NATIONAL ENVIRONMENTAL POLICY ACT DECISION: FINDING OF NO SIGNIFICANT IMPACT

Verdeca, LLC
Increased-Yield and Glufosinate-Ammonium Resistant HB4 Soybean

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality (CEQ) regulations implementing NEPA, and the USDA APHIS NEPA-implementing procedures in Title 7—Code of Federal Regulations, part 372 (7 CFR part 372). This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth this APHIS NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

Verdeca, LLC of Davis, California (referred to as Verdeca in this document) submitted a petition (17-223-01p) to APHIS in May 2017 (Verdeca, 2017) requesting a determination of nonregulated status for 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 genetically engineered (GE) traits: one for increased yield conferred by the *HaHB4v* gene from sunflower (*Helianthus annuus*) and a second for resistance to the herbicide, glufosinate-ammonium (referred to as glufosinate in this document), conferred by the *bar* gene from *Streptomyces hygroscopicus*, encoding the phosphinothricin-N-acetyltransferase (PAT) enzyme.

Verdeca genetically engineered IND-00410-5 soybean to increase soybean yield potential across the current range of growing conditions that occur in environments where soybeans are grown in the United States (Verdeca, 2017). The HR (herbicide-resistance) trait enables growers to apply herbicide products containing glufosinate as the active ingredient to soybeans without injuring the crop (Verdeca, 2018). In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS prepared an Environmental Assessment (EA) to evaluate the potential for significant impacts on the human environment that may result from making a determination about the regulatory status for IND-00410-5 soybean. The EA assesses alternatives for a determination of the regulatory status of IND00410-5 soybean by analyzing the potential environmental and social impacts of each alternative to assess if they are significant.

APHIS Regulatory Authority and the Coordinated Framework

In 1986, the Office of Science and Technology Policy (OSTP) published the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (OSTP, 1986). It established policies for regulating GE organisms consistent with regulations at that time of the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and USDA. Policies of the Coordinated Framework were further clarified and expanded in 1992 to include regulatory guidance by the U.S. Food and Drug Administration (FDA) for foods derived from new plant varieties (FDA, 1992). It was further updated in 2017 (US-EPA, 2017). The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are required to exercise oversight of GE organisms only when there is evidence of "unreasonable" risk. The authorities and regulatory roles for USDA-APHIS, U.S. EPA, and FDA are briefly summarized below.

USDA-APHIS

Protecting animal and plant health is among APHIS' primary strategic goals. APHIS provides leadership in ensuring the health and care of plants and animals. The Agency's strategic goals help improve agricultural productivity and competitiveness, and contribute to the national economy and public health. The USDA asserts that all methods of agricultural production (conventional, organic, or the use of GE varieties) can provide benefits to the environment, consumers, and farm income.

APHIS regulates GE organisms to ensure that they do not pose a plant pest risk pursuant to the Plant Protection Act (PPA) of 2000, as amended (7 USC §§ 7701 et seq.) and APHIS implementing regulations at 7 CFR part 340. APHIS regulations at 7 CFR part 340 govern the importation, interstate movement, and environmental release of GE organisms that may pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR § 340.2) and is also considered a plant pest; such as *Agrobacterium tumefaciens*. A GE organism is also regulated under 7 CFR part 340 when the APHIS Administrator determines or has reason to believe that the GE organism is a plant pest. A GE organism is no longer subject to the PPA or to the requirements of 7 CFR part 340 when APHIS determines that a GE organism is unlikely to pose a plant pest risk.

FDA

FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are derived from GE crops or contain components and/or ingredients derived using genetic engineering. FDA established policy (FDA, 1992) for the regulation of products derived from new plant varieties, including those genetically engineered, and developed a related voluntary consultation process (FDA, 2006) to ensure that human food and animal feed safety issues and other regulatory issues are resolved prior to commercial distribution of foods that contain products derived using genetic engineering. As part of the FDA consultation process, Verdeca initiated a food/feed safety consultation with the FDA

Center for Food Safety and Applied Nutrition for IND 00410-5 soybean (BNF 000155). FDA responded with a notification letter (FDA, 2017) on July 28, 2017. More recently, Verdeca initiated a food/feed safety consultation for the PAT protein expressed by IND 00410-5 soybean on May 22, 2018. An FDA response is pending.

