts from current soybean production in the United States would not be altered if IND-00410-5 soybean were no longer regulated by APHIS. Because there would be no changes in impacts, APHIS concluded that there would not be any cumulative impacts associated with selecting either the No Action Alternative or the Preferred Alternative.

5.3 Cumulative Impacts: Physical Environment

Current agronomic practices for soybeans described in Chapter 3 are important sources of impacts on the physical environment. Agronomic practices that have the potential to impact soil, water, and air quality, such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not change following a determination of nonregulated status of IND-00410-5 soybean because IND-00410-5 soybean is agronomically and morphologically similar to other GE and non-GE soybeans, including high yield varieties. Other practices that benefit these resources, such as contouring, use of cover crops to limit the time soil is exposed to wind and rain, crop rotation, and windbreaks would also remain the same under both Alternatives. Because of its similarity to other commercially available soybean varieties, including high yield varieties, and the likelihood that IND-00410-5 soybean would only replace other similar varieties, it would not change the acreage or locations of current U.S. soybean production. Therefore, any existing impacts on water, soil, and air quality from current U.S. soybean production practices would not change if IND-00410-5 soybean were no longer regulated by APHIS. As a result there would be no difference in impacts from choosing either the Preferred Alternative or the No Action Alternative, and APHIS concluded that selection of either the No Action Alternative or the Preferred Alternative would not result in any cumulative impacts on the physical environment.

5.4 Cumulative Impacts: Biological Resources

Approval of the petition and subsequent commercial cultivation of IND-00410-5 soybean or progeny derived from IND-00410-5 soybean would not be expected to contribute in a cumulative manner to impacts on biological resources, differently than that of cultivation of current soybean varieties. IND-00410-5 soybean is both agronomically and compositionally similar to its comparator, Williams 82, and other nonregulated GE and conventional soybean varieties (Verdeca, 2017). Therefore, if it were no longer regulated, IND-00410-5 soybean would not alter current U.S. soybean agronomic practices, so the impacts of those practices on animal and plant communities, microorganisms, and biodiversity would not change.

The traits for increased yield and glufosinate resistance in IND-00410-5 soybean do not exert any influence on its weediness, so they do not represent any weediness risks that differ from other currently available soybean varieties. If present as a volunteer in crops rotated with soybeans, IND-00410-5 soybean would not be difficult to control because soybean seeds rarely remain viable the following season and are easily managed by hand weeding, cultivation, or herbicide applications other than glufosinate.

The reproductive characteristics of IND-00410-5 soybean are also equivalent to other GE and non-GE soybean varieties (Verdeca, 2017). Since soybean plants are mostly self-pollinating and have limited ability to disperse pollen, there is little or no potential for cross pollination of IND-00410-5 soybean with other soybean varieties. Since no feral or weedy species of soybean exist in the United States (Ellstrand *et al.*, 1999; OECD, 2000), IND-00410-5 soybean poses no potential for either naturally occurring, pollen-mediated gene flow or transgene introgression (USDA-APHIS, 2018d). The risk of gene flow and weediness of IND-00410-5 soybean is no greater than that of other conventional and nonregulated GE soybean varieties.

The maximum amount of herbicide active ingredient applied to varieties of IND-00410-5 soybean stacked with additional HR traits would be limited by the EPA registration for the product used. Other glufosinate-resistant GE soybean varieties that are not regulated are currently available to growers. IND-00410-5 soybean would only replace these as another alternative to growers, so glufosinate use would not change. As with other herbicides used for soybean cultivation, glufosinate used in accordance with EPA registration requirements would continue to ensure that there are no unacceptable risks to non-target organisms or the environment. Since there is no anticipated increase in U.S. soybean acreage in the foreseeable future, and no anticipated change in the acreage of glufosinate-resistant soybeans if IND-00410-5 soybean were no longer regulated, total glufosinate use is unlikely to change because current EPA-labeled uses of glufosinate are expected to remain the same. Possible impacts on biological resources from the application of pesticides to stacked IND-00410-5 soybean varieties would not be any different from those resulting from GE HR soybeans without the IND-00410-5 soybean high yield trait when used in accordance with label instructions.

Results of the Agency's analysis, which is summarized above, support the conclusion that there would be no impacts on biological resources if IND-00410-5 soybean were no longer regulated. In addition, existing impacts on biological resources associated with current soybean cultivation in the United States would not be altered. Because potential direct and indirect impacts on biological resources do not significantly differ between the No Action and Preferred

Alternatives, there are no reasonably foreseeable cumulative impacts that would derive from the commercial cultivation of IND-00410-5 soybean or its progeny.

5.5 Cumulative Impacts: Animal Feed and Human Health

Food and feed derived from GE soybeans must be in compliance with all applicable legal and regulatory requirements. To identify any relevant safety, nutritional, or other regulatory issues regarding food derived from GE crops, producers may seek a voluntary consultation process with the FDA prior to releasing such products into the market place. Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4 protein produced by IND-00410-5 soybean (FDA, 2015). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017 (FDA, 2017). Copies of each document may be viewed on the FDA web site at: <http://www.fda.gov/bioconinventory>.

The outcome of the food/feed safety consultation with the FDA confirmed that there would not be any food and feed safety and health issues associated with products for human or livestock consumption derived from IND-00410-5 soybean. On May 22, 2018, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition on May 22, 2018 for the PAT protein expressed by IND-00410-5 soybean. The FDA response is pending.

