United States Department of Agriculture

Finding of No Significant Impact

BASF Petition (19-317-01p) for Determination of Nonregulated Status of GMB151 Soybean Developed Using Genetic Engineering for Resistance to the Soybean Cyst Nematode and HPPD-inhibiting Herbicides

OECD Unique Identifier: BCS-GM151-6

This document discloses the rationale for the Finding of No Significant Impact and approval of the BASF Corporation petition for nonregulated status.

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

INTRODUCTION

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's (CEQ) regulations implementing NEPA, and the USDA APHIS NEPA-implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a regulatory determination requested in a petition (APHIS Number 19-317-01p) submitted by BASF Corporation (referenced as BASF in this document) for their GMB151 Soybean (hereafter referred to as GMB151 Soybean), which was developed using genetic engineering. GMB151 Soybean expresses a protein toxin derived from a bacterium, *Bacillus thuringiensis*, to protect soybean plants from soybean cyst nematode (SCN) damage. It also expresses a trait for resistance to HPPD-inhibiting herbicides such as isoxaflutole. The EA has been prepared to specifically evaluate the effects on the quality of the human environment[1] that may result from approving the petitioner's request for nonregulated status for GMB151 Soybean. The EA assesses alternatives to a determination of nonregulated status of GMB151 Soybean and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

REGULATORY AUTHORITY

"To protect the health and value of American agriculture and natural resources" is the mission of USDA APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The Agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, and those using crop varieties developed by genetic engineering) can increase farm income, and have positive impacts on consumers and the environment.

The United States government has regulated organisms developed by genetic engineering using a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302, 57 FR 22984) since 1986 (referenced as the "Coordinated Framework" in this document). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing federal statutes in a manner to ensure public health and environmental safety, while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those biotechnology products subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR 5508.14).

the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of biotechnology products only when there is evidence of "unreasonable" risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating organisms developed using genetic engineering: USDA APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

USDA APHIS

APHIS is responsible for regulating organisms and plants developed using genetic engineering under the plant pest provisions of the Plant Protection Act of 2000 (PPA), as amended (7 USC 7701 et seq.) to ensure that they do not pose a plant pest risk to the environment. The Agency's strategic goals help improve agricultural productivity and competitiveness, and contribute to the national economy and public health.

FDA

FDA regulates organisms developed using genetic engineering 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 food and animal feed, including those from plants developed using genetic engineering. To help developers of food and feed derived from such plants comply with their obligations under federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from plants developed using genetic engineering that are currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including plants developed using genetic engineering, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other related regulatory issues (e.g., labeling) are resolved prior to commercial distribution of food and feed from plant developed using genetic engineering.

EPA

EPA regulates plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerances, which are maximum residue limits for pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA). EPA also regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modem biotechnology.

RESPONSE TO BASF PETITION 19-317-01p

Under the authority of the plant pest provisions of the PPA and 7 CFR 340, APHIS has issued regulations for the safe development and use of organisms developed using genetic engineering. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of organisms developed using genetic engineering, including plants such as GMB151 Soybean. When a petition for nonregulated status is submitted, APHIS must make a determination of whether or not an organism developed using genetic engineering is likely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that an organism developed using

genetic engineering is unlikely to pose a plant pest risk, it is no longer subject to the plant pest provisions of the PPA and 7 CFR 340.

Public Involvement for Petition 19-317-01p

BASF submitted a petition (APHIS Number 19-317-01p) to APHIS seeking a determination that their plant variety, GMB151 Soybean, which was developed using genetic engineering, is unlikely to pose a plant pest risk and, therefore, should no longer be regulated under regulations at 7 CFR 340. APHIS made the BASF petition requesting non-regulated status for GMB151 Soybean available for public review in a notification[2] in the *Federal Register* (85 FR 32004 2020) on May 28, 2020. The 60-day public comment period closed on July 27, 2020. APHIS received nine comments. The petition and comments are available for public review on regulations.gov[3], the U.S. federal government web site that serves as an internet portal and document repository for U.S. government documents (Docket No. APHIS-2020-0023): https://www.regulations.gov/document/APHIS-2020-0023-0012/comment

