

**NATIONAL ENVIRONMENTAL POLICY ACT DECISION  
AND  
PRELIMINARY FINDING OF NO SIGNIFICANT IMPACT**

**Bayer CropSciences LP  
Glyphosate and HPPD Inhibitor Resistant GHB811 Cotton**

**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's (CEQ) NEPA implementing regulations, and APHIS NEPA implementing regulations and procedures (7 CFR 372). This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale.

Bayer CropSciences LP (hereinafter referred to as "Bayer") submitted a petition (17-138-01p) to APHIS requesting that genetically engineered (GE) GHB811 cotton, and any progeny derived from it, no longer be considered a regulated article under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). Bayer genetically engineered GHB811 cotton for resistance<sup>1</sup> to the herbicide active ingredients glyphosate and HPPD inhibitors such as isoxaflutole.<sup>2</sup> GHB811 cotton is intended to provide growers an additional choice for the management of agricultural weeds, including the management of herbicide resistant weeds. GHB811 cotton has been regulated by APHIS because it was developed using *Agrobacterium tumefaciens*, a regulated article under 7 CFR part 340.2.<sup>3</sup>

As part of evaluation of Bayer's petition, APHIS conducted an Environmental Assessment (EA) to inform APHIS' decision regarding the regulatory status of GHB811 cotton. The EA evaluates the potential impacts of APHIS' regulatory decision on the quality of the human environment.<sup>4</sup> The EA did not identify any significant impacts that would derive from either an approval or a denial of the petition. Therefore, the Agency has prepared this FONSI, pursuant to 40 CFR §1508.13, which provides a summary of the EA, and the reasons why APHIS' decision to issue a

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<sup>1</sup> The Weed Science Society of America (WSSA) defines "resistance" to herbicides as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type. "Tolerance" is distinguished from resistance as the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment (WSSA 2018). This means that there was no genetic manipulation to make the plant tolerant; it is naturally tolerant. Throughout this FONSI, APHIS uses the terms "resistance" and "tolerance" consistent with the WSSA definitions.

<sup>2</sup> 4-Hydroxyphenylpyruvate dioxygenase (HPPD) is an enzyme in plants involved in the metabolism of the essential amino acid tyrosine. Herbicides that inhibit HPPD prevent plants from creating tyrosine based compounds.

<sup>3</sup> Disarmed *Agrobacterium* is commonly used in the genetic modification of plants. Disarmed means the *Agrobacterium* is non-virulent.

<sup>4</sup> Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR § 1508.14).

determination of nonregulated status for GHB811 cotton will not have a significant impact on the human environment.

### **APHIS Regulatory Authority and the Coordinated Framework**

“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 contributes to the national economy and the public health. 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.

Since 1986, the United States government issued a comprehensive regulatory policy for the regulation of products of biotechnology known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the White House Office of Science and Technology Policy, describes the comprehensive federal system 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 transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies should focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies should exercise oversight of GE organisms 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 GE organisms: USDA’s APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

USDA has regulated products of biotechnology since 1987 pursuant to the Plant Protection Act of 2000 (PPA), as amended (7 USC §§ 7701 et seq.) to ensure that they do not pose a plant health risk.

The 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 genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under federal food safety laws, the FDA encourages them to participate in a voluntary consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, the FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered foods.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The 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 regulates certain genetically engineered organisms, such as algae, under the Toxic Substances Control Act (TSCA). The 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.

### ***Regulated Organisms***

The APHIS Biotechnology Regulatory Services' (BRS) mission is to protect and enhance America's agriculture and natural resources using a science- and risk-based regulatory framework to ensure the safe importation, interstate movement, and confined environmental release of regulated GE organisms. 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 if it is also considered a plant pest. A GE organism is also regulated under 7 CFR part 340 when APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c)(4) sufficient to determine whether the regulated article is unlikely to present a plant pest risk.

### **APHIS' Response to Petitions for Nonregulated Status**

As required by 7 CFR § 340.6, APHIS must respond to petitioners who request a determination of nonregulated status for GE organisms subject to 7 CFR part 340. When a petition for nonregulated status is submitted, APHIS must determine the plant pest risk the GE organism may pose. If APHIS determines, based on a Plant Pest Risk Assessment (PPRA) and other relevant information, 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. As part of review of Bayer's petition for GHB811 cotton, APHIS conducted a PPRA and EA. The PPRA concluded that GHB811 cotton was unlikely to pose a plant pest risk. The EA concluded that a determination of nonregulated status for GHB811 cotton would not result in any significant environmental, human health, or socioeconomic impacts.