Results of previous analyses presented in Chapter 4 in the Human Health and Animal Feed sections described how the Agency considers the EPA pesticide registration process in APHIS EAs for GE organisms that affect how pesticides are used. Under the authorizations of FIFRA, the EPA assesses environmental risks of pesticides, and once they are registered for use, regularly reevaluates them. As part of the registration process, the EPA considers human health impacts from the use of pesticides and must determine that the pesticide will not cause unreasonable adverse effects on human health. Worker safety is also taken into consideration by the EPA in the pesticide registration and reregistration processes. If IND-00410-5 soybean is determined to have nonregulated status and is subsequently stacked in GE soybean varieties with other HR traits, the total amount of herbicides that may be applied would be limited to the per application and per year rates established by the EPA. When used in compliance with EPA registration label specifications, pesticides present minimal risk to human health and worker safety. Pesticide residue tolerances for pesticides listed in 40 CFR § 180 establish residue limits for soybean forage, hay, hulls, and seed (US-EPA, 2010a) that are protective of livestock and human health. EPA has also established an exemption for a tolerance for the PAT protein when it is a plant-incorporated protectant (CFR 174.522).

APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with the effects of a determination of nonregulated status for IND-00410-5 soybean that would adversely impact human health or animal feed. Based on its review of available information, APHIS has concluded that there is no evidence that any impacts that may result from a determination of nonregulated status for IND-00410-5 soybean would compound to cause significant cumulative impacts to human health or animal feed. Therefore, selection of

either the No Action Alternative or the Preferred Alternative would not result in any cumulative impacts on human health and animal feed.

5.6 Cumulative Impacts: Socioeconomics

The increase in U.S. soybean acreage during the past few decades has been associated with an increase in double cropping and the replacement of other crops with soybeans, not by bringing new lands into production (USDA-ERS, 2011d). If it were no longer regulated, IND-00410-5 soybean would likely replace conventional or other GE soybean varieties on existing cropland. Most (94%) U.S. soybean acreage is currently planted with GE soybean varieties (USDA-NASS, 2018b), and combined trials have confirmed that IND-00410-5 soybean is phenotypically and agronomically similar to other soybean varieties, including high yield varieties (Verdeca, 2017). Field tests conducted by Verdeca found IND-00410-5 soybean has a higher yield than its comparator, Williams 82 and its productivity is within the range of other commercially available conventionally bred and other GE high yield varieties (Verdeca, 2017). Breeding the IND-00410-5 soybean trait into conventional soybean lines may increase soybean production yields for some varieties, but other similar conventional and GE high-producing varieties are already commercially available, so adding a new soybean variety would not impact the domestic economic environment. Since impacts to the domestic economic environment would not change, there would not be any cumulative impacts on the domestic economic environment associated with selecting either the No Action Alternative or the Preferred Alternative.

Soybean yields have been increasing for decades. During the past few decades this has resulted from the development of conventionally bred and GE varieties with high yielding traits, and improved management practices (Specht *et al.*, 2006; Pedersen, 2008). U.S. soybean acreage is projected to remain level at least until 2028, but with an anticipated 8% per acre yield gain. Despite potential increased production, prices for soybeans per bushel are not expected to change appreciably (remaining between \$10.30 and \$11.35 per bushel), but annual production net value is expected to increase (USDA-OCE, 2012). Soybean supply is a function of the amount of acreage planted and crop yield. While domestic soybean yield has recently increased primarily without increasing production acreage, demand for soybean products has also increased, offsetting any downward pressure on farm soybean prices from any potential over supply (NRC, 2010).

Nonregulated IND-00410-5 soybean is not expected to adversely impact the current trends affecting the seed, feed, or food trade and may have a negligible impact from increased yields. Apart from its increased yield potential and glufosinate resistance, IND-00410-5 soybean is essentially indistinguishable from other soybean varieties in terms of agronomic, morphologic, and compositional characteristics (Verdeca, 2017). Increased farm productivity if IND-00410-5 soybean were no longer regulated may increase U.S. competitiveness in the global economy, although many other factors affect worldwide prices for soybean, including energy costs, monetary exchange rates, government policies, population size and growth rate, per capita income, global market conditions, and trends and practices in market trading and speculation (Trostle, 2008b; Trostle, 2008a; Irwin and Good, 2009). How any value derived from IND-00410-5 soybean is distributed between consumers in the form of reduced prices and growers as increased profits would be subject to these factors. Based upon the above information, any

impact to soybean market prices from the potential increase to yield from the production of IND-00410-5 soybean would be negligible.

Because yield is highly variable year to year and from field to field, the yield benefits of IND-00410-5 soybean may be masked and not be as readily apparent as, for example, the effect of an HR soybean variety. This would likely slow its adoption, which would tend to reduce the impacts on the domestic socioeconomic environment. IND-00410-5 soybean would also compete with other high yielding soybeans conventionally bred with other GE varieties with other traits (e.g., herbicide- and pest-resistant traits), and conventional, and organic soybean varieties.

Another consideration is that since IND-00410-5 soybean is agronomically and compositionally similar to other commercially available soybean varieties, there would be no major changes to agronomic inputs or practices if it were determined to have nonregulated status. Like any other high yielding soybean variety, IND-00410-5 soybean has been shown to deplete potassium and phosphorous in soil more than other varieties. But as described above, supplementation of these nutrients in soybean production is not uncommon, and soil fertility testing and supplementation as indicated by tests and known crop soil nutrient removal rates is widely recommended in soybean production to achieve yield potential (Snyder, 2000; Specht *et al.*, 2006; Pedersen, 2008; CAST, 2009; Mallarino *et al.*, 2011; Silva, 2011). Advances in soybean yield have been attributed to development of conventionally bred higher yield varieties that also have GE herbicide and or other resistance traits.