Two comments were supportive of removing regulatory constraints on the GMB151 Soybean variety. Some comments addressed the pesticide registration issue about the Cry14Ab-1 protein PIP, urging EPA to make it available as a new active ingredient. Two additional comments, while generally supportive of the development of crops produced using genetic engineering, expressed concerns about the risks and liabilities from possible disruptive effects on U.S. exports if residues from a biotech soybean that is not regulated enter the supply chain in instances where the soybean has not been approved in export markets. They emphasized the need for careful vetting of biotech crops and the need for stewardship measures if commercialized. BASF emphasized in its petition, a commitment to stewardship to meet applicable regulatory requirements for GMB151 Soybean in the country of intended production and for key import countries to ensure compliance, maintain product integrity, and assist in minimizing the potential for trade disruptions (BASF 2020).

Four comments expressed opposition to a determination of nonregulated status for GMB151 Soybean based on general opposition to the use of organisms produced using genetic engineering, but did not cite or provide documentation specific to why the GMB151 Soybean variety should continue to be regulated under 7 CFR 340. All comments were considered, carefully analyzed for relevancy, and addressed in the EA according to NEPA regulatory requirements.

APHIS determined from its initial review of the petition for GMB151 Soybean that the review process for the PPRA and NEPA documents (EA and FONSI) should follow the second approach, as described in the Agency's 2012 revisions (77 FR 13258 2012) to the procedures it follows to promote public participation in its decision making relevant to the regulation of organisms produced using genetic

[2]This notice can be accessed at: https://www.federalregister.gov/documents/2020/05/28/2020-11492/basf-corporation-petition-for-a-determination-of-nonregulated-status-for-plant-parasitic
[3]The docket can be accessed at: https://www.regulations.gov/docket/APHIS-2020-0023
The petition alone is also accessible on the APHIS web site:
https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

engineering. This decision was made because APHIS has not previously analyzed plant pest risk for any soybean varieties that express the Cry14Ab-1 protein.

Public Involvement for the Draft EA for GMB151 Soybean

As part of its NEPA compliance process, APHIS considered all comments submitted for the petition in a Draft EA prepared by the Agency. APHIS also prepared a Draft PPRA (USDA-APHIS 2020) to document the Agency's analysis of the possibility that GMB151 Soybean might pose unacceptable plant health or weediness risks. The public was informed about the availability of both documents for review in a *Federal Register* notice that announced a 30-day comment period that ended on September 16, 2021. APHIS received 2,743 comments. From its review of the comments, the Agency determined that the comments could be classified into five general categories: (1) support for non-regulation of GMB151 Soybean; (2) opposition because it was developed using genetic engineering; (3) opposition because it expresses a novel protein derived from *Bacillus thuringiensis*; (4) opposition because of concerns it will contribute to increased herbicide resistance in weeds; (5) opposition because of safety concerns that will result from increased use of isoxaflutole. The opposition topics are summarized in more detail below. The comments, as submitted, are available for review at: https://www.regulations.gov/document/APHIS-2020-0023-0012/comment

The majority of the comments were similar or identical. Many of these were contained in form letters submitted by different individuals who expressed their general opposition to the concept and use of genetic engineering for any purpose, or for the specific purpose of transferring genetic material from other biological sources to unrelated crops. These were outside the scope of the PPRA, which was to analyze the potential for plant pest risk, and the EA, which was to analyze the potential for significant environmental impacts. None of these comments provided any scientific documentation relevant to either of these analyses.

Some comments objected to an APHIS decision not to regulate GMB151 Soybean because it expresses a novel Cry protein from *Bacillus thuringiensis*, Cry14Ab-1, claiming that it has not been adequately evaluated for its pesticidal uses. However, APHIS emphasizes that this issue was considered by the petitioner (BASF 2020), which documented results of test studies for the non-target effects of the Cry14Ab-1 expressed in GMB151 Soybean. In addition, under the Coordinated Framework, EPA regulates pesticides, including PIPs, and it concluded on June 8, 2020 that available scientific data was sufficient to support a decision that the *B. thuringiensis* Cry14Ab-1 protein residue in or on soybean food and feed commodities is exempt from the requirement of a tolerance, when expressed as a PIP in soybean plants (85 FR 35008; 40 CFR 174.540).

