Bayer CropScience LP Petition 17-138-01p for Determination of Nonregulated Status for Glyphosate Resistant and HPPD Inhibitor Resistant GHB811 Cotton

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Draft Environmental Assessment

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Acronyms and Abbreviations

ae	acid equivalent
a.i.	active ingredient
ACCase	acetyl CoA carboxylase
ALS	acetolactate synthase
APHIS	Animal and Plant Health Inspection Service (USDA)
ARS	Agricultural Research Service (USDA)
BACM	best available control measure (for air quality)
BMP	best management practices
BRS	Biotechnology Regulatory Services (USDA)
Bt	gene from *Bacillus thuringiensis* that confers lepidopteran insect resistance
bw	body weight
2mepsps	gene conferring glyphosate resistance
CAA	Clean Air Act
CFR	Code of Federal Regulations
CSP	Conservation Stewardship Program
CWA	Clean Water Act
DMA	dimethylamine
EA	environmental assessment
EC	effective concentration
EFSA	European Food Safety Agency
EIS	environmental impact statement
EPA	U.S. Environmental Protection Agency
EPSP	5-enolpyruvylshikimate-3-phosphate
epsps	gene that in codes for EPSP Synthase
EPSPS	EPSP Synthase enzyme
ERS	Economic Research Service (USDA)
ESA	Endangered Species Act
EO	Executive Order
EQIP	Environmental Quality Incentives Program
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
FEIS	Final Environmental Impact Statement
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
FSMA	Food Safety Modernization Act
FR	Federal Register
GE	genetically engineered
GR	glyphosate-resistant
HPPD	4-Hydroxyphenylpyruvate dioxygenase

hppdPfW336-1Pa	gene conferring resistance to herbicides that are active on the target enzyme
HR	herbicide-resistant
IPPC	International Plant Protection Convention
IPM	integrated pest management
IWM	integrated weed management
Lb	pound (mass, U.S.)
LC	lethal concentration
LD50	lethal dose for 50 percent of a population
LP	limited partnership
MCPA	(4-chloro-2-methylphenoxy) acetic acid
MOA	mode of action of an herbicide
MY	market year
NAAQS	national ambient air quality standards
NASS	National Agricultural Statistics Service (USDA)
NEPA	National Environmental Policy Act
NHPA	National Historic Preservation Act
NIFA	National Institute for Food and Agriculture (USDA)
NMFS	National Marine Fisheries Service
NO_X	nitrogen oxides
NPDES	National Pollution Discharge Elimination System
NPS	nonpoint source pollution
NRCS	Natural Resources Conservation Service (USDA)
NWQI	National Water Quality Initiative
OECD	Organization for Economic Co-operation and Development
OPP	Office of Pesticide Programs (U.S. EPA)
PBN	Premarket Biotechnology Notification (FDA)
PIP	plant-incorporated protectant
PM	particulate matter
$PM_{2.5}$	particulate matter with aerodynamic diameter of 2.5 micrometer or less
PM_{10}	particulate matter with aerodynamic diameter of 10 micrometer or less
PPA	Plant Protection Act of 2000
PPRA	Plant Pest Risk Assessment
RACM	reasonably available control measure (for air quality)
RED	reregistration eligibility decision
RUP	restricted use pesticide
SDWA	Safe Drinking Water Act
SIP	State Implementation Plan (for air quality standards under the CAA)
spp	species (plural)
TSCA	Toxic Substances Control Act
U.S.	United States
U.S.C.	United States Code
USDA	U.S. Department of Agriculture

VOC	volatile organic compound
WHO	World Health Organization
WPS	Worker Protection Standard (by EPA for agriculture)
WSSA	Weed Science Society of America

1 PURPOSE AND NEED

On July 13, 2017, Bayer CropScience LP (referred to as "Bayer" in this document) of Research Triangle Park, NC, submitted a petition (17-138-01p) to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), requesting a determination of nonregulated status for a genetically engineered (GE) cotton, designated GHB811 cotton. This variety has been genetically engineered for resistance[1] to two types of herbicide modes of action (MOAs), EPSPS and HPPD inhibitors. GHB811 cotton is currently regulated by APHIS because it was developed using the plant pest *Agrobacterium tumefaciens*; a regulated article under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340).

1.1 Background

Prior to submission of its petition, Bayer conducted field trials authorized by APHIS at 15 sites in the United States in seven states: California, Georgia, Louisiana, Mississippi, South Carolina, Texas, and North Carolina.[2] Bayer submitted data from these trials and also from trials it conducted in Argentina and Chile in its petition (Bayer 2017b). APHIS analyzed these and other relevant data and published its conclusions in a Preliminary Plant Pest Risk Assessment (PPRA) (USDA-APHIS 2018).[3]

Bayer's petition asserts that APHIS should not regulate GHB811 cotton because this variety is unlikely to pose a plant pest risk. If a determination of nonregulated status is made, it would pertain to GHB811 cotton, as well as to any progeny derived from crosses between GHB811 cotton and conventional cotton and from crosses between GHB811 cotton and other GE cotton varieties that are not regulated under 7 CFR part 340. APHIS prepared this Environmental Assessment (EA) to determine if its regulatory decision could have any significant impacts on the human environment,[4] as required by the National Environmental Policy Act (NEPA). As part of the evaluation of Bayer's petition, APHIS has developed this EA to seek public comment, which will help inform the APHIS decision regarding the regulatory status of GHB811 cotton.

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[1] The Weed Science Society of America (WSSA) defines herbicide resistance as "the inherited ability of a plant population to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type." The WSSA distinguishes "tolerance" from resistance; it defines herbicide tolerance as "the inherent ability of a species to survive and reproduce following exposure to an herbicide treatment" (WSSA 2018a.). This means that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. Throughout this EA, APHIS has used the terms "resistance" and "tolerance" consistent with the WSSA definitions. Note, however, that different terms for the same concept may be used interchangeably in some instances. In its petition to APHIS, Bayer references GHB811 cotton as "herbicide-tolerant cotton." This terminology can be considered synonymous with "herbicide resistant" used in this EA.

[2] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/sa_permits/ct_status

[3] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

[4] Human environment includes the natural and physical environment and the relationship of people with that environment. When economic or social and natural or physical environmental effects are interrelated, the NEPA analysis may addresses these potential impacts as well (40 CFR §1508.14).

1.2 Purpose of GHB811 Cotton

Bayer genetically engineered GHB811 cotton to resist the herbicidal effects of both glyphosate and HPPD inhibitor herbicides such as isoxaflutole. Because GHB811 cotton contains two herbicide-resistant (HR) traits, it is referred to as a "stacked trait" variety. Bayer developed this variety through *Agrobacterium*-mediated transformation to produce a stable double mutant. GHB811 cotton contains the 5-enol pyruvylshikimate-3-phosphate synthase (*2mepsps*) gene and the 4-hydroxyphenylpyruvate dioxygenase W336 (*hppdPfW336-1Pa*) gene. The *2mepsps* gene encodes for expression of the 2mEPSPS enzyme, which confers resistance to glyphosate-based herbicides. The *hppdPfW336-1Pa* gene encodes for the HPPD W336 enzyme, which confers resistance to herbicides that inhibit 4-Hydroxyphenylpyruvate dioxygenase (HPPD), including isoxaflutole. Bayer will request a label modification from the Environmental Protection Agency (EPA) to permit the use of isoxaflutole-based herbicides with GHB811 cotton.

As a stacked-trait variety utilizing two, and potentially more, herbicide MOAs with additional stacking of traits, GHB811 cotton may provide growers broader options than are currently available for weed control. Glyphosate resistant cotton is widely grown in the United States. A cotton variety that combines glyphosate resistance with isoxaflutole resistance is an additional option for cotton growers to help manage difficult weeds. By combining herbicides[5] with different MOAs, growers are also better able to manage, and help deter, the development of herbicide resistant weeds. Isoxaflutole, which has not been used in cotton crop production, is effective in management of annual grasses and broadleaf weeds that occur in cotton fields. If GHB811 cotton is no longer regulated by APHIS, it may be grown commercially in the United States.

1.3 Coordinated Framework for the Regulation of Biotechnology

Since 1986, the U.S. government has regulated GE organisms pursuant to federal guidance published in the *Federal Register* (51 FR 23302) entitled "The Coordinated Framework for the Regulation of Biotechnology" (referred to as the Coordinated Framework in this document). The Coordinated Framework, published by the Office of Science and Technology Policy, describes

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[5] The term "herbicide" can be used in several ways. An herbicide is a type of pesticide formulated to control weeds. Herbicides contain one or more active ingredients (a.i.). Some active ingredients are comprised of a parent compound or the salt or ester of the parent compound. A parent compound may be formulated as several different salts or esters. The parent compound can be referred to by its common name (for example, glyphosate) or by its chemical name (for example, N-phosphonomethyl glycine). The WSSA maintains a list of the chemical names that correspond to herbicide common names (http://wssa.net/wssa/weed/herbicides/). Active ingredients are formulated to make commercial products that are sold under trade or product names. An active ingredient or ingredients may be sold under different product names. The concentration of the active ingredients and formulations may also vary among products. Each product has a label specific to that product. Herbicides must be used in strict accordance with their product label instructions. Some products may contain the same or similar active ingredient(s) but may have different label instructions. For example, it would not be legal to use a product labeled for terrestrial use in an aquatic application unless that use is allowed specifically by the label for that product. In this document herbicide product names are not used. The use of the common name of the parent compound--unless otherwise specified--is meant to include all formulations of the parent compound and commercial products that contain that active ingredient.

the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products and explains how U.S. agencies will use existing federal statutes 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 are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; 3) agencies are expected to 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-APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). A summary of the roles of each agency follows. A detailed description is available in the original 1986 policy statement (51 FR 23302) and in recent updates to the policy update.[6]

1.3.1 APHIS

APHIS regulations at 7 CFR part 340 are authorized by the plant pest provisions of the Plant Protection Act of 2000 (PPA), as amended (7 United States Code (U.S.C.) 7701–7772). They regulate the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. 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 GE organism is considered a regulated article if the donor organism, recipient organism, vector, or the vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under 7 CFR 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have adequate information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and therefore should not be regulated under the plant pest provisions of the PPA or the regulations at 7 CFR 340. Under §340.6(c)(4), the petitioner must provide information related to plant pest risk that the Agency can use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

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[6] The 2017 update to the Coordinated Framework for the Regulation of Biotechnology resides at: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

1.3.2 Environmental Protection Agency

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. Such pesticides are regulated by the EPA as plant incorporated protectants[7] (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). The EPA also regulates certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq.*).

Before planting a crop containing a PIP, a company must seek an experimental use permit from the EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 Registration with the EPA. When assessing the potential risks of GE PIPs, EPA requires extensive studies examining risks to human health, non-target organisms and the environment, the potential for gene flow, and the need for insect resistance management plans.

Under FIFRA (7 U.S.C. 136 *et seq.*), the EPA regulates the use of pesticides (which include herbicides and insecticides), and requires registration of all pesticide products for all specific uses prior to distribution or sale for a proposed use pattern. The EPA examines: the active ingredient(s) of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, the EPA must determine, through submitted test results (guideline studies), available public literature, and modeling, that the pesticide will not cause unreasonable adverse effects on humans and the environment when used in accordance with label instructions. The EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158.

Once registered, a pesticide may only be legally used in strict accordance with the directions and restrictions on its label. The overall intent of the label is to provide clear directions for effective product use, while meeting the standard of no unreasonable adverse effects to human health and the environment. The Food Quality Protection Act (FQPA) of 1996, which amended FIFRA, enables the EPA to implement periodic registration reviews of pesticides to ensure that they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA 2011a).

The EPA also sets maximum residue limits referred to as “tolerances” for pesticide residues 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). The EPA is required, before establishing a pesticide tolerance, to reach a safety determination based on a finding of

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[7] The term “plant-incorporated protectants” (PIPs) refers to pesticidal substances produced by plants as well as the genetic material necessary for the plant to produce the substance.

reasonable certainty of no harm under the FFDCA, as amended by the FQPA. The FDA enforces the pesticide tolerances set by the EPA.

1.3.3 Food and Drug Administration

The FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 et seq.). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (US-FDA 1992). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under federal food safety laws prior to marketing.

In June 2006, the FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” (US-FDA 2006). This establishes voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with the FDA, but the information may be used later in the biotechnology consultation.

1.4 Purpose and Need for APHIS Action

As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as GHB811 cotton. When a petitioner submits a petition for nonregulated status, APHIS must determine whether the GE organism is unlikely to pose a plant pest risk. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to compare the plant pest risk of the regulated article to that of the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to the petition from Bayer requesting a determination of nonregulated status for GHB811 cotton. APHIS has prepared this EA to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality’s (CEQ) NEPA regulations and the USDA and APHIS NEPA implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from a determination of nonregulated status for GHB811 cotton.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice[8] in the *Federal Register* advising the public about changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, APHIS publishes two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice announces the availability of the petition and the second notice announces the availability of APHIS' decision-making documents. Each of the two notices published in the *Federal Register* provide an opportunity for public involvement. A summary of current practices follows.

1.5.1 First Opportunity for Public Involvement

Once APHIS deems a petition complete, the petition will be made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input that the Agency will consider as it develops its EA and PPRA. APHIS will publish a notice in the *Federal Register* to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice.