The only other possible way that the soybean socioeconomic environment might be impacted by IND-00410-5 soybean would be if it was stacked with other GE soybean traits that altered production costs of the agronomic practices used to produce soybeans. Although conservation tillage is used in conjunction with soybean production, there is an increasing trend to use strip tillage to support adequate soil fertility (Fernandez and White, 2012). Crop rotations that include soybeans have a substantial influence on fertilizer requirements, so they also add substantially to agronomic production costs. More than half of the U.S. soybean crop acreage is in a two-year rotation with corn or wheat. Fertilization of a preceding corn crop is usually made at a level that supports the following soybean crop. However, recent research has shown that high yielding transgenic HR and IR corn varieties may remove more phosphorous than is applied, so soil testing prior to planting of any soybean variety is recommended (Bender *et al.*, 2013). In the South, where soybean crops are not rotated, fertilizer is applied annually (Heatherly, 2012). For double-cropping of soybeans alone, or a wheat, corn-soybean-wheat, or a corn-soybean-wheat rotation, phosphorous application before corn in both rotations and again before wheat in the four-crop rotation is recommended (PPI, 2003).

If no longer regulated, it is expected that IND-00410-5 soybean would not impact the cost of U.S. soybean production any differently than other GE soybean varieties that APHIS previously determined were no longer regulated. GE seed is generally more expensive than conventional seed, and growers who would use IND-00410-5 soybean would likely be charged a technology fee as part of the seed purchase price (NRC, 2010). APHIS has no control over the establishment of technology fees, but assumed that the fee for IND-00410-5 soybean would be

consistent with that for other GE crops. Growers would have to make an independent assessment as to whether the benefits of IND-00410-5 soybean would offset seed cost.

If IND-00410-5 soybean were no longer regulated, it would not be expected to change the choices of production systems soybean growers currently use (i.e., GE, conventional, or organic). Organic soybean growers in particular supply a niche market that is a small portion of the U.S. market. As mentioned above regarding cumulative impacts on organic soybean production, adding GE varieties to the domestic market is not related to the ability of organic production systems to maintain their market share.

Verdeca is likely to seek import clearance and production approval for IND-00410-5 soybean in other major soybean-producing countries. Argentina's Ministry of Agriculture, Livestock and Fisheries has provided approvals for food and environmental safety, and international commerce pending China import approval (USDA-APHIS, 2018f). If IND-00410-5 soybean were to continue to be regulated, its availability only to other countries and not the United States would not likely impact U.S. trade because its adoption by other countries would be contingent upon its perceived value in relation to other high yield soybean varieties. Other countries are increasing their production of GE HR soybean. If it were not regulated, and IND-00410-5 soybean gained approval in other countries, it would be an additional option for a high yield soybean unlikely to impact the U.S. economic trade environment.

It is possible that IND-00410-5 soybean would not be approved for import into other countries. Because the United States and other countries already have access to other high yield soybean varieties, and IND-00410-5 soybean presents another high yield soybean option similar to other varieties already in the marketplace, its availability only to U.S. producers would not likely significantly impact the economic trade environment. In 2011/2012, 42% of domestically produced U.S. soybean was dedicated to the export market (USDA-ERS, 2012d) (USDA-ERS, 2016a). If IND-00410-5 soybean were not approved for import by other countries, but were not regulated in the United States, it would not likely affect the supply of U.S. soybean eligible for export to other countries. In contrast, if it were approved in the United States and for import by other countries, because of its similarity to other high yield soybean varieties, the likelihood is that it would replace other such varieties, so would not increase the acreage or locations of soybean production in the United States. Therefore, it's unlikely IND-00410-5 soybean would impact the supply of U.S. soybean available for export, there would be no potential cumulative impacts related to past and present actions if either the Preferred Alternative or the No Action Alternative is selected.

6 THREATENED AND ENDANGERED SPECIES

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 upon which they depend. To implement the ESA, the U.S. Fish & 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 protection under the ESA, it must be added to the federal list of threatened and endangered wildlife and plants. Threatened and endangered (T&E) species are those plants and animals recognized for being 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 the species to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range
- Overutilization for commercial, recreational, scientific, or educational purposes
- Disease or predation
- The inadequacy of existing regulatory mechanisms
- The natural or manmade factors affecting its survival

Once a species is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of federal activities. Section 7(a)(2) of the ESA requires that federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action “may affect” listed species or designated critical habitat. This is known as a Section 7 Consultation. To facilitate the development of its ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS’ regulatory authority and effects analysis for petitions that request a determination of nonregulated status of GE crop lines. By working with USFWS, APHIS developed a process for conducting an effects determination consistent with the Plant Protection Act (PPA) of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations under Section 7 of the ESA for biotechnology regulatory actions.