Another group of comments focused on a concern that a new soybean crop variety expressing the trait for resistance to isoxaflutole specifically and HPPD-inhibiting herbicides in general would contribute to an increase in the development of weed resistance. APHIS addressed this issue in its PPRA (USDA-APHIS 2020) and concluded that any effects related to HPPD-herbicide resistance would not cause any plant pest risk. The analysis in the EA concluded that there would not be any significant impacts related to weed resistance from a determination of no regulatory authority for GMB151 Soybean. None of the comments received provided any scientific documentation to alter these conclusions.

Another class of comments objected to an APHIS decision not to regulate GMB151 Soybean because it would contribute to an increase in the use of isoxaflutole, which will increase human health and safety hazards and impacts on the environment. APHIS emphasizes that this issue was considered by the petitioner (BASF 2020), which submitted documentation of results of test studies related to human health and safety concerns and non-target effects of isoxaflutole. In

addition, under the Coordinated Framework, EPA regulates pesticides, including chemical herbicides. EPA will continue to address human safety and health concerns, and potential environmental effects of isoxaflutole as part of its regulatory review process. BASF also showed that laboratory and field testing demonstrated that there are no biologically meaningful differences for compositional and nutritional characteristics between conventional and GMB151 Soybean.

In summary, none of the comments received documented evidence that the Agency had failed to consider and analyze in its Draft EA all possible environmental effects for significant impacts from a determination of the regulatory status for GMB151 Soybean. Also, none of the comments provided substantive documentation that the Agency's analysis in its Draft EA had failed to detect that such a determination would result in significant impacts to the human environment, which would require that the Agency prepare an environmental impact statement.

SCOPE OF THE ENVIRONMENTAL ANALYSIS

Although a determination of nonregulated status of GMB151 Soybean would allow for new plantings of GMB151 Soybean to occur anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas where GMB151 Soybean could be grown.

Major Issues Addressed in the EA

The issues addressed in this EA were developed by considering similar ones identified and addressed in prior NEPA documents prepared by APHIS (i.e., environmental assessments and impact statements), those identified in public comments for BASF's petition and other petitions for organisms produced using genetic engineering, information in the scientific literature on agricultural biotechnology, concerns addressed in past legal decisions (e.g., lawsuits), those identified by various stakeholders, and issues identified by APHIS as specific to soybean crop production. 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

Alternatives That Were Fully Analyzed

NEPA implementing regulations (40 C.F.R. § 1502.14) require the evaluation of all alternatives that appear reasonable and appropriate to the purpose and need of an agency's action. For this USDA APHIS action, a regulatory determination for BASF GMB151 Soybean, two alternatives were evaluated in the EA: (1) No Action Alternative, which would continue the current regulated status of GMB151 Soybean if selected; (2) Preferred Alternative, which would result in nonregulated status for GMB151 Soybean if selected.

No Action Alternative: Continue Regulating GMB151 Soybean

Under the No Action Alternative, APHIS would deny the petition request by BASF (BASF 2020), so there would be no change in the regulatory status of GMB151 Soybean; it and any soybean varieties derived from it would continue to be regulated organism under 7 CFR 340. APHIS would continue to require permits for introductions and movement of GMB151 Soybean grown in the United States. Because APHIS has concluded from its PPRA (USDA-APHIS 2020) that GMB151 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 340.

Preferred Alternative: Nonregulated Status for GMB151 Soybean

Under the Preferred Alternative, GMB151 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 340. APHIS has determined that GMB151 Soybean is unlikely to pose a plant pest risk based on available scientific evidence (USDA-APHIS 2020), therefore, if this alternative is selected, permits or notifications acknowledged by APHIS would no longer be required for GMB151 Soybean or progeny derived from it that are not regulated under 7 CFR 340 if grown in the United States. This alternative best meets the purpose and need to respond appropriately to the petition for nonregulated status of GMB151 Soybean based on the requirements in 7 CFR 340 and the Agency's authority under the plant pest provisions of the PPA.