### **Public Involvement**

On October 27, 2017, APHIS published a notice in the Federal Register (82 FR 49782-49783, docket no. APHIS-2017-0073) announcing the availability of Bayer's petition for a 60-day public review and comment period. Comments were due on or before December 26, 2017. A total of 8 comments were received during the comment period. All comments were carefully analyzed to identify new issues, alternatives, or information.

### **Major Issues Addressed in the EA**

APHIS prepared the EA consistent with the CEQ regulations (40 CFR parts 1500-1508) and USDA-APHIS NEPA implementing regulations (7 CFR part 372). APHIS developed a list of topics for consideration in the EA based on issues identified in prior EAs for regulated cotton

varieties, public comments submitted on the petition for GHB811 cotton, other EAs and EISs evaluating petitions for nonregulated status, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated cotton (*Gossypium*) species. The following topics were identified as relevant to the scope of analysis (40 CFR § 1508.25):

### **Agricultural Production**

- Acreage and Areas of Cotton Production
- Agronomic Practices in Cotton Production

### **Environmental Considerations**

- Water Resources
- Soil Quality
- Air Quality
- Animal Communities
- Plant Communities
- Soil Microorganisms
- Biodiversity
- Gene Flow and Weediness
- Weed Management and Herbicide Resistant Weed Management

### **Human Health**

- Human Health and Worker Safety

### **Animal Health**

- Animal Health and Welfare

### **Socioeconomics**

- Domestic Socioeconomic Environment
- International Trade Economic Environment

### **Threatened and Endangered Species**

- Threatened and Endangered Plant Species and Critical Habitat
- Threatened and Endangered Animal Species

### **Alternatives Evaluated in the EA**

The EA considered two alternatives in response to the petition request, to either deny or approve the request for nonregulated status, and analyzed the potential environmental, human health, and socioeconomic impacts that may result from the two alternatives.

#### *No Action: Continuation as a Regulated Article*

One of the alternatives that must be considered by APHIS is a “No Action Alternative,” pursuant to CEQ regulations at 40 CFR part 1502.14. No Action in this instance means no change in regulatory status. Under the No Action Alternative APHIS would deny the petition request for nonregulated status and GHB811 cotton would remain a regulated article under 7 CFR part 340. Because APHIS concluded in its PPRA that GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018) this is not APHIS’ preferred alternative. Choosing this alternative would not be an appropriate response to the petition for nonregulated status, nor satisfactorily meet the

purpose and need for making a regulatory status decision pursuant to the requirements of 7 CFR part 340.

*Preferred Alternative: Determination that GHB811 Cotton is No Longer a Regulated Article*

Under this alternative, GHB811 cotton and progeny derived from it would no longer be subject to 7 CFR part 340 because it was determined that, based on the scientific evidence before the Agency, GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of GHB811 cotton or its progeny. Under this alternative, growers may have future access to GHB811 cotton and progeny derived from it if the developer decides to commercialize GHB811 cotton. This alternative best satisfies the purpose and need to respond appropriately to the petition pursuant to the requirements of 7 CFR part 340.6, the Agency's statutory authority under the PPA, and the biotechnology regulatory policies described for the Coordinated Framework.

**Alternatives Considered but Dismissed from Detailed Analysis**

APHIS evaluated several other alternatives for consideration in the EA. The alternatives considered are summarized below along with the reasons for dismissal from detailed analysis.

*Prohibit the Release of GHB811 Cotton*

APHIS considered prohibiting the environmental release of GHB811 cotton, including denying permits for field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018). In enacting the PPA, Congress included findings that:

*“decisions affecting imports, exports, and interstate movement of products regulated under [the PPA] shall be based on sound science;...” (7 U.S. C. § 7701(4)) and that “The Secretary’s determination on the petition shall be based on sound science” (§ 7711(3)(c)).*

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies, such as genetic engineering, at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

*“Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency”*

Based on the PPRA for GHB811 cotton, APHIS concluded that GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018). Because there is no scientific or legal basis for prohibiting the release of GHB811 cotton, an alternative that would prohibit the environmental release of GHB811 cotton was omitted from further analysis in the EA.