APHIS met with USFWS officials on June 15, 2011, to help determine whether APHIS has specific direct obligations under the ESA for analyzing the effects on T&E species that may occur from use of pesticides associated with the GE crops that APHIS may consider no longer regulating, including changes in use patterns that may be expected with production of a particular crop plant. USFWS and APHIS agreed that it is not necessary for APHIS to perform an ESA effects analysis on pesticide use associated with GE crops because the EPA has both regulatory authority over the labeling of pesticides under FIFRA as well as the necessary

technical expertise to assess pesticide effects on the environment, including T&E species. APHIS has no statutory authority to authorize or regulate the use of glufosinate, or any other herbicide, by soybean growers. Such uses by soybean growers under federal law must be done in strict compliance with their EPA-approved label instructions. Under APHIS' current Part 340 regulations, APHIS has the authority to regulate IND-00410-5 soybean if it has determined that IND-00410-5 soybean is or may pose a plant pest risk (7 CFR § 340.1). APHIS does not have regulatory jurisdiction over any other aspects of GE organisms including risks associated with changes in use patterns of herbicides or other pesticides.

After completing a plant pest risk assessment (PPRA) and presenting relevant information for public comment, APHIS may determine that IND-00410-5 soybean "regulated articles" (e.g., soybean seeds, plants, or parts thereof), do not pose a plant pest risk. If so, then these articles would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340. In that case, APHIS would not have jurisdiction over these articles and can no longer regulate them. As part of its analysis in this EA, APHIS analyzed the potential effects of IND-00410-5 soybean on the environment including, as required by the ESA, any potential effects on T&E species and species proposed for designation, and designated critical habitat and habitat proposed for designation. As part of this process, APHIS thoroughly reviewed the GE product information and supporting data related to the organism. For each GE plant that APHIS receives a petition to no longer regulate, APHIS considers the following:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant, including disease and pest susceptibilities, weediness potential, and agronomic and environmental impacts;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any T&E plant species or a host of any T&E species; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of IND-00410-5 soybean may have, if any, on federally-listed T&E species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Prior to this review, APHIS considered the potential for IND-00410-5 soybean to extend the range of soybean production and also the potential to extend agricultural production into new natural areas. Verdeca's studies demonstrated that agronomic characteristics and cultivation practices required for IND-00410-5 soybean are essentially indistinguishable from practices used to grow other soybean varieties (Verdeca, 2017). Although IND-00410-5 soybean may replace certain other varieties of soybean that are cultivated currently, APHIS does not expect the introduction of IND-00410-5 soybean to

result in new soybean acreage to be planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences that a determination of nonregulated status for IND-00410-5 soybean would have on T&E species in the areas where soybeans are currently grown. Based upon the scope of the EA and production areas identified in the Affected Environment (Chapter 3) of this EA, APHIS reviewed the USFWS list of T&E species (both listed and proposed for listing) for each state where soybeans are commercially produced (US-FWS, 2018). Because this list can change, APHIS continually monitors changes in the status of T&E species, critical habitats, and other relevant actions by USFWS and NMFS.

For its analysis on T&E plants and critical habitat, APHIS focused on: the agronomic differences between IND-00410-5 soybean and soybean varieties 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 focused on the implications of exposure to the novel proteins (HAHB4 and PAT) expressed in IND-00410-5 soybean as a result of the transformation, and the ability of the plants to serve as a host for a T&E species.

6.1 POTENTIAL EFFECTS OF IND-00410-5 SOYBEAN ON T&E SPECIES AND CRITICAL HABITAT

6.1.1 Threatened and Endangered Plant Species and Critical Habitat

The agronomic and morphologic characteristics data provided by Verdeca were used in the APHIS analysis of the weediness potential for IND-00410-5 soybean, and further evaluated for the potential to impact T&E species and critical habitat. Agronomic studies conducted by Verdeca tested the hypothesis that the weediness potential of IND-00410-5 soybean is unchanged with respect to conventional soybean (Verdeca, 2017). No differences were detected between IND-00410-5 soybean and the conventional control Williams 82 in assessed agronomic performance characteristics (e.g., germination, dormancy, emergence, vegetative growth, reproductive development, seed retention and lodging, plant-environment interactions, plant-symbiont interactions, volunteer potential characteristics, and persistence outside of cultivation) other than potential for greater yield in IND-00410-5 soybean (Verdeca, 2017).

Soybeans possess few of the characteristics of successful weeds (OECD, 2000). Soybeans cannot survive in most locations of the country without human intervention, and are easily controlled if volunteers appear in subsequent crops (see Agronomic Practices, Gene Flow and Weediness in Chapter 3 for more details). The expression of the HAHB4 protein providing the increased yield potential in IND-00410-5 soybean is unlikely to appreciably improve seedling establishment or increase weediness potential without changes in a combination of other characteristics associated with weediness, such as hard seed and increased lodging, among others. APHIS has concluded that a determination of nonregulated status of IND-00410-5 soybean would not present a plant pest risk, a risk of weediness, nor an increased risk of gene flow when compared to other currently cultivated soybean varieties (USDA-APHIS, 2018e).

APHIS evaluated the potential of IND-00410-5 soybean to cross with a listed T&E plant species. As previously analyzed in Chapter 4 (see Plant Communities and Gene Flow and Weediness), APHIS has determined there is no risk to unrelated plant species from the cultivation of IND-00410-5 soybean. Soybean is highly self-pollinating and can only cross with other members of *Glycine* species in the subgenus *soja*. Wild soybean species are endemic in China, Korea, Japan, Taiwan and some eastern regions of Russia, in the United States there are no *Glycine* species found outside of cultivation and the potential for outcrossing is minimal (OECD, 2000). After reviewing the list of threatened and endangered plant species in states where soybeans are grown (US-FWS, 2018). APHIS determined that IND-00410-5 soybean would not be sexually compatible with any threatened or endangered plant species currently listed or proposed for listing, as none of these plants are in the same genus nor are known to cross pollinate with species of the genus *Glycine*.