1.5.2 Second Opportunity for Public Involvement

Assuming an EA is sufficient, the EA and PPRA are developed and a notice of their availability is published in a second *Federal Register* notice. This second notice follows one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

Approach 1. GE organisms that do not raise substantive new issues

This approach for public participation is followed when APHIS decides, based on review of the petition and evaluation of public comments received during the 60-day comment period, that the petition involves a GE organism that does not raise substantive new issues. This would include, for example, gene modifications that do not raise new biological, cultural, or ecological issues due to the nature of the modification or APHIS' familiarity with the recipient organism. Under this approach, APHIS will publish a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, PPRA and FONSI for a 30-day public review period.

If no substantive information is received that would warrant substantial changes to APHIS' analysis or determination, APHIS' preliminary regulatory determination will become effective

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[8] This notice resides at: http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf

upon public notification through an announcement on its website. No further *Federal Register* notice will be published announcing the final regulatory determination.

Approach 2. GE organisms that raise substantive new issues not previously reviewed by APHIS.

A second approach for public participation will be used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues. This could include petitions involving a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified by APHIS based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition.

APHIS will solicit comments on its draft EA and preliminary PPRA for 30 days, as announced in a *Federal Register* notice. APHIS will review and evaluate comments and other relevant information, after which it will revise the PPRA, as necessary, and prepare a final EA. Following preparation of these documents, APHIS will either approve or deny the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, NEPA decision document, and regulatory determination.

Enhancements to stakeholder input are described in more detail in the *Federal Register* notice[9] published on March 6, 2012.

1.5.3 Public Involvement for Petition 17-138-01p

On October 27, 2017, APHIS announced in the *Federal Register* (82 FR No. 207, pp. 49782-49783) that it was making Bayer's petition available for public review and comment to help identify potential environmental and interrelated economic impacts that APHIS should consider in evaluation of the petition.[10] APHIS accepted written comments on the petition for a period of 60 days, until midnight on December 26, 2017. At the end of the comment period, APHIS had received a total of 8 comments on the petition.

APHIS evaluated all comments received during the 60-day comment period on the petition. Most of the comments expressed opposition to GE crops. One comment submitted was in support of Bayer's GHB811 cotton petition. Among the concerns expressed by those in opposition to the deregulation, was the potential for misuse of the HPPD inhibitor (e.g., isoxaflutole), prior to EPA issuing a registration decision, and asynchronous approval. In a communication to USDA, Bayer provided its business plans which reassure marketing plans will only include herbicides for which they have obtained EPA registrations. In addition, Bayer has committed to informing the National Cotton Council of its marketing plans to ensure responsible commercial deployment of

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[9] This notice resides at: http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf.

[10] Public comments can be reviewed at: https://www.regulations.gov/document?D=APHIS-2017-0073-0001.

the GHB811 cotton. APHIS evaluated the comments and integrated the concerns raised into this EA. No new issues were presented to APHIS regarding potential environmental, human and animal health, cultural, or socioeconomic impacts relative to GHB811 cotton. Because no new issues were identified in public comments, and due to APHIS' familiarity with GE cotton, and with the glyphosate and HPPD inhibitor resistance traits, APHIS decided this EA will follow Approach 1. All comments received on the petition are available for public review at www.regulations.gov, Docket ID: APHIS-2017-0073.

1.6 Scope of Analysis

APHIS developed a list of topics for consideration in this EA based on issues identified in prior EAs that address similar issues, public comments submitted for Bayer's petition, public comments submitted for other petitions and NEPA documents, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Gossypium* species. The following topics were identified as relevant to the scope of analysis for this EA (40 CFR § 1508.25).

Agricultural Production

- Areas and Acreage 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

Socioeconomic

- Domestic Socioeconomic Environment

- International Trade Economic Environment

Threatened and Endangered Species

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

2 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status for GHB811 cotton. To approve a petition for nonregulated status, APHIS must determine that GHB811 cotton is unlikely to pose a plant pest risk. Based on its Preliminary PPRA (USDA-APHIS 2018), APHIS has concluded that GHB811 cotton is unlikely to pose a plant pest risk. Therefore, APHIS must determine that GHB811 cotton is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA.

NEPA implementing regulations (40 C.F.R. § 1502.14) require agencies to evaluate all alternatives that appear reasonable and appropriate to the purpose and need for the Agency's action. Two alternatives are evaluated in this EA: (1) No Action, denial of the petition, which would result in the continued regulation of GHB811 cotton; and (2) a Preferred Alternative, a determination of nonregulated status for GHB811 cotton, which would represent approval of the petition.

2.1 No Action Alternative: 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. Under the No Action Alternative, APHIS would deny the petition and there would be no change in the regulatory status. GHB811 cotton and progeny derived from GHB811 cotton would continue to be regulated articles under 7 CFR part 340. APHIS would require permits for introductions of GHB811 cotton and measures for physical and reproductive confinement. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of GHB811 cotton.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS 2018) that GHB811 cotton is unlikely to pose a plant pest risk. Choosing this alternative would not satisfy the purpose and need (as discussed in *Section 1.4 – Purpose and Need for APHIS Action*) of making a determination of plant pest risk status and responding to the petition for nonregulated status.

2.2 Preferred Alternative: Determination of Nonregulated Status for GHB811 Cotton

Under this alternative, GHB811 cotton and progeny derived from it would no longer be regulated under 7 CFR part 340 because it was determined that, based on the scientific evidence before the Agency, that GHB811 cotton is unlikely to pose plant pest risks (USDA-APHIS 2018). APHIS would no longer require permits for introductions of GHB811 cotton or progeny derived from it. This alternative best satisfies the purpose and need to respond appropriately to the petition for nonregulated status (Bayer 2017b) pursuant to the requirements of 7 CFR part 340.6 and the Agency's statutory authority under the PPA. Because the agency has concluded that GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018), a determination of nonregulated status of GHB811 cotton is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

2.3 Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS assembled a list of alternatives that it might consider for GHB811 cotton. The Agency evaluated these alternatives in light of the Agency's authority under the plant pest provisions of the PPA, as well as the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality, to identify which alternatives would be further considered for GHB811 cotton. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

2.3.1 Prohibit the Release of GHB811 Cotton

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of GHB811 cotton, including denying permits for field testing.

In enacting the PPA, Congress found that:

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science…§ 402(4).

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:

> [D]ecisions 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 Preliminary PPRA (USDA-APHIS 2018) and the scientific data evaluated therein, APHIS concluded that GHB811 cotton is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for continuing the regulation of or prohibiting the release of GHB811 cotton.

2.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may “approve the petition in whole or in part.” For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. 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 APHIS' 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 dismissed from detailed analysis.

2.3.3 Isolation Distance between GHB811 Cotton and Non-GE Cotton Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating GHB811 cotton from non-GE cotton production. However, because APHIS has concluded that GHB811 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of GHB811 cotton based on the location of production of non-GE cotton in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' Preliminary PPRA for GHB811 cotton, there are no geographic differences associated with any identifiable plant pest risks for GHB811 cotton (USDA-APHIS 2018). APHIS did not analyze this alternative because it concluded that GHB811 cotton is unlikely to pose a plant pest risk. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the PPA, and the regulations codified in 7 CFR part 340.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. However, individuals might choose on their own to isolate geographically their non-GE cotton productions systems from GHB811 cotton or to use isolation distances and other management practices to minimize gene movement between fields. Information to assist growers in making informed management decisions for GHB811 cotton is available from the Association of Official Seed Certifying Agencies (AOSCA 2012).

2.3.4 Requirement of Testing for GHB811 Cotton

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing to identify GE products 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 requirement is inconsistent with the plant pest provisions of the PPA, and the regulations at 7 CFR part 340. Therefore, imposing such a requirement for GHB811 cotton would not meet APHIS' purpose and need to respond appropriately to the petition.

2.4 Comparison of Alternatives

Table 2-1 presents a summary of the potential environmental impacts associated with selection of the alternatives evaluated in this EA. The potential environmental consequences are presented in Chapters 4 and 5 of this EA.

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives

Attribute/Measure	**Alternative 1: No Action – Deny the Petition**	**Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton**
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).
Agricultural Production		
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	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

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Deny the Petition**	**Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton**
	herbicides and may abandon conservation tillage practices and return to more aggressive conventional tillage systems to manage weeds and protect yields.	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 have no effect on the planting of existing varieties of GE canola.	Approval of the petition would provide (subject to FDA consultation and EPA requirements) for cultivation 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.
Physical Environment		
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

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Deny the Petition**	**Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton**
		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).
Air Quality	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. 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. Increased use of herbicides may occur to manage HR weeds. For certain herbicides, this could increase volatilization and drift that could impact air quality.	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.
Biological Resources		
Animal Communities	Commercial cotton fields provide limited food and habitat for wildlife. The EPA regulates pesticides and determines whether they pose	Potential impacts on animals would be the same as that under the No Action Alternative. Isoxaflutole and its degradants are considered

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives

Attribute/Measure	Alternative 1: No Action – Deny the Petition	Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton
	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.	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 only slightly toxic to fish and aquatic invertebrates, birds, and mammals, and practically non-toxic to terrestrial invertebrates. The *2mepsps* and *hppdPfW336-1Pa* transgenes and their gene products present negligible risk wildlife.
Plant Communities	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.	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.

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Deny the Petition**	**Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton**
Soil Microorganisms	Potential impacts on soil biota would be unaffected by denial of the petition.	Commercial production of GHB811 cotton and hybrid crops are not expected to present any impact to soil biota.
Biodiversity	Under the No Action Alternative, GHB811 cotton 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.	Commercial production of GHB811 cotton would affect 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 *G. barbadense* 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	As a stacked trait variety with resistance to multiple herbicide MOAs, GHB811 cotton may provide for effective weed control and management of evolved

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Deny the Petition**	**Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton**
	weed populations will continue.	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 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.
	Human and Animal Health	
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

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Deny the Petition**	**Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton**
		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, will not be available as an animal feed, and current cotton-based feed for livestock will remain unchanged.	A determination of nonregulated status for GHB811 cotton would have no impact on animal health and welfare. Bayer is consulting with the FDA on safety of feed derived from GHB811 cotton.
	Socioeconomics	
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

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives

Attribute/Measure	Alternative 1: No Action – Deny the Petition	Alternative 2: Preferred Alternative-Determination of Nonregulated Status for GHB811 Cotton
		competitiveness of U.S. producers in global markets.
Coordinated Framework		
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.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Compliant	Compliant

3 AFFECTED ENVIRONMENT

This chapter provides an overview of the use and biology of cotton followed by a discussion of the current condition of the human environment that may be affected by a determination of nonregulated status of GHB811 cotton. For the purposes of this EA, those aspects of the human environment are: agricultural production of cotton; the physical environment; animal and plant communities; human health; animal feed; and socioeconomic issues.

Cotton (*Gossypium* spp.) is the world's most widely grown textile fiber crop, accounting for over 40% of fiber production in the world (Meyer et al. 2007), with forecasts that the United States will account for 14% of global cotton harvested area in 2017/2018 (USDA-ERS 2017d). The major cotton by-products include an edible oil refined from seeds (see also *Section 3.5.1 Food Safety*), as well as the use of chaff (hulls and linters), high-protein cake, and flour as livestock feed (OECD 2008).

3.1 Areas and Acreage of Cotton Production

3.1.1 Conventional Cotton Production Areas and Acreage

Cotton (*Gossypium* spp.) is a warm season perennial that is grown mostly as an annual because it cannot withstand frost. Commercial production of cotton requires a long frost-free period, full sun (minimum 6 hours of direct sunlight) and warm temperatures, and moderate rainfall or irrigation, usually from 24 to 47 inches (60 to 120 centimeters) per growing season. It is geographically more limited than other major crops, such as corn and soybeans, in the United States because its growth requires a minimum of 180 frost-free days per year (Smith and Cothren 1999).

In 2017, cotton was planted on approximately 12.6 million acres in the United States (USDA-ERS 2017d). Cotton is planted in 17 states across the southern United States, referred to generally as "The Cotton Belt." 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). The five major cotton-producing states by rounded planted acreages from 2017 are: Texas (6.9 million acres), Georgia (1.3 million acres), Mississippi (0.63 million acres), Arkansas (0.45 million) and Alabama (0.44 million acres) (Table 3-1) (USDA-ERS 2017d; USDA-NASS 2018b). Variations observed in cotton planted acreage are driven by current market conditions, rather than agronomic considerations.