*Approve the Petition in Part*

The regulations at 7 CFR § 340.6(d)(3)(i) provide that APHIS may “approve the petition in whole or in part.” APHIS has concluded that GHB811 cotton is unlikely to pose a plant pest risk

(USDA-APHIS 2018). Because there must be a plant pest risk to deny the petition request, or approve the petition in part, it would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations at 7 CFR part 340 to consider approval of the petition only in part. Consequently, this alternative was omitted from further analysis in the EA.

*Isolation of GHB811 Cotton and Non-GE Cotton and Geographic Restriction*

In response to public concerns regarding gene movement between GE and non-GE plants, APHIS could consider requiring isolation distances for separation of GHB811 cotton from non-GE cotton production systems. APHIS could also consider geographically restricting the production of GHB811 cotton based on the location of production of non-GE cotton, or organic production systems, or production systems for GE-sensitive markets. However, because APHIS has concluded that GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018), prescribing isolation distances or geographic restrictions on production would be inconsistent with APHIS’ statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340. APHIS concluded that GHB811 cotton is unlikely to present a plant pest risk, and consequently, the Agency has no jurisdiction to continue regulating GHB811 cotton. Consequently, this alternative was omitted from further analysis in the EA.

*Requirement of Testing for GHB811 Cotton*

During comment periods for other petitions for nonregulated status, certain commenters requested that the USDA require and provide testing for the presence of GE material in non-GE production systems. Because there are no federal regulations describing testing criteria or quantitative thresholds for GE material in non-GE cropping systems or crop products, nationwide testing and monitoring would be extremely difficult to implement. Additionally, because GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018), the imposition of any type of testing requirements for GHB811 cotton would be inconsistent with the PPA, 7 CFR part 340, and federal regulatory policies embodied in the Coordinated Framework. Consequently, this alternative was omitted from further analysis in the EA.

**Environmental Consequences of APHIS’ Selected Action**

The EA provides analyses of the alternatives APHIS considered, to which the reader is referred for specific details. The following table briefly summarizes the potential environmental consequences of the alternatives evaluated in the EA.

<b>Summary of Issues and Potential Impacts of the Alternatives</b>		
<b>Attribute/Measure</b>	<b>Alternative 1: No Action – Deny the Petition</b>	<b>Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton</b>
Meets Purpose and Need	No	Yes
Unlikely to pose a plant pest risk	Addressed by the use of regulated field trials.	Determined by the plant pest risk assessment (USDA-APHIS 2018).

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<b>Attribute/Measure</b>	<b>Alternative 1: No Action – Deny the Petition</b>	<b>Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton</b>
<b>Agricultural Production</b>		
Acreage and Areas of Cotton Production	Overall acreages of cotton are anticipated to increase modestly through 2024 (USDA-OCE 2017). Total acreage will fluctuate due to global supply and demand, and cotton commodity prices.	Acreage planted would remain about the same as in the No Action Alternative.  GHB811 cotton might replace other cotton varieties currently grown in the United States.  This alternative is not expected to influence the geographic area in which cotton is grown.
Agronomic Practices	Weeds with an evolved resistance to glyphosate and other herbicides are expected to continue to increase. As these HR weeds become more prevalent, growers are expected to shift to other possibly more costly alternative weed control measures and/or switch to other HR crops in order to remain economically viable.  Many cotton growers are likely to use additional herbicides and may abandon conservation tillage practices and return to more aggressive conventional tillage systems to manage weeds and protect yields.	Other than the use of isoxaflutole on GHB811 cotton and the ability to use herbicide mixtures comprised of products with multiple modes of action, the agronomic practices would be the same as those currently used. Isoxaflutole use would be contingent on EPA’s decision to register it specifically for use on GHB811 cotton. Bayer will submit a request for a label expansion to allow for the use of isoxaflutole on GHB811 cotton.
Use of GE Cotton	Approximately 96% of U.S. cotton crops are GE herbicide or insect resistant varieties. Denial of the petition would	Approval of the petition would provide (subject to FDA consultation and EPA requirements) for cultivation