Alternatives Considered but Excluded from Further Analysis in the EA

APHIS considered several other alternatives for this EA. These included: approve the petition only in part as provided for in § 340.6(d)(3)(i) of the regulations (e.g., allow nonregulated status for GMB151 Soybean crops grown in limited regions of the United States); establish mandatory rules for isolation or geographic separation of biotech and non-biotech cropping systems; require testing for the presence of biotech crop plant material in non-biotech crops and commodities.

Based on the PPRA (USDA-APHIS 2020) for GMB151 Soybean and the Agency's past experience with regulating biotech soybean varieties under 7 CFR 340, APHIS concluded that it is unlikely to pose a plant pest risk. Therefore, the imposition of testing, release, and/or isolation requirements on GMB151 Soybean would be inconsistent with the Agency's statutory authority under the plant pest provisions of the PPA, implementing regulations at 7 CFR 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 analysis in the EA.

Comparison of Alternatives

Table 1 includes a summary and comparison of possible impacts associated with selection of each of the alternatives evaluated in the EA.

Table 1.

Summary of Potential Impacts and Consequences of Alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Agricultural Production		
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, biodiesel and exports). U.S. 2020 soybean planted acreage (83.8 million) was up 10% from 2019 (USDA NASS 2020a), and is projected to remain level 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.	If GMB151 Soybean were no longer regulated it would only be expected to be planted as an alternative to other varieties in the United States, so soybean acreage under the Preferred Alternative would be about 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 GMB151 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. Most nematicides for SCN are prescribed as seed treatments to be used in conjunction with resistant varieties. With the exception of SCN, GMB151 Soybean is susceptible to the same insect and other invertebrate pests and pathogens that affect most other commercially available conventional and biotech 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 this HPPD-resistant variety for weed management.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
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 biotech 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 biotech soybean varieties, GMB151 Soybean does not present any new or different issues or impacts for organic soybean producers or consumers. Other HR soybean varieties that are not regulated are currently planted by growers. GMB151 Soybean would only replace these as another HR alternative.
Soybean Seed Production:	Quality control methods, such as those of the Association of Official Seed Certifying Agencies (https://www.aosca.org/) 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 SCN and HPPD resistance traits in GMB151 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 yield on existing cropland would continue unchanged, so any current impacts on water resources from soybean production would not change significantly.	Except for replacing herbicides with other modes of action with HPPD-based herbicides, the production of GMB151 Soybean is not expected to change current agronomic practices, acreage, or the range of production areas, so current effects from runoff on water resources would not change. Use of HPPD-based herbicides likely offsets 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 HPPD HR soybean varieties that APHIS assessed previously (USDA-APHIS 2014, 2013) are not regulated and are currently available to growers. If it is not regulated, GMB151 Soybean will only be another HPPD-resistant alternative to growers, so herbicide use will not change.

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 replacing herbicides with other modes of action with HPPD-based herbicides, the production of GMB151 Soybean is not expected to differ significantly from the No Action Alternative. Use of HPPD herbicides 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. HPPD use is not expected to increase relative to the no action alternative.
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 GMB151 Soybean would not be expected to change cropping practices. Use of HPPD herbicides 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. HPPD use is not expected to increase relative to the no action alternative.
Biological Resources		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal Communities:	Non-biotech and biotech 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.	Field trials demonstrated that growth and disease characteristics of GMB151 Soybean are not significantly different from other soybean varieties that are not regulated, so no changes to soybean agronomic practices potentially impacting animal communities would occur other than the use of HPPD herbicide applications, where HR weeds resistant to other modes of action are a problem. HPPD use is not expected to increase relative to the no action alternative
Plant Communities:	Most commercial soybean acreage is planted with varieties developed using genetic engineering, 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 GMB151 Soybean and other soybean varieties (conventional and those developed using genetic engineering) in growth, reproduction, and susceptibility to pathogens and other pests except the target species (SCN). Except for the option to substitute HPPD herbicides with other herbicides currently used, agronomic practices to cultivate GMB151 Soybean would not differ from the No Action Alternative. HPPD use is not expected to increase relative to the no action alternative. .