Table 3-1. Cotton Area Planted and Harvested: 2013 - 2017

Type of Cotton and States where Grown	Acreage Planted (1,000 acres)					Acreage Harvested (1,000 Acres)				
	2013	2014	2015	2016	2017	2013	2014	2015	2016	2017
Upland Cotton										
Alabama	365	350	315	345	435	359	348	307	343	428
Florida	131	107	85	102	100	127	105	83	100	98
Georgia	1370	1380	1,130	1,180	1,290	1,340	1,370	1,120	1,170	1,280

North Carolina	465	465	385	280	375	460	460	355	260	365
South Carolina	258	280	235	190	250	250	278	124	184	245
Virginia	78	87	85	73	84	77	86	84	72	83
Southeast	*2,667*	*2,669*	*2,235*	*2,170*	*2,534*	*2,613*	*2,647*	*2,073*	*2,129*	*2,499*
Arkansas	310	335	210	380	455	305	330	205	375	438
Louisiana	130	170	115	140	220	128	168	112	137	215
Mississippi	290	425	320	435	630	287	420	315	430	625
Missouri	255	250	185	280	305	246	245	175	266	297
Tennessee	250	275	155	255	345	233	270	140	250	340
Delta	*1,235*	*1,455*	*985*	*1,490*	*1,955*	*1,199*	*1,433*	*947*	*1,458*	*1,915*
Kansas	27	31	16	31	93	26	29	16	31	91
Oklahoma	185	240	215	305	580	125	210	205	290	555
Texas	5800	6200	4,800	5,650	6,900	3,100	4,600	4500	4500	5,900
Southwest	*6,012*	*6,471*	*5,031*	*5,986*	*7,573*	*3,251*	*4,839*	*4,721*	*4,821*	*6,546*
Arizona	160	150	89	120	160	159	149	88	118	158
California	93	57	47	66	91	92	56	46	65	90
New Mexico	39	43	35	47	69	31	33	31	41	55
West	*292*	*250*	*171*	*233*	*320*	*282*	*238*	*165*	*224*	*303*
Total Upland	**10,206**	**10,845**	**8,422**	**9,879**	**12,382**	**7,345**	**9,157**	**7,906**	**8,632**	**11,263**
Pima Cotton										
Arizona	1.5	15	17	14	15	1.5	14.5	17	13	15
California	187	155	117	155	210	186	154	116	154	208
New Mexico	3.5	5.4	7	8	8	3.4	5.3	6.9	7.7	7
Texas	9	17	17	17	14	8.5	16	15	15	13
Total Pima	**201**	**192.4**	**158**	**194**	**247**	**199.4**	**189.8**	**154.9**	**189.7**	**243**
Total all Cotton	**10,407**	**11,037**	**8,580**	**10,073**	**12,629**	**7,544**	**9,347**	**8,061**	**8,822**	**11,506**

Source: (USDA-ERS 2017d; USDA-NASS 2018b)

The most commonly cultivated species of cotton in the United States is upland cotton (*G. hirsutum*), comprising about 98% of the cotton crop planted (USDA-NASS 2015). Upland cotton is also known as short staple cotton, based on the relative length of the cotton fibers (Rude 1984). All 17 cotton-producing states grow upland cotton (USDA-NASS 2015). The remainder of cotton planted is Pima (also known as extra-long staple, ELS, or Egyptian) cotton (*G. barbadense*), which is commercially cultivated in Arizona, California, New Mexico, and Texas (USDA-NASS 2015). Figure 3-1 shows the contiguous U.S. locations of upland cotton planted acres in 2016, while Figure 3-2 shows the location of planted Pima cotton acres in the contiguous United States in 2016. Figure 3-3 shows the number of acres of cotton planted and harvested in the United States from 1998 to 2018.

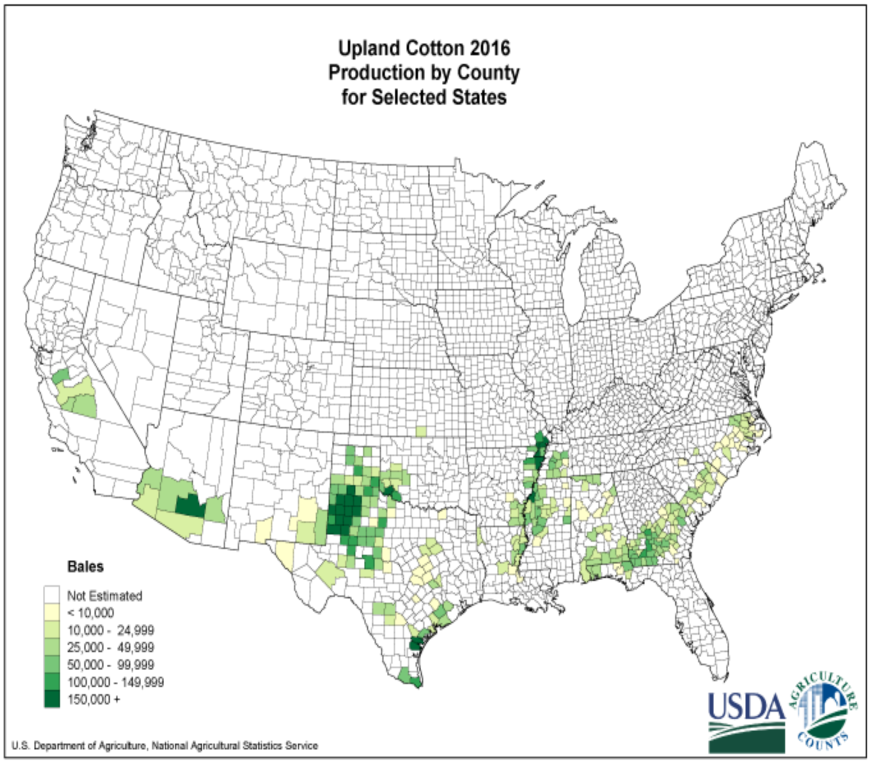

Figure 3-1. Upland Cotton Planted Acres in the United States in 2016
Source: (USDA-NASS 2016a)

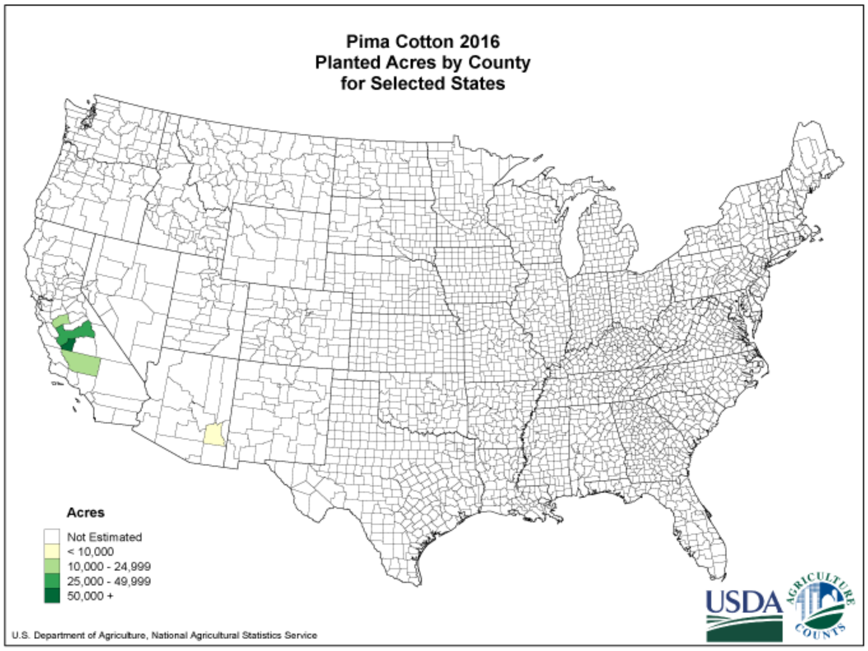

Figure 3-2. Pima Cotton Planted Acres in the contiguous United States in 2016
Source: (USDA-NASS 2016b)

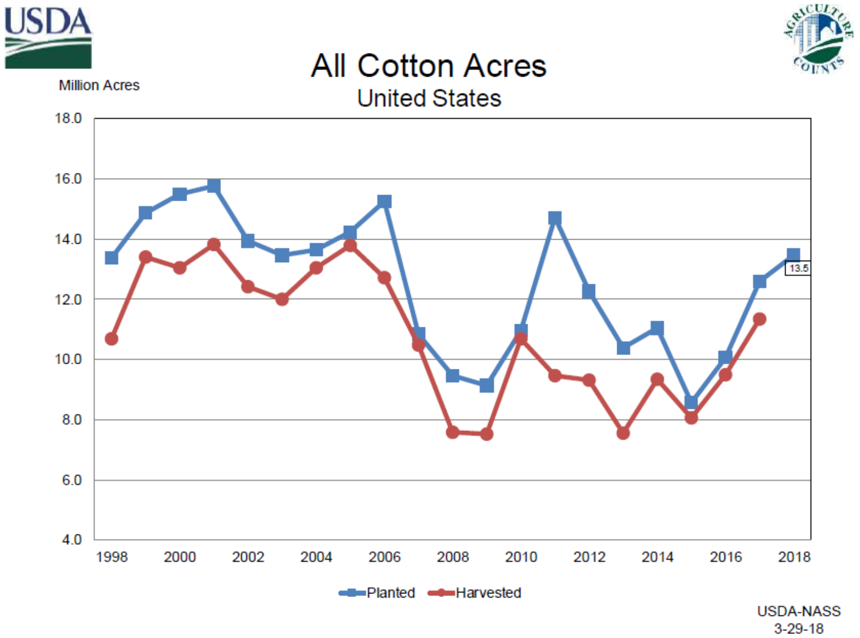

Figure 3-3. Acres of Cotton Planted and Harvested from 1997 to 2017
Source: (USDA-NASS 2018a)

3.1.2 GE Varieties of Cotton

GE varieties of cotton, containing either herbicide resistance (HR), insect resistance (IR), or both traits, comprised 96% of all cotton planted in 2017 (USDA-ERS 2017c). Single trait GE HR cotton comprised 11% of upland cotton acreage in 2017. GE IR cotton (sometimes referred to as Bt[11] cotton) comprised about 5%. Cotton varieties stacked with both kinds of traits has increased in recent years and is the most common variety of upland cotton planted. GE cotton stacked with HR and/or IR traits comprised 80% of cotton acreage in 2017 (USDA-ERS 2017c, a).

Table 3-2. Upland GE Cotton Varieties Containing Insect Resistance and/or Herbicide Resistance Traits as a Percent of Total Upland Cotton Planted in the United States in 2016 and 2017

State	Insect Resistance		Herbicide Resistance	
	2016	2017	2016	2017
	Percent of total area		Percent of total area	
Alabama	6	2	2	3
Arkansas	7	7	8	13
California	3	2	37	27
Georgia	1	4	5	4
Louisiana	10	4	2	5
Mississippi	3	8	2	3
Missouri	12	5	34	36
North Carolina	2	3	1	4

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[11] Insect resistant crops (Bt crops) contain a gene from a soil bacterium, *Bacillus thuringiensis* (Bt), which produces a protein that is toxic to specific lepidopteran insects.

Tennessee	1	2	3	3
Texas	4	5	11	13
Other States [1]	3	3	9	12
United States	**4**	**5**	**9**	**11**
	Stacked Trait Varieties		All GE[2] Varieties	
	2016	2017	2016	2017
	Percent of total area		Percent of total area	
Alabama	90	93	98	98
Arkansas	84	79	99	99
California	38	43	78	72
Georgia	93	91	99	99
Louisiana	86	90	98	99
Mississippi	94	88	99	99
Missouri	48	58	94	99
North Carolina	93	89	96	96
Tennessee	94	94	98	99
Texas	75	76	90	94
Other States [1]	85	82	97	97
United States	**80**	**80**	**93**	**96**

Source: (USDA-ERS 2017a)

[1] Other States includes all other States in the upland cotton estimating program

[2] Genetically engineered varieties may be the result of conventional breeding using genetically engineered parent plants.

Table 3-3 lists GE cotton varieties that were previously regulated by APHIS. APHIS determined upon petition review, and by the conduct of a plant pest risk assessment, that these varieties were not subject to 7 CFR part 340.

Table 3-3. Varieties of Nonregulated Genetically Engineered Cotton

Petition	**Applicant**	**Phenotype/Event**	**Event**	**Effective Date**
13-262-01p	Dow AgroSciences	2,4-D and Glufosinate-Tolerant	DAS-81910-7	7/23/2015
12-185-01p	Monsanto	Dicamba and Glufosinate Tolerant	MON-88701-3	1/20/2015
12-033-01p*	Bayer	Glufosinate Tolerant, Lepidopteran Resistant	T303-3	8/17/2012
08-340-01p	Bayer	Glufosinate Tolerant, Lepidopteran Resistant	T304-40 x GHB119	10/12/2011
07-108-01p	Syngenta	Lepidopteran Resistant	COT67B	9/29/2011
06-332-01p	Bayer CropScience	Glyphosate Tolerant	GHB614	5/22/2009
04-086-01p	Monsanto	Glyphosate Tolerant	MON 88913	12/20/2004
03-155-01p	Syngenta	Lepidopteran Resistant	COT102	7/6/2005
03-036-02p	Dow AgroSciences	Lepidopteran Resistant	3006-210-23	7/15/2004
02-042-01p	Aventis	Phosphinothericin Tolerant	LLCotton25	3/10/2003
00-342-01p	Monsanto	Lepidopteran Resistant	15985	11/5/2002
97-013-01p	Calgene	Bromoxynil Tolerant, Lepidopteran Resistant	31807, 31808	4/30/1997
95-256-01p	Du Pont	Sulfonylurea Tolerant	19-51A	1/25/1996
95-045-01p	Monsanto	Glyphosate Tolerant	1445, 1698	7/11/1995
94-308-01p	Monsanto	Lepidopteran Resistant	531, 757, 1076	6/22/1995
93-196-01p	Calgene	Bromoxynil Tolerant	BXN	2/15/1994

*(Extension of 08-340-01p)

3.2 Agronomic Practices in Cotton Production

Cotton production involves the use of standard agronomic practices and inputs such as crop rotation, crop monitoring, tillage, in some cases irrigation, fertilizers, pesticides, and seeding and harvesting. Standard practices and inputs, some of which can present environmental and human health risks, are summarized below.