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	have no effect on the planting of existing varieties of GE canola.	of the first GE cotton modified for resistance to HPPD inhibitor based herbicides. This would be a novel herbicide mode of action for control of weeds in cotton.
<b>Physical Environment</b>		
Soils	Increased tillage to manage HR weeds may occur in some cotton cropping systems, which can adversely affect soil quality and increase soil erosional capacity.	The agronomic practices and inputs are the same for both GHB811 cotton and existing cotton varieties, save for potential use of isoxaflutole on GHB811 cotton. Therefore, potential direct and indirect impacts to soils would be unchanged. Isoxaflutole presents negligible impacts to impairment of soil quality.
Water Quality	Increased tillage, or adoption of more aggressive tillage practices to manage HR weeds, may occur in some cotton cropping systems. Increased or more aggressive tillage could exacerbate soil erosion and run-off, which can impair water quality.	To the extent GHB811 cotton facilitates effective management of weeds and development of HR weed populations, it could facilitate increased use of conservation and no-till practices, potentially reducing impacts on water quality. In the long term, unless growers implement integrated weed management (IWM) practices, development of HR weeds may be accompanied by increased tillage, which presents impacts to water quality (as described in the No Action Alternative).



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Air Quality	<p>Emission sources, namely tillage and machinery combusting fossil fuels, and the level of emissions associated with cotton crop production would be unaffected by denial of the petition.</p> <p>Increased tillage to manage HR weeds may occur in some cotton cropping systems. This could reduce air quality from increased national ambient air quality standards (NAAQS) pollutant emissions from farm equipment and airborne soil particulates.</p> <p>Increased use of herbicides may occur to manage HR weeds. For certain herbicides, this could increase volatilization and drift that could impact air quality.</p>	<p>Sources of potential impacts on air quality are the same as those under the No Action Alternative. To the extent GHB811 cotton facilitates use of conservation and no-till practices in the management of weeds and HR weeds, benefits to air quality would be expected. Isoxaflutole and glyphosate, which would be used with GHB811 cotton, have low volatility. Overall use of herbicides (e.g., in lbs a.i./acre) on GHB811 cotton is therefore expected to remain the same or may be reduced by better management of HR weeds.</p>
<b>Biological Resources</b>		
Animal Communities	<p>Commercial cotton fields provide limited food and habitat for wildlife. The EPA regulates pesticides and determines whether they pose an unreasonable risk to animals. It is violation of federal law to use a pesticide in a manner that is not in strict accordance with the instructions on its EPA-approved label.</p>	<p>Potential impacts on animals would be the same as that under the No Action Alternative. Isoxaflutole and its degradants are considered practically non-toxic to avian species, rats, and honey bees, and moderately toxic to fish and aquatic invertebrates. Glyphosate use consistent with current EPA label requirements presents only minor risk to wildlife, it is</p>

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		<p>only slightly toxic to fish and aquatic invertebrates, birds, and mammals, and practically non-toxic to terrestrial invertebrates.</p> <p>The 2mepsps and hppdPFW336-1Pa transgenes and their gene products present negligible risk wildlife.</p>
Plant Communities	<p>Potential impacts on plants would be unaffected by denial of the petition. Plants (other than crop plants) in cotton fields are considered weeds as they can impact crop yield and quality. Weeds are managed using a variety of methods, including tillage and herbicides. Plants surrounding cotton fields are generally encouraged as they provide habitat for pollinators and other beneficial insects. The EPA regulates and determines how pesticides can be used. EPA pesticide use requirements are intended to be protective of non-target plants, such as those in adjacent fields.</p>	<p>Potential impacts on plants would be the same as that for the No Action Alternative. Isoxaflutole is highly toxic to non-tolerant plants, however any future use of isoxaflutole on GHB811 cotton would be subject to EPA label use restrictions. The gene and gene products in GHB811 cotton naturally occur in other plant species and would not impact plants.</p>
Soil Microorganisms	<p>Potential impacts on soil biota would be unaffected by denial of the petition.</p>	<p>Commercial production of GHB811 cotton and hybrid crops are not expected to present any impact to soil biota.</p>
Biodiversity	<p>Under the No Action Alternative, GHB811 cotton</p>	<p>Commercial production of GHB811 cotton would affect</p>