EPA

EPA regulates pesticide use, including plant-incorporated protectants, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance under the FFDCA, and has concluded (40 CFR 174.522) that the PAT protein is exempt from a food and feed tolerance when expressed in plants. EPA also regulates certain biological control organisms under the Toxic Substances Control Act. EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

APHIS' Response to Petitions for Nonregulated Status

APHIS regulations at 7 CFR part 340 provide that any person may submit a petition to APHIS requesting that because the GE organism does not pose a plant pest risk, it should not be regulated by APHIS. As required by 7 CFR 340.6, APHIS must respond to petitioners with a regulatory status decision. When a petition for nonregulated status is submitted, APHIS determines if the GE organism of concern is likely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to regulation under 7 CFR part 340. APHIS has prepared a PPRA for IND 00410-5 soybean (USDA-APHIS, 2018) and determined that IND 00410-5 soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that IND 00410-5 soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA.

Public Involvement

APHIS made the Verdeca petition requesting nonregulated status for IND 00410-5 soybean accessible for public review, when the Agency announced its availability in a *Federal Register* notice (82 FR 52873) on November 15, 2017 (Docket No. APHIS-2017-0075). The 60-day public comment period closed on January 16, 2018. APHIS received a total of seven comments during the public comment period for the petition. All comments were considered, carefully analyzed for relevancy and addressed in the EA according to NEPA regulatory requirements. Comments about the petition are available for public review in the docket file at:

https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=APHIS-2017-0075&refD=APHIS-2017-0075-0001

APHIS published a notice in the *Federal Register* (84 FR 9077) announcing the availability of the IND 00410-5 soybean draft EA and draft PPRA for public review and comment on March 13, 2019. The 30-day comment period closed on April 12, 2019. APHIS received two comments during this review process. These comments are available for review at:

https://www.regulations.gov/document?D=APHIS-2017-0075-0009

Both comments expressed a general dislike of the use of GE organisms or expressed concerns about weed resistance, trends in modern mechanized agriculture, and unknown or unspecified health risks. These issues were thoroughly considered and addressed in the EA; the two comments received included no new information that required revisions to the draft EA.

The Environmental Assessment and Scope of Analysis

The EA was prepared consistent with the CEQ regulations (40 CFR parts 1500-1508) and USDA-APHIS NEPA implementing regulations (7 CFR part 372). Topics and issues analyzed in the EA were identified by considering public concerns and issues described in public comments for the petition for nonregulated status of IND 00410-5 soybean, and those in other EAs previously conducted by APHIS for GE organisms. Issues were also identified from a review of legal documents for lawsuits related to GE organisms, and from those provided by various stakeholders. These issues, including those related to the agricultural production of soybeans using various production methods, and the environmental food/feed safety of GE plants, were addressed in the analysis of potential environmental impacts of IND 00410-5 soybean included in the EA.

The following topics were identified as relevant to the scope of analysis (40 CFR § 1508.25):

Agricultural Production:

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

Environmental Resources:

- Water Resources
- Air Quality
- Soil Quality

Biological Resources:

- Animal Communities
- Plant Communities
- Gene Movement
- Soil Microorganisms
- Biological Diversity

Public Health:

- Farm Worker Safety and Health
- Human Health

- Animal Health

Socioeconomics:

- Domestic Economic Environment
- Trade Economic Environment

Cumulative Impacts

Threatened and Endangered Species

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

Alternatives Evaluated in the EA

The EA considered two alternatives in responding to Verdeca's petition: (1) no action and (2) determination of nonregulated status of IND 00410-5 soybean. APHIS assessed the potential for environmental, human health, and socioeconomic impacts that may result from each alternative.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. IND 00410-5 soybean and progeny derived from IND 00410-5 soybean would continue to be regulated articles under 7 CFR part 340. Authorizations by APHIS would continue to be required for introductions of IND 00410-5 soybean into the United States, and measures to ensure physical and reproductive confinement would continue to be applied. APHIS might choose this alternative if there were insufficient evidence to demonstrate a lack of plant pest risk from the unconfined cultivation of IND 00410-5 soybean.

This alternative is not the Preferred Alternative because APHIS concluded through its PPRA that IND 00410-5 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2018). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

Preferred Alternative: Determination That IND 00410-5 Soybean Is No Longer a Regulated Article

Under this alternative, IND 00410-5 soybean and progeny derived from this event would no longer be regulated articles under the regulations at 7 CFR part 340. Authorizations by APHIS would no longer be required for introductions of IND 00410-5 soybean or progeny derived from it. Based on the Agency's conclusion that IND 00410-5 soybean is unlikely to pose a plant pest risk, this alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. Under this alternative, growers may have future access to IND 00410-5 soybean and progeny derived from this event if the developer decides to commercialize IND 00410-5 soybean.

Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS evaluated several other alternatives for consideration in the EA relevant to the Agency's statutory authority under the PPA and APHIS implementing regulations at 7 CFR part 340, but dismissed these alternatives from detailed analysis in the EA. The additional alternatives considered are summarized in the EA with the reasons for dismissal from detailed analysis.

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which the reader is referred for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences chapter of the EA.

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 the risk assessment (USDA-APHIS, 2018)
Agricultural Production		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Areas and Acreage of Soybean Production:	Current trends in acreage and areas of production are likely to continue to be driven by market conditions and federal policies that influence demand for U.S. soybeans (e.g., demand for animal feed and biodiesel). Current U.S. soybean acreage distribution (USDA-NASS, 2016a) is not expected to change, and is projected to remain level at about 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 about the same as for the No Action Alternative.
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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
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 and pathogens 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 may choose glufosinate for weed management.
Organic Soybean Production:	Methods currently used for certified seed production to maintain soybean seed identity and meet National Organic Standards would continue unchanged. The availability of GE soybean is unrelated to the market share proportion of organic soybeans.	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, 2019) 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
Water Resources:	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.	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 no different 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.
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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil Quality:	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.	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 not be modified any 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 or reduce soil quality losses from erosion. Application of EPA-registered glufosinate formulations in accordance with label instructions would prevent unacceptable risks to current soil quality conditions.
Biological Resources		
Animal Communities:	Non-GE and GE soybeans that are not regulated have been shown to have no allergenic or toxic effects on animal communities. Soybean agronomic practices such as tillage, cultivation, farm chemical applications, and the use of mechanized agricultural equipment would continue to impact animal communities unchanged.	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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Plant Communities:	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; alternative 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.	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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Gene Movement:	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.	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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil Microorganisms:	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.	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* spp. 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 be another alternative to growers, so glufosinate use would not change. Glufosinate used in accordance with the EPA registration requirements would continue to ensure that no unacceptable risks to non-target microorganisms would occur.
Biological Diversity:	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, and row spacing, 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 remain the same.	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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Public Health		
Farm Worker Safety and Health:	Farm workers are exposed to potential allergens from soybean plants, hazards from farm equipment used to grow and harvest soybeans, and pesticides applied to soybeans. The EPA sets pesticide use requirements to prevent unreasonable risks to workers. Hazards to farm workers would not change from selection of the No Action Alternative.	The EPA Worker Protection Standards (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.
Human Health:	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.	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 for the HAHB4v protein produced by IND-00410-5 soybean. It also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean. FDA evaluated the submission and responded (FDA, 2017) with a memorandum dated July 28, 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.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal Feed:	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 not to pose any risk to animal health.	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 for the HAHB4v protein produced by IND-00410-5 soybean. It also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean. FDA evaluated the submission and responded (FDA, 2017) with a memorandum dated July 28, 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.
Socioeconomic Environment		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Domestic Economic Environment:	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.	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. Since 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, and no adverse impact to the domestic economic environment would occur under this alternative.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Trade Economic Environment:	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, 2016b). 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).	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 regulatory system with applicable regulations. 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.
Other Regulatory Approvals		
U.S. Agencies:	Existing approvals for other nonregulated GE soybeans would not change.	FDA: Verdeca completed an Early Food Safety Evaluation for the HAHB4v protein produced by IND-00410-5 soybean. It also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean. FDA evaluated the submission and responded with a memorandum dated July 28, 2017 (FDA, 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. 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.
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

Finding of No Significant Impact

The APHIS analysis in the EA indicates that there will not be any significant impacts, individually or cumulatively, on the quality of the human environment as a result of its regulatory action for IND 000410-5 soybean. Assessment of significant impacts, as required by NEPA regulations (40 CFR § 1508.27), entails the consideration of both the context and intensity of potential impacts. The EA considered and this FONSI is based upon, in part, the following factors.

Context - The term "context" identifies potentially affected resources, the locations, and the specific circumstances and conditions in which the environmental impacts may occur. This action has potential to affect conventional and organic soybean production systems, including surrounding environments and agricultural workers, human food and animal feed production systems, and foreign and domestic commodity markets.

U.S. soybeans are grown mostly in the Midwest on about 90.1 million acres (USDA-OCE, 2018). Soybean acreage in these states is commonly grown in rotation with corn. 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 (USDA-NASS, 2017a; 2017b). For example, in the past 20 years soybean acreage increased from 70 million to nearly 90 million acres, and in the past 30 years soybean yields have increased about 53%. 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, 2017) than wheat or older soybean varieties.