Based on agronomic field data, literature surveyed on soybean weediness potential, and lack of sexually compatible T&E species with soybean, APHIS has concluded that IND-00410-5 soybean will have no effect on T&E plant species, or on critical habitat.

6.1.2 Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products in IND-00410-5 soybean would be those T&E species that inhabit soybean fields and feed on IND-00410-5 soybean. To identify potential effects to T&E animal species, APHIS evaluated the risks to T&E animals from consuming IND-00410-5 soybean. Soybean commonly is used as a feed for many livestock. Also, wildlife may use soybean fields as a food source, consuming the soybean plant itself, or insects that live on the plants. However, T&E animal species generally are found outside of agricultural fields (USFWS, 2011). Few if any are likely to use soybean fields because they do not provide suitable habitat. Only whooping crane (*Grus americana*), sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), interior least tern (*Sterna antillarum*), and Sprague's pipit (*Anthus spragueii*; a candidate species) occasionally feed in farmed sites (USFWS, 2011). Bird species may visit soybean fields during migratory periods, but would not be present during normal farming operations (Krapu *et al.*, 2004; USFWS, 2011). In a study of soybean consumption by wildlife in Nebraska, results indicated soybeans do not provide the high energy food source needed by cranes and waterfowl (US-FWS, 2018)..

The HAHB4v protein is expressed in IND-00410-5 soybean through *Agrobacterium*-mediated transformation of soybean variety Williams 82, incorporating a variant of the *HaHB4* gene which was derived from sunflower (*Helianthus annuus*) (Verdeca, 2017). The expression levels of HAHB4v protein in IND-00410-5 soybean seed and leaf were determined from field samples collected at multiple sites in Argentina during the 2012-2013 growing season and in the United States during the 2013 growing season. Verdeca showed that HAHB4v protein was detected only in two of the field samples at a low level of 0.005 µg/g (5ng/g) dry weight, while levels in all the other field samples were below the method limit of detection (Verdeca, 2017). Therefore, the expression level of HAHB4v protein in IND-00410-5 soybean is very low compared to the native HAHB4 protein levels in sunflower ranging from 0.0252 to 0.0623 µg/g (25.2 to 62.3 ng/g) dry weight (Verdeca, 2017).

Verdeca evaluated the potential toxicity and allergenicity of HAHB4 by comparing its sequence homology with known toxins and allergens, and showed that HAHB4 protein has no significant homology to known protein toxins and allergens (Verdeca, 2017). Furthermore, *HaHB4* belongs to a large class of transcription factors that are present in many plant species including edible plants, suggesting HAHB4v protein has a history of prior exposure and a history of safe use (Verdeca, 2017). Also, as described above, the levels of HAHB4v in seed and forage tissues of IND-00410-5 soybean grown under field trial conditions were extremely low.

Recombinant HAHB4 protein was expressed in *Escherichia coli* to facilitate the safety characterization of HAHB4 protein. *E. coli*-produced HAHB4 protein was shown to be equivalent to the protein expressed in IND-00410-5 soybean based on LC-MS, MALDI-TOF and N-terminal sequence analysis (Verdeca, 2017). The *E. coli*-produced HAHB4 protein was degraded rapidly *in vitro* with simulated gastric fluid with no observed protein fragments after the first 30 seconds of digestion (Verdeca, 2017). After reviewing the data provided by Verdeca, APHIS concluded that the HAHB4 protein lacks toxic and allergenic potential based on the broad weight of evidence (USDA-APHIS, 2018c).

The *bar* gene from *Streptomyces hygroscopicus*, expresses a PAT protein in IND-00410-5 soybean that is 187 amino acids in length with an approximate molecular weight of 22 kDa. It is an enzyme that inactivates the active ingredient, glufosinate, so confers resistance to herbicides that contain that active ingredient (Thompson, 1987; Strauch, 1988). Verdeca showed that the average PAT levels ranged from 23 to 69 µg/g fresh weight in seeds and from 5 to 13 µg/g fresh weight in leaves (Verdeca 2017). These PAT levels in IND-00410-5 soybean fall within the broad PAT protein ranges of existing glufosinate tolerant crops (Center for Environmental Risk Assessment, 2011). Verdeca also demonstrated that the PAT protein expressed in IND-00410-5 soybean does not have toxic and allergenic potential (Verdeca, 2017).

The PAT protein has been used extensively to confer herbicide resistance to GE crops cultivated under field conditions and in research laboratories as a selectable marker for selection of transgenic plants during the transformation process. The safety of the PAT proteins has been previously well established (OECD, 1999; Herouet *et al.*, 2005; ILSI, 2011). In the United States, APHIS has issued 28 determinations of nonregulated status for crops that express the PAT protein, including several varieties of GE soybeans (USDA-APHIS, 2017), and FDA has completed several food and feed consultations for various crops that express the PAT protein, including soybean varieties (USDA-APHIS, 2018c; USFDA, 2018). Also, in the United States, residues of the PAT enzyme are exempt from the requirement of a tolerance, when used as a plant-incorporated protectant inert ingredient in all food commodities (40 CFR 174.522).