3.2.1 Tillage

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

Conventional tillage is associated with intensive plowing and leaving less than 15% crop residue in the field (Stichler et al. 2006). In contrast, reduced tillage is associated with 15% to 30% crop residue. Conservation tillage relies on methods that result in less soil disruption and leaves at least 30% of crop residue on the surface. Conservation and reduced tillage practices include mulch-till, eco-fallow, strip-till, ridge-till, zero-till, and no-till (Stichler et al. 2006). No-till farming only disturbs the soil between crops. The new crop is planted into residue or in narrow strips of tilled soil, which results in less soil disruption. Under no-till practices, there is no turning of the soil to break up compacted areas. The advantages of conservation tillage over conventional tillage include: reducing cultivation cost; allowing crop residues to act as an insulator and reducing soil temperature fluctuation; building up soil organic matter; and conserving soil moisture by reducing evaporation and runoff (Papendick and Moldenhauer 1995; USDA-NRCS 2006a).

Conservation tillage can enhance soil quality, preserve soil moisture, and have other environmental benefits, but it also presents potential challenges for disease and pest management (Rude 1984; Papendick and Moldenhauer 1995). Reduced tillage in cotton, may enhance conditions for the development of economically significant pest and disease populations that can be efficiently managed with conventional tillage practices (NRC 2010). Despite soil property benefits, the recent trend toward low-till or no-till cotton has resulted in an increase in the frequency and severity of seedling diseases. Pathogens from a previous crop can overwinter in crop debris, which is preserved by reduced tillage practices. Emerging seedlings in subsequent crops can become infected (Thiessen 2018). Reduced till practices can also facilitate crop pests. For example, cotton aphids survive on crop residues and reach peak population densities more rapidly than in conventionally tilled fields where little crop residue remains (Leonard 2007). Effective pink bollworm and nematode control in cotton requires tillage operations to reduce soil-borne populations of these pests. A series of diskings provides a host-free period that is usually needed to reduce pest populations where pink bollworm is a problem (Mitchell et al. 2012; Kirkpatrick and Thomas).

Cotton fields are typically tilled just prior to planting (Albers and Reinbott 1994). Pre-plant tillage activities in cotton may include smoothing the soil or creating raised ridges for permanent or semi-permanent beds (Albers and Reinbott 1994). In conventional cotton cultivation, after the prior crop is harvested, the surface material is shredded and roots are undercut and mixed with the soil (Albers and Reinbott 1994; Mitchell et al. 2012). There may be more than five field operations prior to seeding the cotton crop (plow under weeds, incorporate herbicides, break-up soil clods, shape the uniform planting beds, prepare for furrow irrigation or dry mulch) (Albers and Reinbott 1994; Mitchell et al. 2012).

In general, GE HR cropping systems are associated with conservation tillage (NRC 2010). While a clear cause and effect relationship between GE HR cropping systems and conservation tillage has not been established, both GE HR crops and the percentage of cropping area farmed with no-till and reduced-till practices have increased over the last two decades (NAS 2016). In 2010-2011, no-till and strip-till accounted for 33% of cotton acres. No-till/strip-till adoption in 2010-11 was 11.9% higher than 2007 cotton (Wade et al. 2015). Strip-till systems are widely used in the coastal plains region of the southeastern United States for crops such as cotton as a means to break up the naturally settling and consolidating subsoil layers that are routinely formed in this region. The objective of strip-till is to loosen compacted subsoil zones for seeding while leaving the majority of the soil surface and crop residues relatively undisturbed (AgPro 2014).

While conservation tillage has increased and has been widely practiced in U.S. cotton crop production over the last 2 decades, the development of HR weed populations has resulted in growers in some areas including (or intensifying) tillage in recent years to control weeds. In some instances, tillage is one of the few effective means available to manage particular HR weeds. For example, Palmer amaranth (*Amaranthus palmeri)* has become a particular problem in southeastern U.S. cotton production because of evolved resistance to the herbicide active ingredient glyphosate and conventional inversion tillage is one of the few effective tools available for its management (CAST 2012). In brief, the development and management of HR weeds has emerged as a determining factor in the type of tillage cotton crop producers, both GE and non-GE, will use. In the southern states conventional tillage is becoming a more common practice in cotton due to the evolution of glyphosate resistant weeds (CAST 2012).

3.2.2 Crop Rotation

Crop rotation is the successive planting of different crops in the same field over a specific number of years. The goals of crop rotation include maximizing economic returns and sustaining the productivity of the agricultural system (UC-IPM 2013; Cotton-Incorporated 2018). Crop rotation achieves these goals by reducing disease inoculum, pest incidence, weeds, and selection pressure for weed resistance to herbicides (Cotton-Incorporated 2018).

Many factors at the individual farm level affect the crop rotation system chosen, including: the soil type present in an individual field; extant pest, disease, and weed pressures; the expected commodity price; the need to hire labor; the price of fuel; and the price of agricultural inputs (UGA 2016; Bullen 2018). In addition, production costs, relative rate of return, and the current market conditions dictate which crops growers rotate with cotton or whether to grow cotton continuously. Capital invested in local infrastructure and regulations related to participation in the U.S. government cotton commodity support program also influence the decision to plant cotton continuously rather than rotate in other crops (Pettigrew et al. 2006). Ideally, cotton should be rotated with other crops on a regular basis in order to maintain soil productivity and reduce the incidence of various weeds, insect pests or diseases (Hake et al. 1991).

Figure 3-4 shows the crop rotation patterns of cotton in the United States from 1997 through 2007. According to the USDA Agricultural Resource Management Survey (ARMS) data, continuous (non-rotated) cotton acreage (appearing as “Cotton-Cotton” in the figure) has remained steady, between 60% and 70%, during this time period (Osteen et al. 2012). Other crops used in rotation with cotton vary regionally and include corn, soybeans, sorghum, peanuts, and wheat (Pettigrew et al. 2006). Rotating cotton with monocot crops, such as corn, can help to reduce the soil inoculum level of the seedling disease fungi *Pythium* and *Rhizoctonia*. These seedling diseases can increase in continuous cotton cropping systems (Smith and Cothren 1999). Crop rotation may also include fallow periods, or sowing with cover crops to prevent soil erosion and to provide livestock forage between cash crops (Hake et al. 1991; Sulc and Franzluebbers 2014).

Effective nematode and disease suppression through crop rotation is a long-term management strategy that depends on the host range of the pathogen, the type of rotational crop used, and the length of the rotation. The goal of the rotation is to reduce pathogen populations substantially by not planting crops that are susceptible. For example, rotation to a monocot crop can suppress seedling diseases in subsequently planted cotton, but rotation to a legume cover crop is not likely to reduce cotton seedling disease (Hake et al. 1991).

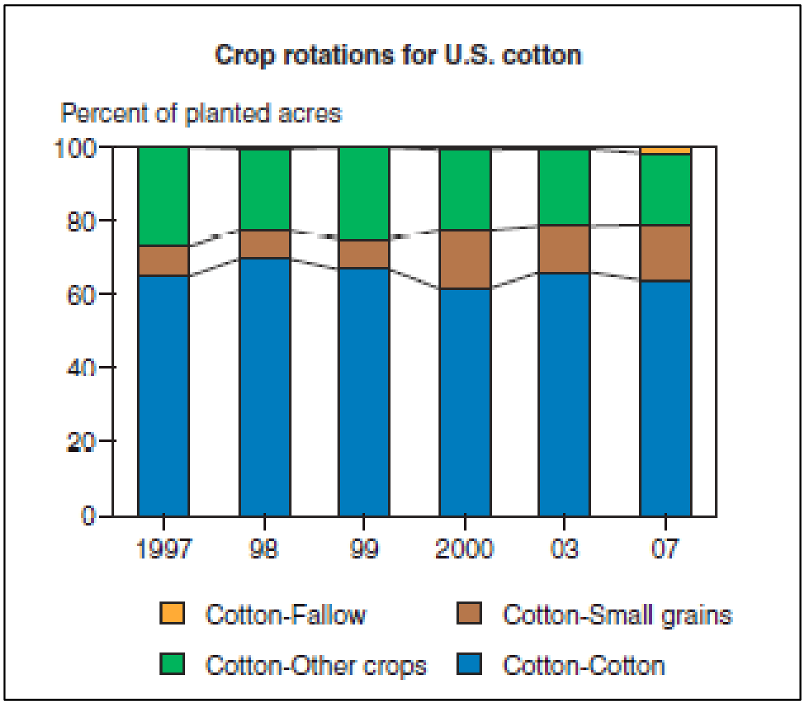

Figure 3-4. Cropping Patterns for Cotton in the United States, 1976-2007
Source: (Osteen et al. 2012)

Winter cover crops are also utilized in cotton production. Cover crop rotations typically consist of planting a winter cereal or legume in the fall followed by cotton in the spring. These cover crops are used to provide winter soil cover and protection, build soil nitrogen and organic matter, reduce nitrogen leaching, suppress weeds, and provide a habitat for beneficial predatory and parasitic insects and spiders. These rotations create an economical control strategy for soil-borne diseases, nematodes, and resistant weeds. Typically, cover crop rotations provide erosion control and improve soil tilth (the soil's physical condition, especially in relation to its suitability for planting or growing a crop).

Growers may benefit from rotating cotton with other crops to decrease disease inoculum and nematode populations in the soil; however, crop rotation tends not to supply nutritional needs for cotton (Hake et al. 1991). Diversification increases economic stability when profitable crops are rotated with cotton, but rotation out of monoculture may not be needed if pests can be otherwise managed (Hake et al. 1991).

3.2.3 Nutrient and Fertilizer Use

Cotton has lower nutritional needs than other major crops. Consequently, when cotton is grown in rotations, it is the nutritional needs of the other crops that determine the amounts of phosphorus (P), potassium (K) and micronutrients that must be added to the soil (Hake et al. 1991). Nevertheless, the nutrients needed in the largest amounts are N, P, K, calcium, magnesium, and sulfur (Rude 1984). Other essential nutrients needed in very small amounts are iron, boron, manganese, zinc, molybdenum, copper, and chlorine (Rude 1984). Commercially available fertilizers usually contain a mixture of the macronutrients nitrogen (N), phosphorus (P), and potassium (K), which are essential for plant growth (Vitosh 1996). To fill specific crop needs in soils that are deficient, various concentrations of micronutrients may be included in fertilizer formulations (Jones and Jacobsen 2003). Fertility needs can also be met by applying organic matter which may alter the soil's naturally occurring level of nutrients that are available for plant growth (Jones and Jacobsen 2003).

Maintaining optimum crop nutrition is critical in achieving high yields and quality in cotton. Pre-season soil test results for N, P, and K plus determination of pH, together with previous cropping and fertilization history determine the fertilizer and liming needs for the upcoming cotton crop. Pre-plant soil analysis and leaf petiole analysis during the season can be very useful in monitoring the nitrogen status of the crop. Early season applications of N at or before planting are seldom recommended unless the residual N content in the soil is very low. This is because young stands of cotton have a very low N requirement and soluble nitrates can be easily leached when irrigation water is applied during germination and early season growth. Efficient fertilizer use in cotton requires there to be no excessive N at the end of the season because N applied too late triggers the need for extra applications of defoliants (UC-IPM 2013). About half of the N applied in a chemical form is not taken up by plants but is lost to the atmosphere and to surface and below-ground water (Ellington et al. 2007).

3.2.4 Pest Management

Cotton is susceptible to injury at nearly every stage of growth, and consequently, cotton fields must be monitored regularly. In all cotton production regions in the United States, insect and mite pests are a common and continuous threat, which can result in decreased yield and reduced quality. The most damaging insect pests of cotton attack the cotton square (the flower bud) or the cotton boll (the ovary containing developing seeds and fibers) (Gianesi and Carpenter 1999). Because of its perennial nature, remaining cotton stalks can regrow following harvest, allowing the development from early buds to squares and bolls where boll weevils can feed and reproduce (Lemon et al. 2003).

In 2016, the total costs and losses in cotton production due to insects amounted to $569.5 million, with overall yields reduced by 2.60%. The top ranked pests in terms of yield loss in 2016 are shown in Table 3-4. The highest yield losses (0.734%) were associated with lygaeid bugs, followed by stink bugs (0.640%) and thrips (0.423 %). Bollworm/budworm complex ranked fourth at 0.413%, and spider mites and cotton fleahoppers caused reduced yields by 0.120% and 0.091%, respectively. No other pest exceeded 0.1% yield loss. The direct management costs for arthropods were $34.05 per acre (Williams 2016).