Summary of Issues and Potential Impacts of the Alternatives		
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	could be grown in field trials under permit or notification. Because of the relatively small acreage and transient nature of field trials, long-term impacts on biodiversity would be unlikely. Biodiversity in and around commercial cotton crops would remain unaffected.	biodiversity in and around GHB811 cotton crops no differently than other cropping systems used for other cotton varieties. Since GHB811 cotton is compositionally and agronomically the same as other types of cotton in production, and since GHB811 cotton is expected to be grown as a replacement crop where cotton is currently grown, any impacts would be the same as the No Action Alternative.
Gene Flow and Weediness	Denial of the petition would not change the varieties of conventional and GE varieties of cotton planted and would therefore have no impact on potential matters concerning gene flow and weediness associated with commercial cotton production.	The transgenes present in GHB811 cotton are unlikely to increase the rate of successful transgene introgression from GHB811 cotton into native or naturalized <i>G. barbadense</i> populations relative to the rate of gene introgression from conventional cultivars.
Herbicide Resistant Weeds	Planting of currently available GE HR cotton varieties is likely to remain at current levels. Selection pressure for evolved HR in weed populations will continue.	As a stacked trait variety with resistance to multiple herbicide MOAs, GHB811 cotton may provide for effective weed control and management of evolved resistance in weed populations. The rate of development of new evolved HR weed populations, as well as the overall number of HR weed populations, would likely decline in this cropping

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		system, depending on the IWM program employed. Implementation of recommended IWM practices is expected to reduce the development of evolved herbicide resistance in weed populations, including the potential for evolved resistance to multiple types of herbicide MOAs.
<b>Human and Animal Health</b>		
Human Health and Safety	Denial of the petition would have no impact on human health or worker safety. EPA regulation of pesticides and worker protection standards would remain unchanged.	Bayer submitted a Premarket Biotechnology Notification to the FDA on April 17, 2017 for consultation on the safety of products derived from GHB811 cotton. The EPA conducted human health risk assessments for glyphosate and HPPD inhibitors, such as isoxaflutole, and establishes pesticide use restrictions and food tolerance limits that are intended to be protective of human health. Approval of the petition would have no impact on EPA regulation of pesticides or worker protection standards; potential risks and protections for workers would be no different from that of the No Action Alternative.
Animal Health and Welfare	Denial of the petition would have no impact on animal health. GHB811 cotton will remain a regulated article,	A determination of nonregulated status for GHB811 cotton would have no impact on animal health

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<b>Attribute/Measure</b>	<b>Alternative 1: No Action – Deny the Petition</b>	<b>Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton</b>
	will not be available as an animal feed, and current cotton-based feed for livestock will remain unchanged.	and welfare. Bayer is consulting with the FDA on safety of feed derived from GHB811 cotton.
<b>Socioeconomics</b>		
Socioeconomics	Denial of the petition would have no impact on the domestic cotton markets. Cotton products (fiber, linters, hulls, oil, and meal) would be exported subject to market demand. There would be no impacts on trade under the No Action Alternative.	GHB811 cotton is not expected to have any impacts on domestic cotton markets, conventional, organic, or GE. The primary purpose of GHB811 cotton is to help manage weeds and HR weeds. Where GHB811 cotton is produced with an effective IWM program, it is possible that adopters of GHB811 cotton may realize long-term savings in weed management costs from reduced expenditure on herbicides, applications, and tillage. Approval of the petition is unlikely to have substantial impacts on the global trade of cotton products. However, to the extent that adoption of GHB811 cotton facilitates growers minimizing or reducing weed populations and control costs, its introduction may enhance the competitiveness of U.S. producers in global markets.
<b>Coordinated Framework</b>		

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<b>Attribute/Measure</b>	<b>Alternative 1: No Action – Deny the Petition</b>	<b>Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton</b>
FDA Consultations and EPA Registrations	Denial of the petition would have no impact on the roles of the FDA and EPA in oversight of GHB811 cotton.	Bayer submitted a Premarket Biotechnology Notification to the FDA on April 17, 2017. A label expansion to allow the use of isoxaflutole on GHB811 cotton has not been submitted to the EPA.
<b>Regulatory and Policy Compliance</b>		
ESA, CWA, CAA, SDWA, NHPA, EOs	Compliant	Compliant

**Finding of No Significant Impact**

Based on the analysis presented in the EA, a determination of nonregulated status for GHB811 cotton will not have a significant impact, individually or cumulatively, on the quality of the human environment. 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 the following factors.