To demonstrate that IND-00410-5 soybean is compositionally equivalent to soybean varieties currently grown, Verdeca analyzed samples grown at 11 field sites (five in the U.S. and six in Argentina), and compared results with the parental variety, Williams 82, and commercial reference varieties representing a range of the natural variability (Verdeca, 2017). The metabolic analysis included 1) soybean seed nutrient components, including proximates (moisture, protein, fat, ash, and carbohydrates), fiber (acid detergent fiber (ADF), neutral detergent fiber (NDF) and crude fiber); minerals (phosphorus and calcium), fatty acids, amino acids, and vitamins E and K1; 2) seed anti-nutrient components, including isoflavones (daidzein, genistein, and glycitein),

stachyose, raffinose, phytic acid, lectin, and trypsin inhibitors; and 3) soybean forage nutrient components, including proximates (moisture, protein, fat, ash, and carbohydrates), fiber (ADF, NDF), and minerals (phosphorus and calcium) (Verdeca, 2017).

Two seed nutrient components, cysteine (an amino acid) and vitamin K1 showed a significant difference between IND-00410-5 soybean and Williams 82 parental variety (Verdeca, 2017). The content of cysteine in IND-00410-5 soybean seed was significantly lower when compared to Williams 82. However, the cysteine level of IND-00410-5 soybean is within the range of cysteine levels found in the commercial reference varieties (Verdeca, 2017). The value of vitamin K1 in IND-00410-5 soybean was also significantly lower and similar to that of Williams 82 control. However, Williams 82 was also lower than the levels observed among commercial reference varieties, suggesting a legacy from the Williams 82 parental variety (Verdeca, 2017; USDA-APHIS, 2018c). Nevertheless, the vitamin K1 values in both IND-00410-5 soybean and Williams 82 were within the range of values found in soybean varieties (Verdeca, 2017). All the other seed nutrients and the forage nutrients in IND-00410-5 soybean were similar to those found in the Williams 82 control and within the range of the commercial reference varieties (Verdeca, 2017).

Although some anti-nutrients showed significant differences between the IND-00410-5 soybean and Williams 82 control, the levels in all cases were within the values obtained for commercial varieties and/or reported in the literature (Verdeca, 2017).

Based on these results, it can be concluded that IND-00410-5 soybean is compositionally and nutritionally equivalent to conventional soybean varieties. It can be concluded that the incorporation of the *HaHB4v* and *bar* genes and the accompanying expression of the HAHB4v and PAT proteins in IND-00410-5 soybean does not result in any biologically meaningful differences between IND-00410-5 soybean and non-transgenic hybrids (Verdeca, 2017; USDA-APHIS, 2018c). There are no observed or anticipated unintended metabolic composition changes in IND-00410-5 soybean that could impart any new plant pest or disease risk than non-GE soybean varieties (USDA-APHIS, 2018c).

In addition to evaluating Verdeca's comparisons of IND-00410-5 soybean with the non-transgenic parent (Williams 82) for potential differences, APHIS also considered the FDA regulatory assessment in making its determination of the potential impacts of a determination of nonregulated status of the new agricultural product. As described in Chapter 4 (Animal Communities), Verdeca initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF No. 000155). The FDA has completed their evaluation and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017. Copies of each document can be viewed on the FDA web site at: <http://www.fda.gov/bioconinventory>. On May 22, 2018, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for the PAT protein expressed by IND-00410-5 soybean. The FDA response is pending.

Because there is no toxicity or allergenicity potential from IND-00410-5 soybean, there would be no direct or indirect toxicity or allergenicity impacts on T&E animal species that feed on soybean or the associated biological food chain of organisms if it were no longer regulated.

Based on Verdeca’s findings, the conclusion of the FDA’s analyses, and that consumption of IND-00410-5 soybean plant parts (seeds, leaves, stems, pollen, or roots) by T&E animal species would be unlikely, APHIS concluded that exposure and/or consumption of IND-00410-5 soybean would have no effect on any listed threatened or endangered animal species or animal species proposed for listing.

APHIS considered the possibility that IND-00410-5 soybean could serve as a host plant for a threatened or endangered species (i.e., a listed insect or other organism that may use the soybean plant to complete its lifecycle). A review of the T&E species list confirmed that there are none that would use soybean as a host plant (USFWS, 2018).

6.2 SUMMARY OF POTENTIAL EFFECTS OF IND-001410-5 SOYBEAN ON T&E SPECIES

After reviewing the possible effects of a determination of nonregulated status of IND-00410-5 soybean, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed T&E species or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. APHIS also considered the potential effect of a determination of nonregulated status of IND-00410-5 soybean on designated critical habitat or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other soybean varieties. As described above, soybean is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings. Soybean is not sexually compatible with, nor does it serve as a host species for any listed species or species proposed for listing under the ESA. Consumption of IND-00410-5 soybean by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that a determination of nonregulated status of IND-00410-5 soybean, and the corresponding environmental release of this soybean variety, will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this “no-effect” determination, consultation under Section 7(a)(2) of the ESA or the concurrences of the USFWS or NMFS are not required.

7 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 Federal Laws and Regulations

The statutes most relevant to APHIS determinations of regulatory status are 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 the other relevant laws, NEPA, CWA, SDWA, CAA, and NHPA, is specifically addressed in the following subsections.

7.1.1 National Environmental Policy Act (NEPA)

NEPA is designed to ensure transparency and communication on the possible environmental effects of federal actions prior to implementation of a proposed federal action. The Act and implementing regulations require federal agencies to document, in advance and in detail, the potential effects of their actions on the human environment, so as to ensure that both decision makers and the public fully understanding the possible environmental outcomes of federal actions. APHIS has prepared this draft EA in order to document the potential environmental outcomes of the alternatives considered, consistent with the requirements of NEPA (42 United States Code (U.S.C) 4321, *et seq.*) and Council on Environmental Quality implementing regulations at 40 CFR parts 1500-1508.