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Gene Movement:	GMB151 Soybean would continue to be cultivated only under regulated conditions. The availability of biotech, conventional, and organic soybeans would not change as a result of the continued regulation of GMB151 Soybean. Because there are no wild soybean relatives in the United States, and soybeans are mostly self-pollinated, 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 GMB151 Soybean that influence gene flow or weediness, when compared to soybean varieties that are not regulated. Traits for SCN resistance and HPPD herbicide resistance would not change gene movement characteristics, 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:	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 GMB151 Soybean with its *Rhizobium* spp. symbionts. GMB151 Soybean would not result in any significant changes to current soybean cropping practices that may impact microorganisms except that HPPD herbicides may be substituted for herbicides with other modes of action, where HR weeds are a problem. Other HPPD HR soybean varieties developed using genetic engineering that APHIS assessed previously (USDA-APHIS 2014, 2013) are not regulated and are currently available to growers. If it is not regulated, GMB151 Soybean will only be another HPPD-resistant alternative to growers, so herbicide use would not be expected to change.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Biological Diversity:	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.	GMB151 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 other than its resistance to SCN. GMB151 Soybean poses no potential for naturally occurring, pollen-mediated gene flow and introgression of genes modified using genetic engineering, so is not expected to affect genetic diversity. Testing has confirmed that the Cry14Ab-1e protein expressed by GMB151 Soybean does not have unacceptable risks to or impacts on non-target organisms (BASF 2020).
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. Hazards to farm workers would not change from selection of the No Action Alternative.	EPA Worker Protection Standards (WPS)implement protections for agricultural workers, handlers, and their families 40 CFR 170). If the Preferred Alternative were selected, GMB151 Soybean would not change current soybean cropping practices, so hazards would be the same as under the No Action Alternative.

Human Health:	Compositional and nutritional characteristics of nonregulated biotech 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 biotech and conventional soybean cultivation. Use of registered pesticides in accordance with EPA-approved labels protect human health and worker safety. 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 conventional and GMB151 Soybean. Safety testing of the GMB151 Soybean Cry14Ab-1 and HPPD proteins showed that they are degraded rapidly and completely in simulated gastric fluid. Testing also showed that the GMB151 Soybean Cry14Ab-1 and HPPD proteins have no similarities to known allergens, and are not toxic to mammals. On January 28, 2019, BASF initiated a consultation (BNF 172) with FDA that included molecular, compositional, nutritional data, and other food and feed safety assessment data related to GMB151 Soybean (BASF 2020). EPA has established a permanent exemption (82FR57137) from the requirement for a tolerance for the HPPD-4 protein expressed in all food commodities when used as an inert ingredient. In addition, EPA concluded on June 8, 2020 that *B. thuringiensis* Cry14Ab-1 protein residue in or on soybean food and feed commodities are exempt