*Context*

The term “context” means identification of the locations and resources that could potentially be affected by the Agency’s action. The EA identified the areas in which cotton is grown and may be cultivated in the United States, and those aspects of the human environment potentially affected by the Agency’s regulatory decision. This action has the potential to affect GE and non-GE cotton cropping systems; environments adjacent to and associated with GHB811 cotton cropping systems; cotton fiber and seed oil post-harvest processing systems; and domestic and foreign commodity markets. In 2017, cotton was planted on approximately 12.6 million acres in the United States (USDA-ERS 2017a). According to USDA-NASS data, cotton has been planted on approximately 10 to 12 million acres over the last several years (USDA-NASS 2015). GE-derived varieties of cotton, containing either HR, insect resistance, or both traits, comprised 96 percent of all cotton planted in 2017 (USDA-ERS 2017b). Cotton is grown in 17 states across the southern United States. These states include Alabama, Arizona, Arkansas, California, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia (USDA-NASS 2015).

A determination of nonregulated status for GHB811 cotton is not expected to result in any increase in agricultural acreage utilized for cotton production, or change in the areas where cotton is grown, because it is not substantially different, phenotypically and agronomically, from existing cotton, and will be used to provide the same cotton commodities, fiber and oil, as non-GE varieties.

### *Intensity*

Within the context discussed above, intensity refers to the degree or severity of potential impacts. As recommended by CEQ (40 CFR § 1508.27), the following were considered in evaluating intensity and making this NEPA determination.

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

The EA evaluated the potential impacts of approval and denial of the petition, those impacts that would be potentially adverse, as well as beneficial. These are summarized below.

Potentially Beneficial: Approval of the petition would likely result in availability of GHB811 cotton, a stacked-trait HR variety that may expand the range of options available to growers for management of weeds, including extant HR weed populations, and may help slow the emergence of additional HR weed populations. HPPD inhibitors (e.g., isoxaflutole), to which GHB811 cotton is resistant, provide a new herbicide mode of action (MOA) in cotton and is effective in the control of many of the broadleaf and grass weed species currently found in cotton fields. HPPD inhibitors provide control of weeds before emergence of the crop plant, while glyphosate provides control of weeds post-emergence.

Bayer currently has no plans to market GHB811 cotton as a standalone product. Bayer plans to cross GHB811 cotton with other lines of herbicide and insect resistant cotton, and offer as commercial products stacked-trait varieties that will be resistant to HPPD inhibitors, glyphosate, and glufosinate. In addition, GHB811 cotton may be stacked with traits for insect (lepidopteran) resistance (Cry1Ab, Cry2Ae, and Vip3Aa19). It is anticipated that the HPPD inhibitor herbicide will be labeled for pre-emergence and early post-emergence use with GHB811 cotton. The availability of stacked-trait GHB811 cotton varieties utilizing multiple herbicide MOAs could help growers effectively manage agricultural weeds, to include HR weeds. Use of multiple herbicide MOAs may reduce the likelihood of development of additional HR weed populations.

HR weeds have forced cotton growers in some areas to include or intensify tillage to control them in order to sustain maximum yields and profitable returns. For example, in the southern states, conventional tillage is becoming a more common practice because of the development of HR weeds (Hollis 2015), which increases risks to water resources from soil run-off. Effective use of GHB811 cotton within an IWM program could potentially promote the continued use, or in some instances the return to, conservation and no-till practices. Reduced and no-tillage practices significantly contribute to

reductions in soil erosion from water and wind. Reduced tillage also contributes to reduced fossil fuel use, less air pollution from dust, improved soil moisture retention, and reduced soil compaction. Relative to the types of tillage currently used, any reduction in tillage under the Preferred Alternative would be a benefit to air, soil, and water resources.

Potentially Adverse: Over the long-term, IWM practices utilizing combinations of cultural, mechanical, chemical, biological, and crop rotation strategies will need to be implemented with GHB811 cotton for this variety to remain an effective tool for weed management. Reliance on the chemical management of weeds alone may result in the continued emergence of HR weed populations over the long-term.

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

Approval of the petition would have no impact on public health or safety. GHB811 cotton does not differ compositionally from other cotton varieties currently in production.

Any pesticide used with GHB811 cotton will be regulated by the EPA. The EPA conducts human health and environmental risk assessments for pesticide active ingredients and provides use restrictions that are intended to be protective of human and environmental health. Bayer submitted a Premarket Biotechnology Notification to the FDA on April 17, 2017, to consult with the FDA on the safety of products derived from GHB811 cotton.