7.1.2 Clean Water Act, Safe Drinking Water Act, and Clean Air Act

The CWA, SDWA, and CAA authorize the EPA to regulate air and water quality in the United States. This EA evaluates the potential changes in soybean crop production and byproducts associated with approving the petition for a determination of nonregulated status to IND-00410-5 soybean. APHIS determined that the cultivation of IND-00410-5 soybean would not lead to the increase in or expansion of the area in soybean production. Because IND-00410-5 soybean is compositionally, agronomically, and phenotypically equivalent to other non-GE and GE commercially cultivated soybean (Verdeca, 2017), the potential impacts to water and air quality from the commercial cultivation of IND-00410-5 soybean would be no different than that of currently cultivated soybean varieties. The herbicide resistance conferred by the genetic modification of IND-00410-5 soybean is not expected to result in any changes in water usage for cultivation or post-harvest processing of soybean. APHIS assumes any use of glufosinate will be compliant with the EPA registration and label requirements. Based on these analyses, APHIS concludes that a determination of nonregulated status for IND-00410-5 soybean would not lead to circumstances that resulted in non-compliance with the requirements of the CWA, CAA, and SDWA.

7.1.3 NATIONAL HISTORIC PRESERVATION ACT (NHPA) OF 1966 AS AMENDED

The National Historic Preservation Act of 1966 (NHPA; Public Law 89-665; 16 U.S.C. 470 *et seq.*) designates federal agencies that are proposing federally funded or permitted projects on

historic properties (buildings, archaeological sites, etc.) to consider the impacts using the required Section 106 Review process.

The NHPA and its implementing regulations (36 CFR 800) require federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause impacts on historic properties; and 2) if so, to evaluate the impacts of such undertakings on historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

A determination of nonregulated status of IND-00410-5 soybean would not directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. It would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of important scientific, cultural, or historical resources.

Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands, including the use of EPA-registered pesticides. Adherence to the EPA label use restrictions for pesticides will mitigate impacts to the human environment, including historic and cultural resources.

In general, common agricultural activities that would be used in cultivation of IND-00410-5 soybean do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in impacts on the character or use of historic properties. These cultivation practices are already being conducted throughout the soybean production regions. If IND-00410-5 soybean were available for cultivation, it would not change any of these agronomic practices that would result in an adverse impact under the NHPA.

7.2 EXECUTIVE ORDERS WITH DOMESTIC IMPLICATIONS

The following executive orders (EOs) require consideration of the potential impacts of the federal action to various segments of the population.

- **EO 12898 (US-Archives, 1994) "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"** 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, low-income communities, and Indian Tribes from being subjected to disproportionately high and adverse human health or environmental effects.
- **EO 13045 (US-Archives, 1997), "Protection of Children from Environmental Health Risks and Safety Risks,"** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The 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.

- **EO 13175 – Consultation and Coordination with Indian Tribal Governments**

Executive departments and agencies are charged with engaging in consultation and collaboration with 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 tribal officials when proposed federal actions have potential tribal implications.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898, EO 13045 and EO 13175. Neither alternative is expected to have a disproportionate adverse impact on minorities, low-income populations, children, or tribal entities. APHIS determined that the cultivation of IND 00410-5 soybean would not lead to the increase in or expansion of the area in soybean production. A determination of nonregulated status of IND 00410-5 soybean is not likely to impact cultural resources on tribal properties. Any farming activities by farmers on tribal lands are only conducted at a Tribe's request. Thus, the Tribes would have control over any potential conflict with cultural resources on tribal properties. The Proposed action, a determination of nonregulated status of IND 00410-5 soybean is not expected to impact cultural resources on tribal properties.

Prior to the publication of this EA, APHIS sent a letter to tribal leaders in the continental United States on November 15, 2017. This letter contained information regarding IND-00410-5 soybean and asked tribal leaders to contact APHIS if they believed that there were potentially significant impacts to tribal lands or resources that should be considered. One response was received by APHIS from Keweenaw Bay Indian Community regarding IND-00410-5 soybean.

Available mammalian toxicity data associated with the HAHB4 protein confirmed the safety of IND-00410-5 soybean and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken with nonregulated IND-00410-5 soybean.

Based on the information submitted by the applicant and assessed by APHIS, IND-00410-5 soybean is agronomically, phenotypically, and biochemically comparable to conventional soybeans except for the introduced *HaHb4v* gene, the protein (HAHB4v) it expresses, the *bar* gene and the PAT protein it expresses. The information provided in the petition indicates that the protein expressed in IND-00410-5 soybean is not expected to be allergenic, toxic, or pathogenic in mammals (USDA-APHIS, 2018f). Also, Verdeca completed an Early Food Safety Evaluation with the FDA on August 7, 2015 for the HAHB4 protein produced by IND-00410-5 soybean (FDA, 2015). On May 12, 2016, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017 (US-FDA, 2017b; 2017a). On May 22, 2018, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and

Applied Nutrition for the PAT protein expressed by IND-00410-5 soybean. The FDA response is pending.

APHIS assumes that growers will adhere to herbicide use precautions and restrictions. Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. As discussed in Chapter 4 (under Human Health), it is expected that EPA-registered pesticides, fertilizers, and other chemicals that are currently used for soybean production would continue to be used by growers on IND-00410-5 soybean using application rates currently approved for other GE and non-GE soybean varieties and found by the EPA not to have adverse impacts to human health when used in accordance with label instructions. Based on these factors, a determination of nonregulated status of IND-00410-5 soybean is not expected to have a disproportionate adverse impacts on minorities, low-income populations, or children.