Soybean production 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) by 2012 (USDA-NASS, 2012). 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, 2012). By 2017, the harvest was 49 bushels per acre (USDA-NASS, 2018).

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, 2018).

Soybean varieties have historically been developed conventionally without GE 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.

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.

Intensity – Intensity is a measure of the degree or severity of potential impacts. As recommended by CEQ (40 CFR § 1508.27), the following factors were considered in evaluating intensity and making this NEPA determination.

1. *Impacts that may be both beneficial and adverse*.

   A determination of nonregulated status of IND 00410-5 soybean will have no significant environmental impact on the availability of GE, conventional or organic soybean varieties. As considered and analyzed in Chapter 4 of the EA, a determination of nonregulated status of IND 00410-5 soybean is expected to neither directly result in an overall change in U.S. soybean production acreage nor the acreage of U.S. GE-soybean production. The availability of IND 00410-5 soybean will not alter the areas of soybean cultivation in the United States, and there are no anticipated changes in the availability of GE and non-GE soybean varieties on the market. A determination of nonregulated status of IND 00410-5 soybean will only add another GE soybean variety available to commercial growers; it is not expected to change the market demands for GE soybeans nor that for soybeans produced using non-GE varieties or by organic cultivation methods.

   APHIS analyzed the data provided by Verdeca (Verdeca, 2017; 2018) and has concluded in the Agency's EA that the availability of IND 00410-5 soybean will not alter the agronomic practices, locations of soybean production, nor the production methods and quality characteristics of conventional and GE soybean seed production. The introduction of IND 00410-5 soybean will provide an alternative to other conventional and high-yield soybean varieties. The trait for resistance to glufosinate is the same as that in other GE glufosinate-resistant soybean varieties, so it will not alter the current agronomic dynamics influencing the development of weed resistance to glufosinate.

2. *The degree to which the proposed action affects public health or safety*.

   A determination of nonregulated status of IND 00410-5 soybean would have no significant impacts on human or animal health. Compositional tests conducted by Verdeca indicate that IND 00410-5 soybean is compositionally similar to other commercially available GE soybean varieties (Verdeca, 2017; 2018). Verdeca completed an Early Food Safety Evaluation for the HAHB4v protein produced by IND-00410-5 soybean. It also initiated a food/feed safety consultation with the FDA Center for Food Safety and Applied Nutrition for IND-00410-5 soybean. FDA evaluated the submission and responded (FDA, 2017) with a memorandum dated July 28, 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. 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.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

   There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status for IND 00410-5 soybean. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance, nor cause any physical destruction or damage to property, wildlife habitat, or landscapes, and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of IND 00410-5 soybean. The product will be planted on agricultural land currently suitable for production of soybeans, will only replace existing varieties, and is not expected to increase the acreage of soybean production. This action would not convert nonagricultural land, and therefore would have no adverse impact on prime farm land. 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. The applicant's adherence to EPA-label-use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of IND 00410-5 soybean, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to soybean production sites.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

   The effects on the quality of the human environment following a USDA determination of nonregulated status for IND 00410-5 soybean are not highly contested by scientists or those who may be in a position to supply substantive information. Although APHIS received public comments opposed to a determination of nonregulated status of IND 00410-5 soybean, this action is not likely to be highly controversial in terms of size, nature or effect on the natural or physical environment. As considered and analyzed in Chapter 4 of the EA, a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to soybean production in general, nor acreage devoted to GE soybean cultivation. A determination of nonregulated status of IND 00410-5 soybean would only add another GE-soybean variety to the market and is not expected to change the market demands for GE soybeans, non-GE soybeans produced conventionally or those produced using organic methods. A determination of nonregulated status of IND 00410-5 soybean will not change current practices for planting, tillage, fertilizer application or use, cultivation, pesticide application or use, or volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of IND 00410-5 soybean on wildlife or biodiversity is no different than that of other GE soybeans currently used in agriculture, or other GE or non-GE soybeans produced in conventional agriculture in the United States.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

   The potential impacts of soybean production on the human environment are well understood and thoroughly evaluated in the EA. As concluded from the analysis included in Chapter 4 of the EA, a determination of nonregulated status of IND 00410-5 soybean is expected to neither directly

cause an increase in U.S. agricultural acreage devoted to soybean production in general, nor GE-soybean cultivation. A determination of nonregulated status of IND 00410-5 soybean will not result in changes in the current practices of planting, tillage, fertilizer application/use, pesticide application/use or volunteer control.