Table 3-4. Cotton Insect Losses, 2016				
Insect	**Acres Infested**	**Acres Treated**	**Number of Applications per Acre Treated**	**Yield loss (%)**
Lygus	4,906,100	2,374,603	3	0.734
Stink bugs	4,390,201	2,623,231	2	0.640
Thrips	9,477,763	3,340,547	1	0.423
Bollworm/budworm complex	3,709,377	1,480,156	1	0.413
Spider mites	2,066,204	687,779	1	0.120
Cotton fleahoppers	6,229,625	1,355,471	1	0.091

Source: (Williams 2016)

The quantity of insecticide applied to cotton has trended downwards since 1972, following replacement of DDT and other older insecticides with different products (requiring the use of smaller quantities), the eradication of the boll weevil, and the adoption of insect resistant (IR) cotton (Fernandez-Cornejo et al. 2014a). Farmers generally use less insecticide when they plant IR cotton compared to non-IR cotton. The amount of insecticide applied to cotton crops has continued to decline over the course of the last 15 years. In 2014, cotton growers planted IR cotton to control pests such as tobacco budworm, cotton bollworm, and pink bollworm on 84% of U.S. cotton acreage, increasing from 35% of the cotton acreage in 2000 and 52% in 2005. Planting IR cotton seed is associated with higher net returns when pest pressure is high (Fernandez-Cornejo et al. 2014b).

In 2010, approximately 55% of cotton acreage planted was treated with insecticide (USDA-NASS 2011). Approximately 40 insecticides across 16 insecticide classes are registered for use in cotton (Greene 2016). Growers typically scout for pests and apply insecticides only when economic thresholds are met. The development of evolved resistance in pest populations to various classes (differing MOA) of insecticides requires growers to make and implement management decisions to achieve effective control at various times during the production of a crop (US-EPA 2018b).

Cotton growers use a combination of agronomic practices to manage pests. This integrated pest management (IPM) approach is based on selection and implementation of a variety of cultural, biological, and chemical strategies (US-EPA 2018a). Pre-plant tillage and crop rotation are important agronomic and cultural practices used to reduce insect populations prior to planting cotton. Other agronomic practices are used to promote early maturity and reduce the period of time that the crop is susceptible to insect and mite pests, thereby increasing the probability that an acceptable yield can be produced before pest densities exceed economic threshold levels (Smith and Cothren 1999). Selection of short-season determinate varieties, adherence to optimum planting periods, and early season insect and disease management strategies can shorten the production season and limit crop exposure to late season insect pressure. In addition, implementation of conservation tillage systems usually provides timely planting and crop management, which promote an earlier-maturing crop. Biological control involves the use of predators, parasites, and pathogens (together, considered “natural enemies”) of pests of cotton and constitutes a major component of integrated pest management programs in cotton production (Smith and Cothren 1999).

The IPM approach can be used both to control pest populations and to eradicate localized populations of pests. IPM has been used successfully in the eradication program for the pink bollworm, a pest in California, Arizona, New Mexico, and Texas, and adjacent areas of northern Mexico. Pink bollworm has increased costs to cotton producers for prevention, control, and produced yield losses. A three-phase eradication program began in 2002 with four primary components: 1) extensive survey; 2) GE IR cotton; 3) pheromone application for mating disruption; and, 4) sterile pink bollworm moth releases (NCCA 2015).

In the late 1970s, APHIS launched the National Boll Weevil Eradication Program along the Virginia-North Carolina border and, over time, all states where cotton is grown have been involved in the program. The boll weevil is eradicated from all cotton-producing states except Texas, where it persists in the Lower Rio Grande Valley. APHIS anticipates that this region will remain susceptible to infestation because of its proximity to boll weevil-infested cotton producing areas in Mexico (USDA-APHIS 2014). The eradication program uses IPM and involves the selection of a particular control method or combination of methods for an individual site, based on factors including variations in boll weevil biology, availability of overwintering sites, environmental concerns, weather patterns, and crop production requirements (USDA-APHIS 1999). The program uses three main techniques to eradicate the boll weevil: pheromone traps to detect the weevil’s presence, cultural practices (i.e., habitat modification) to decrease its food supply, and chemical treatments (primarily insecticides containing malathion) to reduce weevil populations. Through cultural control methods, growers can make conditions less favorable for pest reproduction and survival, using techniques such as growing short-season cotton varieties and requiring mandatory stalk destruction (TDA 2018). Growers kill cotton stalks by applying herbicides, such as 2,4-D, after shredding (Lemon et al. 2003).

3.2.5 Weed Management and Herbicide Resistance in Weeds

Weed Management in Cotton

Weed control in cotton is essential for efficient crop production. In cotton, weeds cause several direct and/or indirect negative impacts, such as (a) reducing fiber quality, (b) reducing crop yield, (c) increasing production costs, (d) reducing irrigation efficiency, and (e) serving as hosts and habitats for insect pests, disease-causing pathogens, nematodes, and rodents (Ashigh et al. 2012). The slow, early growth of cotton does not permit crop plants to aggressively compete against weeds that often grow more rapidly and use the available water, nutrients, light, and other resources for growth (UGA 2016). Across the Cotton Belt, many annual and perennial weeds occur, resulting in yield loss, poorer fiber quality, and losses in economic returns (Ashigh et al. 2012).

Weeds allowed to compete with crops can ultimately result in crop yield loss. Once a critical period of weed control has been reached (i.e., the point where weed populations impact crop plant growth), and if weed control is delayed or ineffective, the magnitude of yield loss can increase rapidly. Barnyardgrass, crabgrass, pigweed species (including Palmer amaranth), morning glory species, common cocklebur, and lambs quarters are common annual weeds in almost all cotton-growing regions. Johnson grass, bermudagrass, and nutsedge are common perennial weeds. Nightshade species, such as groundcherry, are more common in the Southwest and West regions. Palmer amaranth, morning glory and nutsedges have been frequently reported as “hard-to-control weeds” in cotton (Webster et al. 2009; WSSA 2018b). For scientific names of these weeds please see the WSSA Composite List of Weeds.[12] Table 3-5 summarizes the most common weeds for each of the four major cotton-growing regions (Southeast, Midsouth, Southwest, and West).

Table 3-5. Common Weeds in Cotton Production

Number of States by Region Reporting Each Weed as One of the Ten Most Common Weeds*		
Southeast Region (AL, FL, GA, NC, SC, and VA)		
crabgrass spp** (6)	pigweed spp (3)	crowfootgrass (1)
morningglory spp (6)	common cocklebur (2)	horseweed (marestail) (1)
prickly sida (5)	common lambsquarters (2)	jimsonweed (1)
Florida pusley (4)	common ragweed (2)	johnsongrass (1)
nutsedge spp. (4)	Florida beggarweed (2)	smartweed spp. (1)
sicklepod (4)	palmer amaranth (2)	spurge spp (1)
broadleaf signalgrass (3)	Texas millet (2)	volunteer peanut (1)
goosegrass (3)	bermudagrass (1)	
Midsouth Region (AR, LA, MS, MO, and TN)		
morningglory spp (5)	velvetleaf (3)	common cockleburr (1)
broadleaf signalgrass (4)	barnyardgrass (2)	cutleaf evening-primrose (1)
crabgrass spp (4)	horseweed (marestail) (2)	goosegrass (1)
nutsedge spp (4)	johnsongrass (2)	hemp sesbania (1)
prickly sida (4)	palmer amaranth (2)	henbit (1)
spurge spp (4)	bermudagrass (1)	spurred anoda (1)
pigweed spp (3)	browntop millet (1)	
Southwest Region (KS, OK, TX, and NM)		
johnsongrass (4)	pigweed spp (2)	smartweed (1)
nutsedge spp (4)	Russian thistle (2)	smellmelon (1)
common cockleburr (3)	barnyardgrass (1)	spurred anoda (1)
Palmer amaranth (3)	bermudagrass (1)	red sprangletop (1)
silverleaf nightshade (3)	bindweed, field (1)	sunflower (1)
common lambsquarters (2)	foxtail spp (1)	Texas blueweed (1)
large crabgrass (2)	groundcherry spp (1)	Texas millet (2)
devil’s claw (2)	kochia (1)	velvetleaf (1)
morningglory spp (2)	horseweed (marestail) (1)	woolyleaf bursage (1)

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[12] http://wssa.net/wssa/weed/composite-list-of-weeds

Table 3-5. Common Weeds in Cotton Production

mustard spp (2)	shephards purse (1)	
West Region (AZ and CA)		
barnyardgrass (2)	common lambsquarters (1)	silverleaf nightshade (1)
morningglory spp (2)	johnsongrass (1)	Palmer amaranth (1)
sprangletop (2)	junglerice (1)	common purslane (1)
bermudagrass (1)	nutsedge spp (1)	horse purslane (1)
field bindweed (1)	pigweed spp (1)	volunteer corn (1)
cupgrass, southwestern (1)	black nightshade (1)	
groundcherry spp (1)	hairy nightshade (1)	

Source: (Monsanto 2013)

* Numbers provided in parenthesis are the number of states in the region reporting the weed as one of the ten most common.

** “spp” refers to multiple species

Weed control requirements vary in the extent and variety of weeds, geography, and soil characteristics. Growers manage weeds with various weed control strategies including tillage, such as plowing and between-row harrowing or cultivating, applying herbicides, the use of cover crops, and hand-weeding. Herbicides can be applied in several ways and at different times, but they may only be applied in a way that is specifically allowed by their label instructions. For cotton, weed control during the first four to eight weeks after planting is critical to prevent weeds from competing for water, light, nutrients and other resources, which otherwise would suppress yields (Smith and Cothren 1999; Ashigh et al. 2012). Herbicide applications may occur before planting the crop, referred to as pre-plant incorporated, after the crop is planted but before the weeds and crop have emerged from the soil, referred to as pre-emergence, or after the weeds and crops have emerged from the soil, referred to as post-emergence.

The planting of winter cover crops such as winter wheat and rye can also be used as an effective component of a diversified weed management strategy or integrated weed management (IWM) program. As discussed in *Section 3.2.2 – Crop Rotation*, cover crops, such as forage grasses, legumes, or small grains can protect and improve soil quality, reduce erosion, serve as surface mulch and may be used in no-till cropping practices. Cover crops can also provide habitat for beneficial insects (Guerena and Sullivan 2003). Small grain crops such as rye are commonly used as a cover crop; incorporating rye or oats as a cover crop have been shown to suppress the germination and growth of Palmer amaranth, a weed in cotton fields (Price et al. 2011). However, the planting of cover crops in general incurs additional costs to the grower that may not be offset by benefits. Cover crops are not typically a frequently used weed management practice in cotton production systems.

GE HR cotton varieties have become widely adopted since their introduction in the mid-late 1990s because of their usefulness in weed management strategies. GE varieties of cotton, containing either herbicide resistance (HR), insect resistance (IR), or both traits, comprised 96% of all cotton planted in 2017 (USDA-ERS 2017b, a). Current GE HR varieties include those resistant to herbicides that contain: both 2,4-D and glufosinate, both dicamba and glufosinate,

glufosinate, glyphosate, bromoxynil, and sulfonylurea type herbicides, the latter two are less commonly used.

Among herbicides used in recent years, two different formulations of the herbicide active ingredient glyphosate, the potassium and isopropylamine salts, were the most widely applied active ingredients at 47% and 37% of planted acres, respectively, followed by trifluralin at 32%, and diuron at 23% (USDA-NASS 2017a). Table 3-6 lists the most widely used herbicides in U.S. cotton production in 2015.

Table 3-6. Most Widely Used Herbicides in U.S. Cotton Production – 2015

Herbicide active ingredient	Total pounds active ingredient per year	Pounds active ingredient per year	No. of applications	Treated: % of area planted
GLYPHOSATE POTASSIUM SALT	9,138,000	2.41	2.1	47
GLYPHOSATE ISOPROPYLAMINE SALT	4,935,000	1.63	1.9	37
TRIFLURALIN	2,551,000	0.97	1	32
ACETOCHLOR	1,886,000	1.64	1.2	14
S-METOLACHLOR	1,170,000	1.24	1.2	12
DIURON (DCMU)	1,095,000	0.57	1.1	23
PENDIMETHALIN	894,000	0.87	1.1	13
GLUFOSINATE-AMMONIUM	847,000	0.79	1.5	13
2,4-D, DIMETHYLAMINE SALT	419,000	0.73	1.1	7
PROMETRYN	390,000	0.8	1.1	6
MSMA	381,000	1.81	1	3
FLUOMETURON	347,000	1.03	1.1	4
GLYPHOSATE	313,000	1.05	1.5	4
FOMESAFEN SODIUM	311,000	0.24	1	16
2,4-D, 2-EHE	264,000	1.2	1.4	3
METOLACHLOR	124,000	1.11	1.5	1
DICAMBA, DIMETHYLAMINE SALT	73,000	0.27	1	3
FLUMIOXAZIN	64,000	0.07	1.1	11
PYRITHIOBAC-SODIUM	47,000	0.08	1	7
DICAMBA, DIGLYCOLAMINE SALT	39,000	0.31	1	2
LINURON	26,000	0.43	1.1	1
DICAMBA, SODIUM SALT	18,000	0.43	1.5	1
CARFENTRAZONE-ETHYL	11,000	0.02	1.2	7
CLETHODIM	10,000	0.16	1	1
OXYFLUORFEN	5,000	0.42	1.4	(Z)
THIFENSULFURON	2,000	0.01	1	2
PYRAFLUFEN-ETHYL	1,000	0	1	6
RIMSULFURON	1,000	0.02	1	1
SAFLUFENACIL	1,000	0.03	1	(Z)
TRIFLOXYSULFURON-SODIUM	1,000	0.01	1.1	2
CHEMICAL, HERBICIDE: (TOTAL)	26,334,000			92

Source: (USDA-NASS 2017a)

Note: "a.i." refers to active ingredient; 2-EHE refers to 2-Ethylhexyl ester.