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
		from the requirement of a tolerance when expressed as a PIP in soybean plants (85 FR 35008; 40 CFR 174.540).
Animal Feed:	GMB151 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 biotech and conventional soybean varieties. Nonregulated biotech soybean varieties used as animal feed have been previously determined not to pose any risk to animal health.	Laboratory and field testing demonstrated that there are no biologically meaningful differences for compositional and nutritional characteristics between conventional and GMB151 Soybean. Safety testing of the GMB151 Soybean Cry14Ab-1 and HPPD proteins showed that they have no toxic potential to mammals, and are degraded rapidly and completely in simulated gastric fluid, when present in animal feed. On January 28, 2019, BASF initiated a consultation (BNF 172) with the FDA that included molecular, composition, and nutrition data, and other food and feed safety assessment data related to GMB151soybean (BASF 2020). In addition, EPA concluded on June 8, 2020 (40 CFR 174.540) that the Cry14Ab-1 protein is exempt from a food and feed tolerance, when it is expressed in soybean plants.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Socioeconomic Environment		
Domestic Economic Environment:	GMB151 Soybean would remain regulated by APHIS. Domestic growers would continue to utilize biotech and conventional 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 herbicide- and pest-resistant varieties currently used to optimize yield and reduce production costs would be expected to continue unchanged. 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 GMB151 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 conventional and biotech soybean varieties and subject to the same variables affecting agronomic practices and yields as other varieties. GMB151 Soybean would likely only replace other varieties of biotech soybean on existing cropland and not impact organic soybean production or markets. Since biotech soybeans represent over 90% of soybeans produced, the addition of GMB151 Soybean will have little incremental impact on the biotech sensitive market. Because losses from SCN would be reduced, soybean growers would likely experience improved profits under Alternative B.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Trade Economic Environment:	If GMB151 Soybean remains regulated by APHIS, U.S. soybean plantings will not be affected and are projected to rebound and remain relatively steady over the course of the next decade. U.S. soybeans will continue to be a major component of global production, and as a source of supply in the international market (USDA 2020). 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 for GMB151 Soybean is not expected to have an effect on current trends affecting the trade economic environment. GMB151 Soybean is similar to other varieties developed using genetic engineering. If it becomes commercially available as a non-regulated variety, it would only be substituted to replace other varieties where SCN- and/or HPPD-resistant varieties are required for pest management. If the Preferred Alternative is selected, there would not be any difference from choosing the No Action Alternative. BASF emphasized in its petition a commitment to stewardship to meet applicable regulatory requirements for GMB151 Soybean in the country of intended production and for key import countries to ensure compliance, maintain product integrity, and assist in minimizing the potential for trade disruptions (BASF 2020).
Other Regulatory Approvals		
U.S. Agencies:	Existing approvals for other nonregulated soybeans developed using genetic engineering would not change.	EPA has concluded (40 CFR 174.540) that the Cry14Ab-1 protein is exempt from a food and feed tolerance, when it is expressed in soybean plants.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Other countries	The existing status of other soybeans developed using genetic engineering that are regulated in other countries would not change.	No Change from the No Action Alternative. BASF emphasized in its petition a commitment to stewardship to meet applicable regulatory requirements for GMB151 Soybean in the country of intended production and for key import countries to ensure compliance, maintain product integrity, and assist in minimizing the potential for trade disruptions (BASF 2020).
Compliance with Other Laws		
CAA, CWA, EOs:	Fully compliant	Fully compliant
	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 GMB151 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, on 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 organic and conventional soybean crop production systems and those using varieties developed using genetic engineering, including surrounding environments and agricultural workers, human food and animal feed production systems, and foreign and domestic commodity markets.

Most U.S. soybeans are grown in 31 states, predominantly in the Midwest on about 90.1 million acres (USDA-OCE, 2018). Soybean acreage in these states is commonly grown in rotation with corn. Herbicide-resistant soybean varieties developed using genetic engineering make up an estimated 93% of the U.S. soybean crop. 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, 2020a; 2020b). For example, in the past 20 years soybean acreage increased from 70 million to about 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, providing 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 plant breeding using genetic engineering 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, are resistant to pests, and can out-compete weeds.

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 GMB151 Soybean will have no significant environmental impact on the availability of other conventional or organic soybean varieties. Or those developed using genetic engineering. As considered and analyzed in Chapter 5 of the EA, a determination of nonregulated status of GMB151 Soybean is expected to neither directly result in an overall change in U.S. soybean production acreage nor the acreage of U.S. soybean crops planted in varieties developed using genetic engineering. The availability of GMB151 Soybean will not alter the areas of soybean cultivation in the United States, and there are no anticipated changes in the availability of conventional soybean varieties or those developed using genetic engineering that are currently on the market. A determination of nonregulated status of GMB151 Soybean will only make another soybean that was developed using genetic engineering available to commercial growers; it is not expected to change the market demands for conventional soybean varieties, those developed using genetic engineering nor those used in by organic cultivation systems.

APHIS analyzed the data provided by BASF (BASF 2020) and has concluded in the Agency's EA that the availability of GMB151 Soybean will not alter the agronomic practices, locations of soybean production, nor the production methods and quality characteristics of seed production for conventional varieties or those for varieties developed using genetic engineering. The introduction of GMB151 Soybean will provide an alternative to other currently available conventional varieties or those developed using genetic engineering. The trait for resistance to HPPD-resistance, is the same as that in other crop varieties developed using genetic engineering, so it will not alter the current agronomic dynamics influencing the development of weed resistance. The trait for Cry14Ab-1 protein expression will reduce economic losses from SCN and costs of applying nematicides, which will also reduce environmental impacts by reducing the need for applications of nematicides.