Management practices and seed standards for production of certified soybean seed would not change. The effect of IND 00410-5 soybean on wildlife or biodiversity is neither different from that of other GE crops currently used in agriculture, nor that of other GE or non-GE soybean produced in conventional agriculture in the United States. As described in Chapter 3 of the EA, well-established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in commercial soybean crop and seed production systems in the United States. Therefore, it is reasonable to assume that farmers who produce soybeans (either GE or non-GE varieties) with conventional agronomic practices, or non-GE soybeans using organic methods, will continue to use those reasonable, commonly-accepted, best-management practices for their chosen systems and varieties during agricultural soybean production. GE soybeans are also currently planted on most of U.S. soybean acreage. Based upon historic trends, conventional production practices that use GE varieties will likely continue to prevail in terms of acreage with or without a determination of nonregulated status of IND 00410-5 soybean. Given the extensive experience that APHIS, stakeholders, and growers have with the use of GE soybean products, the possible effects to the human environment from the release of an additional GE-soybean variety are already well known and understood. Therefore, the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

   A determination of nonregulated status for IND 00410-5 soybean would not establish a precedent for future actions with significant impacts, nor would it represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and independently undergoes this review to determine if the regulated article poses a plant pest risk.

   APHIS has reviewed and approved petitions for nonregulated status of GE soybeans since 1993. All petitions submitted were reviewed independently, and determinations of regulatory status were issued in part based on plant pest risk assessments and relevant NEPA analyses specific for the GE organism subject of the petition. Each petition that APHIS receives is specific for a particular GE organism-trait combination and undergoes an independent review to determine if the regulated article may pose a plant pest risk. The requirements for petitions for nonregulated status, applicable to both APHIS and the petitioner, are described in 7 CFR part 340. These requirements have been reviewed above under the sections summarizing APHIS' regulatory authority, and APHIS' requirements to respond to petitions for nonregulated status.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

No significant cumulative impacts that may result from the incremental impact of a determination of nonregulated status of IND 00410-5 soybean when added to past, present, and reasonably foreseeable future actions were identified during this assessment. As described in Chapter 5 of the EA, APHIS considered the potential cumulative impacts on soybean management practices, human and animal health, and the environment, and concluded that such impacts were not significant. Impacts from the cultivation of IND 00410-5 soybean would not be cumulatively significant, so would not differ from those occurring with soybean varieties cultivated currently.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*

   The EA concluded that a determination of nonregulated status of IND 00410-5 soybean would not directly or indirectly alter the character or use of properties protected under the National Historic Preservation Act. A determination of nonregulated status of IND 00410-5 soybean would not impact districts, sites, highways, structures, or objects listed in, or eligible for listing in the National Register of Historic Places, nor cause any loss or destruction of significant scientific, cultural, or historic 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 EPA-label-use restrictions for all pesticides will mitigate impacts to the human environment. The crop production practices used in the cultivation of soybean do not introduce significant visual impairments, or noise, in a manner that would impact the use and enjoyment of historic properties in areas proximate to soybean fields. Any farming activities that may be undertaken on tribal lands are only conducted under the tribe's approval; tribes have control over any potential conflict with cultural resources on tribal properties.

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

   As described in Chapter 6 of the EA, APHIS has analyzed the potential effects of IND 00410-5 soybean on threatened and endangered species (TES), species proposed for listing, and designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of IND 00410-5 soybean, APHIS has concluded that a determination of nonregulated status of IND 00410-5 soybean would have no effect on federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*

    The EA evaluated the federal, state, and local laws and regulations, executive orders, and policy related to Verdeca's petition. The EA concluded that approval of the petition would not lead to circumstances that resulted in non-compliance with federal, state, or local laws and regulations providing protections for environmental and human health. The EPA will regulate the use of pesticides on IND 00410-5 soybean. Verdeca completed an Early Food Safety Evaluation with the FDA. 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 (FDA, 2017) with a memorandum dated July 28, 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. There are no other federal, state, or local permits needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA and determined that the analyses and conclusions support a Finding of No Significant Impact (FONSI) from the deregulation of Verdeca's petition for IND 00410-5 soybean.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." Based upon our evaluation and analysis, the Preferred Alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect the health and value of American agriculture and natural resources using a science-based regulatory framework that allows for the safe development and use of GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations pursuant to 7 CFR part 340. As APHIS has not identified any plant pest risks associated with IND 00410-5 soybean, the continued status of IND 00410-5 soybean as a regulated article would be inconsistent with the plant pest provisions of the PPA, APHIS regulations at 7 CFR part 340, and the biotechnology regulatory policies of the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of IND 00410-5 soybean will not have any significant impacts on the human environment.

8/1/2019

Ibrahim M. Shaqir
Acting Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date

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