Volunteer Cotton

In some crop rotation systems, cotton can volunteer in a subsequent crop cycle, which can be problematic for growers (Fromme et al. 2011). Volunteer plants are considered weeds because they can compete for nutrients, water, space, and light, with the intended crop for that year and result in yield loss. The primary methods for removing volunteer cotton are tillage and/or herbicides. Management of volunteers is also important for any region that has an active Boll Weevil Eradication Program, one of the goals of which is to control or destroy cotton after harvest. In order to reduce potential over-wintering and breeding habitat for weevils, growers typically remove cotton stalks after harvest by applying herbicides to halt growth and dry the plant material. They may also shred cotton stalks or plow them under. Currently, Texas is the only state with an active eradication program (USDA-APHIS 2013).

Weediness of Cotton

Upland cotton is a domesticated perennial plant grown as an annual crop; it does not generally persist in areas outside of cultivation and is not considered a significant agricultural or environmental weed (Keeler et al. 1996). In suitable areas, such as southern Florida, Hawaii, and Puerto Rico, upland cotton can become locally feral or naturalize (USDA-APHIS 2018). Upland cotton (*G. hirsutum*) is not listed as a weed in major weed references (USDA-APHIS 2018), nor is it present on the lists of noxious weed species distributed by the federal government (7 CFR part 360). Cotton does not possess any of the attributes commonly associated with weeds, such as persistence of the seeds or other propagules in the soil, or having the ability to disperse, invade, or become a dominant species in areas outside of cultivation. Commercial cultivars are not frost tolerant and do not survive freezing winter conditions.

Herbicide Resistant Weeds

The use of herbicides imparts selection pressures on plant populations that can result in survival of individual plants that may be inherently resistant to one or more active ingredients in an herbicide (Owen 2011; Vencill et al. 2012). HR weed populations naturally develop when these HR individuals survive and reproduce after repeated exposure to an herbicide, passing the inherent (non-GE) HR trait on to their progeny. Herbicides with different brand names may contain the same or very similar active ingredient or ingredients. Therefore, the use of different herbicide products may not ensure that active ingredients with differing MOA are being applied. The use of a single herbicide year after year places a repeated selection pressure on local plant populations, which may become resistant to active ingredients in the herbicide that was used. In subsequent years, herbicides that contain the active ingredient that the plants have become resistant to may become ineffective. Over-reliance on a single type of herbicide has resulted in the evolution of several HR weed biotypes (Vencill et al. 2012). In addition to the evolution of HR weed biotypes in fields, the Integrated Weed Management Resource Center reports that “Spread via field machinery is a primary way that herbicide resistant seeds are spread from field to field and across state lines” (IWMRC 2018).

The development of evolved herbicide resistance in weeds is not a recent phenomenon nor is it unique to GE crops. The evolution of weeds in U.S. agroecosystems predates herbicide resistant crops by several decades (Owen 2011). HR weed populations have been occurring since the advent and widespread use of chemical herbicides in the 1950s. Repeated use of single herbicides in cotton production over the past several decades has led to the evolution of HR weed biotypes that no longer respond to the herbicides that producers previously relied upon. This has become a primary concern for crop producers. It should be noted that weeds could also become resistant to cultural control practices, such as tillage, if they are over used.

A detailed and continuously updated list of HR weed biotypes is maintained on the International Survey of Herbicide Resistant Weeds website (Heap 2017). Forty-nine states report the presence of HR weed populations (not limited to cotton production). Currently, there are 82 reported HR weed species in the United States (Heap 2017). Because many of these HR weed are resistant to more than one herbicide MOA, there are 160 unique cases of HR weed (weed species x MOA) (Heap 2017). Weed species resistant to multiple herbicide MOAs are becoming more widespread and diverse; the growing HR weed problem requires adjustments in production practices. As of 2017, there were 52 species resistant to 2 MOAs, 18 species resistant to 3 MOAs, and 9 species to 4 MOAs, 4 species exhibiting resistance to 5 MOAs, and 1 species resistant to 7 MOAs (Heap 2017). No additional herbicide active ingredients with completely novel MOAs have been developed in recent decades.

Development of herbicide resistance has occurred most frequently with the long-used triazine type herbicides, which block photosynthesis (specifically photosystem II), such as atrazine, and herbicides that inhibit the plant enzyme acetolactate synthase (ALS) such as imazethapyr, tribenuron-methyl, imazamox, and mesosulfuron-methyl, as shown in Figure 3-5. However, resistance to other types of herbicide has also been reported.

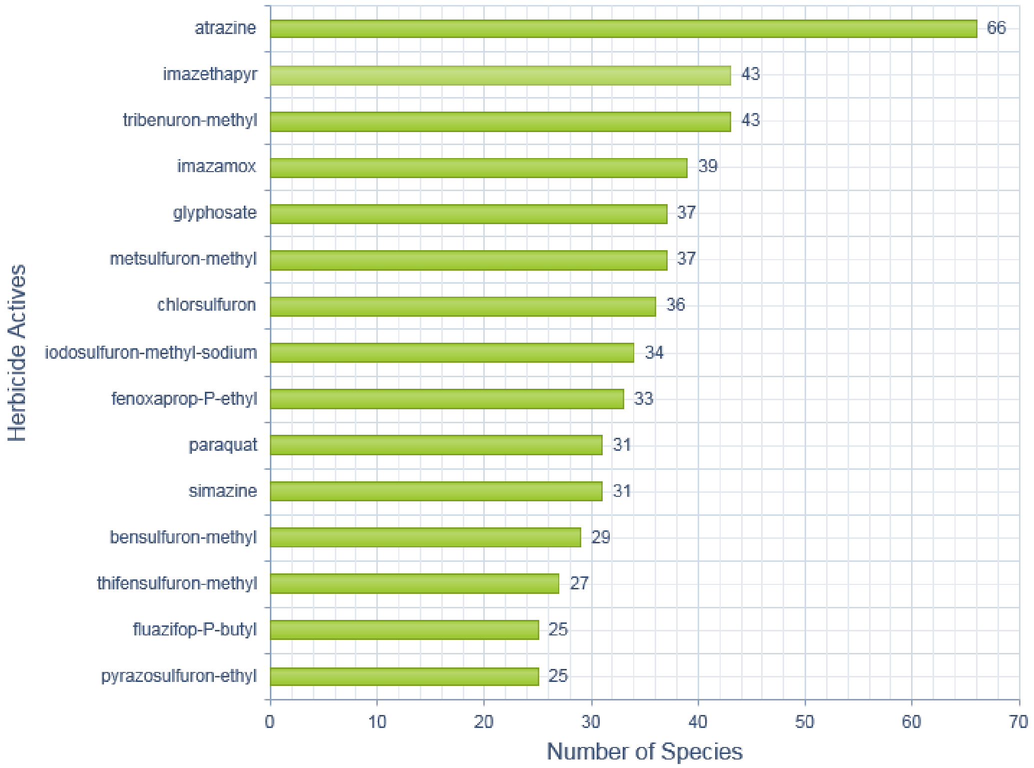

Figure 3-5. Global Top 15 Herbicide Individual Active Ingredients and the Number of Herbicide Resistant Weed Species, 2017

Source: Adapted from (Heap 2017)

Note: Data do not represent the number of distinct species resistant to a given herbicide MOA; rather, they represent the number of unique cases of “species x MOA resistance.” This includes those cases where a particular species has been reported as resistant to two or more herbicide MOAs.

In relation to HPPD inhibitors, there are 2 resistant weed species in the United States (Table 3-7), which can occur in corn, soybean, and sorghum crops: Palmer amaranth (*Amaranthus palmeri*) and tall waterhemp (*A. tuberculatus*) have developed evolved resistance to the HPPD inhibitors mesotrione, tembotrione, topramezone, and isoxaflutole. For glyphosate, which is commonly used on GE HR crops, there are currently 37 unique cases of resistant weeds (Table 3-8). Weeds exist that are resistant not only to HPPD inhibitors and glyphosate, but to other herbicide MOA as well; in some cases, a single weed population may be resistant to 3, or even 4 herbicide MOAs.

Table 3-7. Weeds Resistant to HPPD Inhibitors

Resistant Weed	**Location, Crop**	**Herbicide Active Ingredient**
1. Palmer Amaranth***,*** ***Amaranthus palmeri***	2009 - Kansas *Multiple - 3 MOA's [corn and sorghum]	atrazine, mesotrione, pyrasulfotole, tembotrione, thifensulfuron-methyl, and topramezone

Table 3-7. Weeds Resistant to HPPD Inhibitors

	2011 - Nebraska [corn]	mesotrione, tembotrione, and topramezone
	2014 - Nebraska *Multiple - 2 MOA's [corn]	atrazine, mesotrione, tembotrione, and topramezone
	2014 - Wisconsin *Multiple - 2 MOA's [corn]	imazethapyr, tembotrione, and thifensulfuron-methyl
2. Tall Waterhemp***, Amaranthus tuberculatus (=A. rudis)***	2009 - Illinois *Multiple - 3 MOA's [corn]	atrazine, chlorimuron-ethyl, imazethapyr, mesotrione, tembotrione, and topramezone
	2009 - Iowa *Multiple - 3 MOA's [corn]	atrazine, mesotrione, rimsulfuron, tembotrione, thifensulfuron-methyl, and topramezone
	2011 - Iowa *Multiple - 4 MOA's [corn and soybean]	atrazine, chlorimuron-ethyl, glyphosate, imazamethabenz-methyl, isoxaflutole, mesotrione, and thifensulfuron-methyl
	2011 - Nebraska [corn]	mesotrione, tembotrione, and topramezone
	2016 - Illinois *Multiple - 5 MOA's [corn and soybean]	2,4-D, acifluorfen-sodium, atrazine, chlorimuron-ethyl, fomesafen, imazethapyr, lactofen, mesotrione, tembotrione, and topramezone

*MOA = mode of action
Source: (Heap 2017)

Table 3-8. Weeds Resistant to EPSPS Inhibitors (glyphosate)

Amaranthus palmeri	***Amaranthus tuberculatus (=A. rudis)***
Palmer Amaranth	Tall Waterhemp
2005 - Georgia	2005 - Missouri *Multiple - 3 MOA's
2005 - North Carolina	2006 - Illinois *Multiple - 2 MOA's
2006 - Arkansas	2006 - Kansas
2006 - South Carolina	2006 - Texas
2006 - Tennessee	2007 - Minnesota
2007 - New Mexico	2007 - Minnesota *Multiple - 2 MOA's
2008 - Alabama	2008 - Ohio
2008 - Georgia *Multiple - 2 MOA's	2009 - Illinois *Multiple - 4 MOA's
2008 - Mississippi *Multiple - 2 MOA's	2009 - Indiana
2008 - Missouri	2009 - Iowa
2009 - Tennessee *Multiple - 2 MOA's	2009 - Missouri *Multiple - 2 MOA's
2010 - Georgia *Multiple - 3 MOA's	2010 - Kentucky
2010 - Illinois	2010 - Mississippi
2010 - Kentucky	2010 - North Dakota
2010 - Louisiana	2010 - South Dakota
2010 - Ohio	2011 - Iowa *Multiple - 4 MOA's
2010 - South Carolina *Multiple - 2 MOA's	2011 - Oklahoma
2011 - Kansas	2011 - Tennessee
2011 - Michigan	2012 - Nebraska
2011 - Texas	2013 - Wisconsin
2011 - Virginia	2015 - Arkansas
2012 - Arizona *Multiple - 2 MOA's	2015 - Louisiana

Table 3-8. Weeds Resistant to EPSPS Inhibitors (glyphosate)

2012 - Delaware
2012 - Indiana
2013 - Florida
2013 - Florida *Multiple - 2 MOA's
2013 - Illinois *Multiple - 2 MOA's
2013 - Pennsylvania
2013 - Wisconsin
2014 - Delaware *Multiple - 2 MOA's
2014 - Maryland *Multiple - 2 MOA's
2014 - New Jersey
2015 - California
2015 - Tennessee *Multiple - 2 MOA's
2016 - Illinois *Multiple - 2 MOA's
2016 - Nebraska *Multiple - 2 MOA's

Amaranthus spinosus
Spiny Amaranth
2012 - Mississippi

Ambrosia trifida
Giant Ragweed
2004 - Ohio
2005 - Arkansas
2005 - Indiana
2005 - Kentucky
2006 - Kansas
2006 - Minnesota
2006 - Ohio *Multiple - 2 MOA's
2007 - Tennessee
2008 - Minnesota *Multiple - 2 MOA's
2009 - Iowa
2009 - Missouri
2010 - Mississippi
2010 - Nebraska
2011 - Missouri *Multiple - 2 MOA's
2011 - Wisconsin

Conyza bonariensis
Hairy Fleabane
2007 - California
2009 - California *Multiple - 2 MOA's