The following EO addresses federal responsibilities regarding the introduction and effects of invasive species:

- **EO 13751 – Safeguarding the Nation from the Impacts of Invasive Species**

Invasive species are defined as those species that are both not native to the ecosystem under consideration and that also harm the environment, economy or human health. Collectively, they constitute a major concern in the United States and elsewhere. This second EO regarding invasive species 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; adds additional members to the Council; clarifies the operations of the Council; incorporates increased 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.

Soybean is not listed in the United States as a noxious weed species by the Federal government (USDA-NRCS, 2013b), nor is it listed as an invasive species by major invasive plant data bases. Cultivated soybean seed does not usually exhibit dormancy and requires specific environmental conditions to grow as a volunteer the following year (OECD, 2000). Any volunteers that may become established do not compete well with the succeeding planted crop and are easily managed using standard weed control practices. Field trials and laboratory tests indicate IND-00410-5 soybean has no plant pathogenic properties or weediness characteristics. The agronomic, compositional, and reproductive characteristics of IND-00410-5 soybean are substantially equivalent to other GE and non-GE soybean varieties (USDA-APHIS, 2018f). The trait for increased yield is not expected to contribute to increased weediness without changes in a combination of other characteristics associated with weediness, such as hard seed and increased lodging, among other characteristics. Non-engineered soybean, as well as other HR soybean varieties, are widely grown in the United States. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, IND-00410-5 soybean plants are sufficiently similar in fitness characteristics to other soybean varieties currently grown and are not expected to become weedy or invasive.

The following executive order requires the protection of migratory bird populations:

- ***EO 13186 (US-Archives, 2001) “Responsibilities of Federal Agencies to Protect Migratory Birds,”*** states that federal agencies taking actions that have, or are likely to have a measurable negative impact on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in soybean fields. While soybean does not meet the nutritional requirements for many migratory birds (Krapu *et al.*, 2004), they may forage for insects and weed seeds found in and adjacent to soybean fields. As described in Chapter 4 (under Animal Communities), data submitted by the applicant has shown no difference in compositional and nutritional quality of IND-00410-5 soybean compared with other GE soybean or non-GE soybean varieties, apart from the presence of the HAHB4 and PAT proteins. IND-00410-5 soybean is not expected to be allergenic, toxic, or pathogenic to wildlife. In addition, both the HAHB4 and PAT proteins are degraded rapidly and completely (Verdeca, 2017). The results provided by Verdeca indicate that the HAHB4 and PAT proteins are unlikely to be a toxin in animal diets. Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean (BNF 000155). The FDA has evaluated the submission and responded with a memorandum dated July 28, 2017 and a cover letter dated August 2, 2017. On May 22, 2018, Verdeca also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for the PAT protein expressed by IND-00410-5 soybean. The FDA response is pending.

Based on the Agency’s assessment of IND-00410-5 soybean, APHIS concluded it is unlikely that a determination of nonregulated status of IND-00410-5 soybean would have any negative effects on migratory bird populations.

7.3 INTERNATIONAL IMPLICATIONS

- ***EO 12114 (US-Archives, 2010), “Environmental Effects Abroad of Major Federal Actions”*** requires federal officials to take into consideration any potential environmental impacts outside the United States, its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the United States if it makes a determination of nonregulated status for IND-00410-5 soybean. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean varieties internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of IND-00410-5 soybean subsequent to a determination of nonregulated status would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC) (IPPC, 2013). The purpose 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, 2013). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention. There are currently 183 IPPC⁸ countries. In April 2004, a standard for Plant 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 Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the Plant Risk Analysis for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for GE organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* is a treaty under the United Nations Convention on Biodiversity that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol became effective on September 11, 2003, and currently, there are 198 parties⁹ that have signed the Protocol. Although the United States is not a party to the Convention on Biodiversity, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States, and within the OECD. NAPPO has completed three modules of the *Regional Standards for Phytosanitary Measures No. 14, Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2003).

APHIS also participates in the *North American Biotechnology Initiative*, a forum for information exchange and cooperation on agricultural biotechnology issues for the United States, Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

⁸ For a list of countries, go to: <https://www.ippc.int/en/countries/all/list-countries/>

⁹ For a list of signers, go to: <http://bch.cbd.int/protocol/parties/>

7.4 IMPACTS ON UNIQUE CHARACTERISTICS OF GEOGRAPHIC AREAS

A determination of nonregulated status of IND-00410-5 soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Verdeca has presented results of agronomic field trials for IND-00410-5 soybean. The results of these field trials demonstrate there are no differences in agronomic practices between IND-00410-5 soybean and non-GE hybrids needed for their cultivation. The common agricultural practices that would be carried out in the cultivation of IND-00410-5 soybean are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be grown on agricultural land currently suitable for production of soybean and would only replace existing varieties; it is not expected to increase the acreage of soybean production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of IND-00410-5 soybean. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to IND-00410-5 soybean, including the use of EPA-registered pesticides. Adherence by growers to EPA label requirements for all pesticides will prevent adverse effects on the human environment.

Based on these findings, including the assumption that pesticide label requirements are in place to protect unique geographic areas and that those requirements will be adhered to, a determination of nonregulated status for IND-00410-5 soybean will not impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

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