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

A determination of nonregulated status of GMB151 Soybean will have no significant impacts on human or animal health. Compositional tests conducted by BASF indicate that GMB151 Soybean is compositionally similar to other commercially available soybean varieties developed using genetic engineering (BASF 2020). On January 28, 2019, BASF initiated a food/feed safety consultation (BNF 172) with FDA that included molecular, compositional, nutritional data, and other food and feed safety assessment data related to GMB151 Soybean (BASF 2020). In addition, based on the same safety assessment data, EPA concluded on June 8, 2020 that *B. thuringiensis* Cry14Ab-1 protein residue in or on soybean food and feed commodities is exempt from the requirement of a tolerance when expressed as a PIP in soybean plants (85 FR 35008; 40 CFR 174.540).

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 will be adversely impacted by a determination of nonregulated status for GMB151 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 GMB151 Soybean. The product will be planted on agricultural land currently suitable for production of soybeans; it 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 with GMB151 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. If a determination of nonregulated status of GMB151 Soybean is made, 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 GMB151 Soybean are not considered highly controversial by scientists or those who may be in a position to provide substantive information. Although APHIS received public comments opposed to a determination of nonregulated status of GMB151 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 5 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 cultivation of soybean varieties developed using genetic engineering. A determination of nonregulated status of GMB151 Soybean would only add another one to the market, and is not expected to change the market demands for soybeans produced from any of the productions systems currently used. A determination of nonregulated status of GMB151 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 GMB151 Soybean on wildlife or biodiversity is no different than that of other soybean varieties grown 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 5 of the EA, a

determination of nonregulated status of GMB151 Soybean is expected to neither directly cause an increase in U.S. agricultural acreage devoted to soybean production in general, nor that for used to grow varieties developed using genetic engineering. A determination of nonregulated status of GMB151 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 will not change. The effect of GMB151 Soybean on wildlife or biodiversity is neither different from that of other crop varieties developed using genetic engineering that are used in agriculture, nor that grown conventional production systems in the United States. As described in Chapter 4 of the EA, well-established management practices, production controls, and production practices (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 by any of the systems currently in use will continue to use those reasonable, commonly-accepted, best-management practices for their chosen systems and varieties during agricultural soybean production. Most U.S. soybean acreage is planted in a variety developed using genetic engineering. Based on historic trends, conventional production practices that use such varieties will likely continue to prevail in terms of acreage with or without a determination of nonregulated status of GMB151 Soybean. Given the extensive experience that APHIS, stakeholders, and growers have with the use of products from such soybean varieties, the possible effects to the human environment from the release of an additional varieties developed using genetic engineering 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 GMB151 Soybean will not establish a precedent for future actions with significant impacts, nor will 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 340. Each petition that APHIS receives is specific to a particular organism developed using genetic engineering, and independently undergoes this review to determine if the regulated organism poses a plant pest risk.

APHIS has reviewed and approved petitions for nonregulated status of soybean varieties developed using genetic engineering 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 soybean variety that is the subject of the petition. Each petition that APHIS receives is specific for a particular organism-trait combination that has been developed using genetic engineering, and undergoes an independent review to determine if the regulated organism 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 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 GMB151 Soybean, when added to past, present, and reasonably foreseeable future actions were identified during this assessment. As described in Chapter 6 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 GMB151 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 GMB151 Soybean will not directly or indirectly alter the character or use of properties protected under the National Historic Preservation Act. A determination of nonregulated status of GMB151 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 7 of the EA, APHIS has analyzed the potential effects of GMB151 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 GMB151 Soybean, APHIS concluded that a determination of nonregulated status of GMB151 Soybean will not have any 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 the BASF petition. The EA concluded that approval of the petition will not lead to circumstances that resulted in non-compliance with federal, state, or local laws and regulations

providing protections for environmental and human health. There are no federal, state, or local permits, authorizations or other actions 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 GMB151 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 organisms developed using genetic engineering; and (2) it allows APHIS to fulfill its regulatory obligations pursuant to 7 CFR 340. As APHIS has not identified any plant pest risks associated with GMB151 Soybean, the continued status of GMB151 Soybean as a regulated organism would be inconsistent with the plant pest provisions of the PPA, APHIS regulations at 7 CFR 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 GMB151 Soybean will not have any significant impacts on the human environment.

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Date: 2022.03.09 18:16:24 -05'00'

Bernadette R. Juarez
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date:

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