Echinochloa colona
Junglerice
2008 - California

Eleusine indica
Goosegrass
2010 - Mississippi
2011 - Tennessee

Helianthus annuus

2016 - Minnesota *Multiple - 2 MOA's
2016 - Wisconsin *Multiple - 2 MOA's

Ambrosia artemisiifolia
Common Ragweed
2004 - Arkansas
2004 - Missouri
2006 - Kentucky
2006 - North Carolina
2006 - Ohio *Multiple - 2 MOA's
2007 - Indiana
2007 - Kansas
2007 - North Dakota
2007 - South Dakota
2008 - Minnesota
2008 - Pennsylvania
2010 - Minnesota *Multiple - 2 MOA's
2013 - Alabama
2013 - Nebraska
2013 - New Jersey
2014 - Mississippi
2015 - North Carolina *Multiple - 3 MOA's

Conyza canadensis
Horseweed
2000 - Delaware
2001 - Kentucky
2001 - Tennessee
2002 - Indiana
2002 - Maryland
2002 - Missouri
2002 - New Jersey
2002 - Ohio
2003 - Arkansas
2003 - Mississippi
2003 - North Carolina
2003 - Ohio *Multiple - 2 MOA's
2003 - Pennsylvania
2005 - California
2005 - Illinois
2005 - Kansas
2005 - Virginia
2006 - Nebraska
2007 - Michigan
2007 - Mississippi *Multiple - 2 MOA's
2007 - West Virginia
2009 - Oklahoma
2010 - Delaware *Multiple - 2 MOA's
2010 - South Dakota
2011 - Iowa
2013 - Alabama

Table 3-8. Weeds Resistant to EPSPS Inhibitors (glyphosate)

Common Sunflower
2015 - Texas

Kochia scoparia
Kochia
2007 - Kansas
2009 - South Dakota
2011 - Nebraska
2012 - Colorado
2012 - Montana
2012 - North Dakota
2013 - Kansas *Multiple - 4 MOA's
2013 - Kansas *Multiple - 2 MOA's
2013 - Montana *Multiple - 2 MOA's
2013 - Oklahoma
2014 - Idaho
2014 - Oregon
2014 - Wyoming

Lolium rigidum
Rigid Ryegrass
1998 - California

Salsola tragus
Russian-thistle
2015 - Montana

Sorghum halepense
Johnsongrass
2016 - Oregon
2007 - Arkansas
2008 - Mississippi
2010 - Louisiana

2013 - Wisconsin
2014 - California *Multiple - 2 S MOA's
2015 - Montana

Lolium perenne* ssp. *multiflorum
Italian Ryegrass
2004 - Oregon
2005 - Mississippi
2008 - Arkansas
2008 - California
2009 - North Carolina
2010 - Oregon *Multiple - 2 MOA's
2012 - Tennessee
2014 - Louisiana
2015 - California *Multiple - 3 MOA's
2016 - California *Multiple - 4 MOA's

Parthenium hysterophorus
Ragweed Parthenium
2014 - Florida

Poa annua
Annual Bluegrass

2010 - Missouri
2011 - Tennessee
2013 - California

MOA = mode of action
Source: (Heap 2017)

Herbicide Resistant Weeds in U.S. Cotton Crops

Herbicide resistant weed populations are present in all states where cotton is produced. Currently, the majority of HR weed populations in cotton exhibit resistance to a single herbicide MOA. However, HR weed populations exhibiting resistance to two MOAs are increasingly present in cotton. HR weed populations in cotton resistant to both EPSPS (e.g., glyphosate) and ALS inhibitors were identified in Georgia and Mississippi in 2008, Missouri and Tennessee in 2009, South Carolina in 2010, and in Arizona in 2012 (Heap 2017). Table 3-9 lists weeds with resistance to one or more herbicides that occur in U.S. cotton crops.

Table 3-9. Herbicide-Resistant Weeds in Cotton with Resistance to One or More Herbicides

Mode of Action (MOA)	**Weed-Common Name**	**States Present**
ACCase inhibitors[1]	Johnsongrass	Louisiana, Mississippi, Tennessee
ALS inhibitors	Palmer Amaranth	South Carolina, Tennessee
	Spiny Amaranth	Mississippi
	Tall Waterhemp	Missouri
	Horseweed	Kansas
EPSP[2] synthase inhibitors	Palmer Amaranth	Arkansas, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Texas
	Spiny Amaranth	Mississippi
	Tall Waterhemp	Arkansas, Louisiana, Tennessee, Texas
	Common Ragweed	Alabama, North Carolina
	Giant Ragweed	Tennessee
	Horseweed	Alabama, Arkansas, Kansas, Mississippi, Missouri, North Carolina, Tennessee
	Junglerice	California
	Goosegrass	Mississippi
	Kochia	Kansas
	Italian Ryegrass	Louisiana, Mississippi, North Carolina
Microtubule inhibitors	Palmer Amaranth	South Carolina, Tennessee
	Goosegrass	Alabama, Arkansas, Georgia, Mississippi, North Carolina, South Carolina, Tennessee
	Johnsongrass	Mississippi
Nucleic acid inhibitors	Common cocklebur	Alabama, Arkansas, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee
Multiple Resistance: 2 MOAs - ALS inhibitors & EPSP[2] synthase inhibitors	Palmer Amaranth	Arizona, Georgia, Mississippi, South Carolina, Tennessee
	Tall Waterhemp	Missouri

Source: (Heap 2017)

[1] ACCase refers to acetyl CoA carboxylase.

[2] EPSP refers to 5-enolpyruvylshikimate-3-phosphate.

Herbicide Resistant Weed Management

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

Developers of GE HR varieties provide stewardship and IWM guidance (e.g., Bayer 2017a) to crop producers that is in accordance with and responsive to EPA requirements and Weed Science

Society of America (WSSA) recommendations. In 2017, EPA issued Pesticide Registration Notice 2017-2, *Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship* (US-EPA 2017f). Through this notice, the EPA provides HR weed management guidance for herbicides undergoing registration review and for label registration (i.e., new herbicide active ingredients, new uses proposed for herbicide-resistant crops, and for other case-specific registration actions). To assist growers in managing weeds, individual states track the prevalent weeds in crops in their area and provide the most effective means for their management, typically through state agricultural extension services, which work with USDA (IPM 2015).

3.3 Physical Environment

3.3.1 Water Resources

This section considers water resources, including the quality and quantity of water in surface and groundwater. It also discusses the impacts from human consumption, particularly irrigation water for agricultural production. Groundwater and surface water in rivers, streams, creeks, lakes, reservoirs, wetlands, and estuaries provide water for drinking, irrigation, industrial, recreational, and other public uses.

In 2010, freshwater withdrawals supplied 86% (about 306 billion gallons per day) of all withdrawals in the United States (USGS 2014). Surface runoff from rain, snowmelt, or irrigation can affect surface water quality by depositing sediment, minerals, and contaminants into streams, rivers, lakes, wetlands, and coastal waters. The amount of surface runoff is influenced by meteorological factors (such as rainfall intensity and duration) and biophysical factors (such as vegetation, soil type, and topography).

Groundwater residing in natural geologic formations called aquifers can flow underground and to the surface where it contributes to streams, rivers, and other water bodies. In 2010, groundwater sources contributed to about 20% (76 billion gallons per day) of freshwater used in the United States (Maupin et al. 2014). In 2010, approximately 37% of water withdrawn for public water supply was from groundwater (Maupin et al. 2014).

3.3.1.1 Water Quantity and Water Use in Agriculture

Both groundwater and surface water can be used for irrigation, which accounts for approximately 38% of withdrawals from fresh water sources in 2010 (Maupin et al. 2014). Based on 2010 data, the largest use of groundwater in the United States is irrigation, representing approximately 65% of all the groundwater pumped each day (Maupin et al. 2014). More than 90% of the areas irrigated in Mississippi and Missouri used groundwater (USDA-FSA 2010). Groundwater sources for irrigation are especially important in Arkansas, California, and Texas (Maupin et al. 2014). In addition to irrigation, water is used in agriculture for pesticide and fertilizer applications, crop cooling (e.g., light irrigation), and frost control.

Irrigation maintains adequate moisture for a crop, increases yields per acre and makes more acreage (i.e., dry lands) usable. Irrigation also moderates fluctuations in product and seed quality. This is because moisture requirements for most cotton crops tend to vary during development and an adequate water supply allows crop growth during critical periods of the growing cycle. Efficient irrigation can reduce runoff and deep percolation (leaching) losses (TAMU 2014).

Cotton is generally grown in deep arable soils with good drainage and a high moisture-retention capacity (OECD 2008). For cotton production, the amount of water needed depends on rainfall and the nature of the soil profile (Rude 1984). The need for water increases dramatically from less than 1 inch per week at emergence to 2 inches per week at first bloom. The critical period to avoid water stress occurs during flowering and boll development, which corresponds to peak water need. Drought during this interval causes the plant to shed small squares (late buds). Continued water stress leads to the plant shedding larger squares and then bolls. As increased water stress corresponds to cotton plants allocating proportionately greater biomass into reproductive growth, growers can also manipulate water stress along the sequence in order to increase yield (Gibbs et al. 2005). On average, at least 500 millimeters of rainfall (about 20 inches) are required during the growing season for non-irrigated cotton crops (OECD 2008).

When cotton is grown as an irrigated crop, careful timing of irrigation allows the optimization of flowering and boll production (OECD 2008). Nationally, approximately 40% of cotton acres have been irrigated in recent years (USDA-NASS 2009; Schaible and Aillery 2012). In 2012 (latest census data) 3.6 million out a total 9.1 million acres of upland cotton was irrigated, about 39% (USDA-NASS 2014). In 2007 36% of upland cotton was irrigated (3.7 out of 10.2 million acres). Cotton is heavily irrigated in California, Arizona, western Texas, Georgia, and the Mississippi River Valley (Figure 3-7).

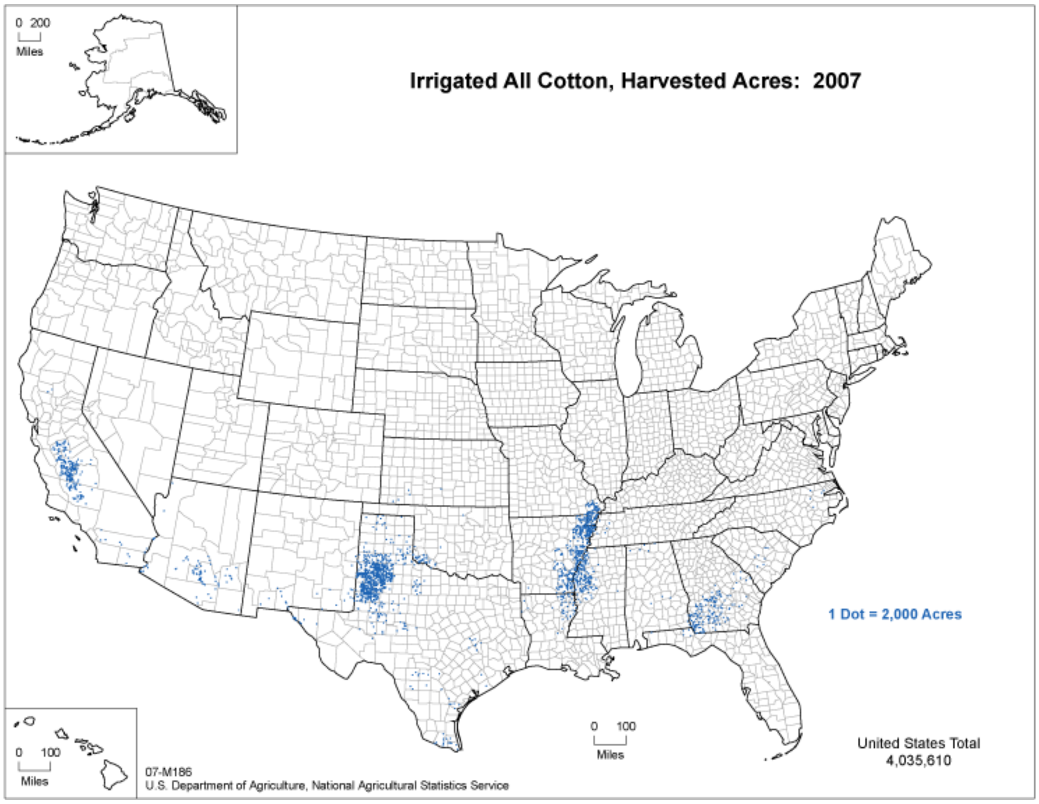

Figure 3-6. Irrigated Cotton Acreage in the United States in 2007
Source: USDA National Agricultural Statistics Service Map # 07-M080 (USDA-NASS 2009)

Crops grown in rotation with cotton may have different water quantity demands. Under drought conditions, growers may choose not to rotate out of cotton, as other rotation crops—such as such as corn and sugarcane—are more sensitive to drought than cotton (Table 3-10).