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.*

The EA concluded that it is unlikely that historic or cultural resources, park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas would be significantly impacted by approval of the petition. Cotton volunteers may occur in areas where GHB811 cotton is cultivated and due to spilling of seed during transport. However, invasion of park lands, wetlands, wild and scenic areas, or ecologically critical areas by GHB811 cotton or feral hybrids is considered unlikely. APHIS conducted a PPRA and concluded that it is unlikely that GHB811 cotton will become weedy or invasive, nor would gene introgression from GHB811 cotton to wild cotton populations increase the weediness wild cotton hybrids (USDA-APHIS 2018).

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

APHIS received public comments opposing the petition, however, approval of the petition for nonregulated status for GHB811 cotton and its progeny is not an action



considered highly controversial in nature. There would be no significant changes to the agricultural practices and inputs used for cotton production, nor the potential impacts of these practices and inputs on the human environment. The potential sources of impacts of GHB811 cotton production on physical and biological resources are similar to that of currently cultivated cotton varieties. Use of the HPPD inhibitor MOA herbicide in GHB811 cotton production would be new and subject to EPA approval and label use requirements. There are no potential impacts on the human environment that would derive from approval of the petition that are controversial in nature.

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

There are no unique or unknown impacts associated with GHB811 cotton. As discussed in the EA, the mechanisms by which the GE 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme and 4-Hydroxyphenylpyruvate dioxygenase (HPPD W336) enzyme confer herbicide resistance are well understood. The *2mepsps* transgene was derived from corn. The *hppdPfW336-1Pa* transgene was derived from *Pseudomonas fluorescens*, a naturally occurring soil bacterium. These transgenes and their respective enzymes pose no risk to plants and animals. Since 1994, APHIS has evaluated over 15 different GE cotton varieties, some of which were glyphosate resistant and comprised of the *2mepsps* transgene and respective 2mEPSPS enzyme. APHIS has previously evaluated HPPD resistance in soybean.

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.*

Approval of Bayer's petition would not establish a precedent for future actions that would result in significant impacts on the human environment, nor would it represent a decision in principle about a future decision. Approval of the petition is based upon an independent determination of whether GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018) pursuant to 7 CFR part 340, and an EA consistent with NEPA and CEQ implementing regulations. APHIS has reviewed and approved petitions for nonregulated status since 1992; each of these petitions reviewed independent of the others, and determinations of regulatory status 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.*

The EA discusses potential cumulative impacts on agricultural practices and inputs, human and animal health, physical and biological resources, and on the selection pressure for herbicide-resistant weed populations. Impacts from the cultivation of GHB811 cotton would not be considered cumulatively significant nor greater than that which occurs with currently cultivated cotton varieties.

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 historical resources.*

The EA concluded that approval of the petition is not an action that would directly or indirectly alter the character or use of properties protected under the National Historic Preservation Act. It would have no impact on districts, sites, highways, structures, or objects listed in, or eligible for listing in, the National Register of Historic Places, nor cause any loss or destruction of significant scientific, cultural, or historic resources. GHB811 cotton would be cultivated on lands zoned for agricultural uses. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of cotton would be used in cultivation of GHB811 cotton, including the use of EPA registered pesticides. The crop production practices used in the cultivation of cotton do not introduce significant visual impairments, or noise, in a manner that would impact the use and enjoyment of historic properties. 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 an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

APHIS analyzed the potential effects of GHB811 cotton on threatened and endangered species and critical habitat in Chapter 6 of the EA. APHIS concluded that approval of the petition for nonregulated status for GHB811 cotton, and any subsequent commercial production of this cotton variety, will have no effect on listed species or species proposed for listing, nor would it affect designated habitat or habitat proposed for designation. Because of this no-effect determination, neither consultation under Section 7(a)(2) of the Act nor the concurrences of the U.S. Fish and Wildlife Service and National Marine Fisheries Services are required.

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 Bayer’s petition. The EA concluded that approval of the petition would not present a risk to violation of federal and state laws and regulations governing environmental and human health protections. The EPA will regulate the use of pesticides on GHB811 cotton, and Bayer is consulting with the FDA as to the food and feed safety of products derived from GHB811 cotton.

**NEPA Decision and Rationale**

I have carefully reviewed the EA and determined the analyses and conclusions support a Finding of No Significant Impact (FONSI) from a determination of nonregulated status for GHB811 cotton.

As stated in 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.” The Preferred Alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social 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. As APHIS has not identified any plant pest risks associated with GHB811 cotton, the continued status of GHB811 cotton 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 for GHB811 cotton will not have any significant environmental impacts.

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Biotechnology Regulatory Services  
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Date:

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