Table 3-10. Comparison of Water Needs and Drought Sensitivity for Some Globally Important Crops

Crop	Minimum-maximum water (mm needed over total growing period)	Sensitivity to drought
Alfalfa	800-1600	low-medium
Citrus	900-1200	low-medium
Cotton	700-1300	low
Corn (Maize)	500-800	medium-high
Soybean	450-700	low-medium
Sugarbeet	550-750	low-medium
Sugarcane	1500-2500	high
Sunflower	600-1000	low-medium
Tomato	400-800	medium-high

Source: (Brouwer and Heibloem 1986)

USDA projections indicate that demands on agricultural water supplies are likely to increase over time as alternative non-farm uses of water continue to grow. For many states, the scope of water demands for the environment have expanded from a “minimum in-stream flow” to an “environmental-flows” standard (i.e., a concept requiring water to meet the needs for water quality, and to also rehabilitate ecosystems). Additional demands may further draw from this supply in the future. Potential Native American water rights claims were estimated at nearly 46 million acre-feet annually and could impact the distribution and cost of irrigation water in the West. Energy-sector growth is expected to significantly increase water demands for an expanding biofuels sector, utility-scale development of solar power, innovation in thermoelectric generating capacity, and commercial oil-shale and deep shale natural gas development (Schaible and Aillery 2012).

Changes in climate, including warming temperatures, shifting precipitation patterns, and reduced snowpack, is expected to further reduce water supplies and increase water demand across much of the West. These trends place greater pressure on existing water allocations, heightening the importance of U.S. water management and conservation for the sustainability of irrigated agriculture (Schaible and Aillery 2012). Expansion in competing areas of national water demand may present U.S. cotton producers with more difficult farming decisions and fewer socioeconomic options (e.g., whether to purchase enough water for a crop or to clear or even sell land).

3.3.1.2 Water Quality

The principal law governing the nation’s water resources is the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act (CWA). The CWA establishes water quality standards, permitting requirements, and monitoring to protect water quality. The CWA provides for two types of discharge permits: (1) Section 402 permits (National Pollutant Discharge Elimination System, or NPDES, permits) address the discharge of most point source pollutants,[13] and (2) Section 404 permits address the discharge of dredged or fill material into navigable waters of the United States at specified sites. Along with States, the EPA regulates discharges to waters and permitting requirements. Most agricultural discharges do not fall within the definition of point source, a “discernible, confined and discrete conveyance,” and thus are outside of the jurisdiction of the NPDES permitting program. Unlike point source-based pollution, nonpoint source (NPS) pollution comes from many diffuse sources. Rainfall or snowmelt moving over the ground, also known as runoff, picks up and carries away natural and human-made pollutants, creating NPS pollution. The pollutants may eventually be transported by runoff into lakes, rivers, wetlands, coastal waters, and groundwater.

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[13] The CWA defines the term “point source” as: [A]ny discernable, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged. This term does not include agricultural stormwater discharges and return flows from irrigated agriculture.

The CWA exempts from Section 404 permit requirement discharges associated with normal farming, ranching, and forestry activities such as plowing, cultivating, minor drainage, and harvesting for the production of food, fiber, and forest products, or upland soil and water conservation practices (Section 404(f)(1)(A)). To be exempt, however, these activities must be part of an established, ongoing operation. Drinking water is protected under the Safe Drinking Water Act of 1974 (SDWA) (Public Law 93-523, 42 U.S.C. 300 *et seq.*). As part of the SDWA, the EPA establishes limits for the levels of contaminants in drinking water (Maximum Contaminant Level), to include pesticides and fertilizers.[14]

Tillage and agronomic inputs can potentially lead to the impairment of surface waters through soil erosion and run-off, as well as impairment of groundwater through the leaching of pesticides and fertilizers. Agricultural run-off is a primary source of NPS contaminants that can impact surface waters such as rivers and lakes; it represents the third most noted cause of impairment to estuaries (US-EPA 2017g, h). The most common NPS contaminants in agricultural run-off are sediment, nutrients such as nitrogen and phosphorus, and pesticides; all of which can adversely affect aquatic ecosystems. For rivers and streams, the EPA lists sediments as the second most frequent cause of impairment of streams and rivers, nutrients third, and pesticides sixteenth (US-EPA 2017i). For lakes, reservoirs, and ponds, nutrients are second, sediments twelfth, and pesticides thirteenth (US-EPA 2017i). Pesticides may enter water through spray drift, runoff, improper disposal of pesticides, lack of strict adherence to pesticide label requirements (such as improper cleaning of pesticide application equipment), soil and water erosion, and/or leaching through soil to groundwater. In general, sediment and nutrient loading are the principal NPS concerns in crop production, although pesticides will always remain a monitored agronomic input due to their potential to affect adversely both aquatic and terrestrial biota. For example, the United States Geological Survey (USGS) monitors and maintains information on pesticide concentrations in surface and groundwater in its Pesticide National Synthesis Project (USGS 2018).

Due to the potential impacts of agriculture on water resources, various national and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself, such as the EPA's Mississippi River/Gulf of Mexico Hypoxia Task Force (US-EPA 2017j) and USDA Natural Resources Conservation Service's (NRCS) National Water Quality Initiative (NWQI) (USDA-NRCS 2017). For example, through the NWQI, the NRCS and partners (e.g., local and state agencies, nongovernmental organizations) work with producers and landowners to implement voluntary conservation practices that improve water quality in high-priority watersheds, while maintaining agricultural productivity.

3.3.2 Soil Quality

Soils consist of a mixture of weathered minerals, organic matter, air and water. At any given location, soil properties, such as temperature, pH, soluble salts, amount of organic matter, the

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[14] https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations

carbon-nitrogen ratio, numbers of microorganisms, and soil fauna all vary seasonally, and shifts in these parameters also occur over longer periods.

Cotton is cultivated in a wide variety of soils, but develops best in deep, arable soils with good drainage, high organic content, and a high moisture-retention capacity (OECD 2008). Irrigation allows cultivation in poor quality soils with necessary nutrients provided in the irrigation water (OECD 2008).

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

Conventional tillage removes essentially all plant residues and weeds from the soil surface prior to planting. This practice increases the potential for soil loss from wind and water erosion (NCGA 2007). Soil compaction associated with tillage machinery moving across fields may also damage young, developing cotton crops (Rude 1984; Mitchell et al. 2012).

3.3.3 Air Quality

The Clean Air Act (CAA) and its amendments identify air pollutants that may affect air quality and, subsequently, human health and the environment. The CAA requires the EPA to establish National Ambient Air Quality Standards (NAAQS) for certain common and widespread pollutants. The EPA has set air quality standards for six common "criteria pollutants," which include: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and particulate matter (PM). States may adopt requirements stricter than those of the national standards. Air sheds within each state, mostly broken up as counties, are determined by EPA to be either in attainment or in nonattainment for each criteria pollutant under the NAAQS. For air sheds that are in nonattainment, states are required by EPA to prepare a State Implementation Plan containing strategies to achieve and maintain the national standard of air quality. State plans also must control emissions that drift across state lines and harm air quality in downwind states.

Harmful ground-level ozone is not usually directly emitted, but formed in the atmosphere as a result of chemical reactions between nitrogen oxides (NO_x) and volatile organic compounds (VOC) in the presence of sunlight. Some cotton crop production practices can generate NAAQS pollutants and may contribute to challenges in maintaining regional NAAQS. The main criteria pollutants associated with cotton production are ozone precursors (the pollutants that lead to the formation of ozone) and PM (USDA-NRCS 2011). Overall, there are not many areas of the United States where cotton crop production is substantially responsible for nonattainment of PM and ozone NAAQS (US-EPA 2017a).

Fertilizers and pesticides applied to soil and plant surfaces may introduce chemicals to the air, which then may affect non-target plant, vertebrate, and invertebrate species, and may impact human health. Pesticide spraying may impact air quality through both drift and diffusion.

Particulate matter is made up of various compounds, including acids, organic chemicals, metals, soil or dust particles, and allergens (such as pollen or mold spores). Particulates with diameters less than 10 micrometers (PM_{10}) are inhalable and have the greatest potential to impact human health, as these small particles can get deep into the lungs, with some even entering the bloodstream. Larger particulates do not present as serious health concerns, but may irritate the eyes, nose and throat. Particulate deposition may also adversely affect ecosystems by causing nuisance dusting, changing pH balance, damaging plants or by adding additional nitrogen to the environment (USDA-NRCS 2012c).

Particulates may be released through a variety of agricultural practices (Yang and Sheng 2003; Lemieux et al. 2004). Burning releases smoke, and cropping activities (such as planting, tillage, and harvesting) generate airborne soil particulates (Lemieux et al. 2004). Tillage releases PM into the air (Madden et al. 2009) as soil is disturbed. Varying sizes of PM emissions, including $PM_{2.5}$, arise from direct releases of dust from roads, harvesting, or tillage, as well as smoke from combustion processes. In addition, PM may be formed by atmospheric chemical reactions of PM precursor pollutants, NO_x, VOCs, and SO_2. Sources of PM precursor gases include engines, fertilizer application, and animal operations (USDA-NRCS 2012c).

Primary sources of emissions associated with cotton crop production include exhaust from motorized equipment, such as tractors and irrigation equipment; suspended soil particulates from tillage and wind-induced erosion; smoke from burning of fields; drift from sprayed pesticides; and nitrous oxide emissions from the use of nitrogen fertilizer (USDA-NRCS 2006b; Aneja et al. 2009).

Crop residue burning is a land treatment used under controlled conditions to burn a pre-specified area in order to accomplish various resource management objectives such as controlling insect pests and diseases, reducing pesticide and herbicide usage, and minimizing the potential of wildfires, which results in better long-term air quality (US-EPA 2012). Crop residue burning of fields is mainly used as a pre-planting option for cotton production, based on individual farm needs. Agricultural and other prescribed burning is limited under regulations of individual State Implementation Plans to achieve compliance with the NAAQS.

Gases, such as carbon dioxide (CO_2), methane and other hydrocarbons, along with VOCs, are released through equipment exhaust (particularly diesel exhaust) and causing disturbance of the soil, which then causes population changes among the microbial flora and potentially other organisms. Fertilizer applications are associated with release of NO_x, particularly during their manufacture. NO_x is also formed as a result of the breakdown or decomposition process, primarily from nitrification/denitrification, in addition to fuel combustion and burning (USDA-

NRCS 2012e). In agriculture, VOCs can come from the decomposition of biological materials, the combustion from farm equipment, burning of biological materials, and pesticide application.

Aerosols from pesticide and fertilizer applications to crops are another source of molecules that impact air quality. The effects of aerosols are complex because these various molecules can: 1) drift from the target site, 2) volatilize to increase the area impacted, and 3) adsorb onto soil particles (Felsot 2005; Hernandez-Soriano et al. 2007). Drift is defined by EPA as the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application (US-EPA 2018c). Pesticides are typically applied to crops by ground spray equipment or from aircraft. Small, lightweight droplets are produced by equipment nozzles. Many droplets are small enough to remain suspended in air for long periods allowing them to be moved by air currents until they adhere to a surface or drop to the ground.

The amount of drift varies widely and is influenced by a range of factors, including weather conditions, topography, the crop or area being sprayed, application equipment and methods, and other practices followed by the applicator. For example, the fine droplet size of pesticides applied through center-pivot irrigation systems can lead to evaporation and drift unless minimized by addition of Low Elevation Spray Application applicators or Low Energy Precision Application irrigation methods (New and Fipps 2000).

Pesticides applied to crops may also volatilize, thereby introducing chemicals to the air. Volatilization occurs when pesticide surface residues change from a solid or liquid to a gas or vapor after application. Once airborne, volatilized pesticides may be carried long distances from the treatment location by air currents. In addition to impacting air quality, vapor drift can lead to injury of non-target species.

Tillage and wind-induced erosion may lead to suspended soil particles in the air and adsorbed aerosols becoming airborne (Felsot 2005; Hernandez-Soriano et al. 2007). The USDA- NRCS has approved conservation systems and activities aimed at targeting air emissions from agricultural sources in areas where these activities are impacting air quality. These practices may be implemented to achieve air quality improvements specified in the CAA (40 CFR Part 51) through reasonably available control measure and best available control measure levels of control (USDA-NRCS 2012a). Other conservation practices, as required by USDA to qualify for crop insurance and beneficial federal loans and programs (USDA-ERS 2009), effectively reduce crop production impacts to air quality through the use of windbreaks, shelterbelts, reduced tillage, and cover crops that promote soil protection on highly erodible lands. Practices to improve air quality include conservation tillage, residue management, wind breaks, road treatments, burn management, pruning, shredding, feed management, manure management, integrated pest management, chemical storage, nutrient management, fertilizer injection, chemigation and fertigation (inclusion in irrigation systems), conservation irrigation, scrubbers, and equipment calibration (USDA-NRCS 2006b).

Reductions in tillage generate fewer suspended particulates and lower rates of soil wind erosion (Towery and Werblow 2010). Reducing the number of times tillage is done through a growing season reduces vehicle emissions from farm equipment, as well. Both of these benefits to air quality are variable and are affected by factors such as soil moisture and the specific tillage regime employed. Conservation tillage practices resulting in improved air quality include: fewer tractor passes across a field, thus decreasing dust generation and tractor emissions; an increase in surface plant residues and untilled organic matter which physically hold the soil in place and reduce wind erosion (Baker et al. 2005; USDA-NRCS 2006b). The USDA has estimated that the adoption of conservation management plans in the San Joaquin Valley of California had reduced air emissions by 34 tons daily, or more than 20% of the total emissions attributed to agricultural practices after a year of implementation (Baker et al. 2005; USDA-NRCS 2006b).

The EPA’s Office of Pesticide Programs, which regulates the use of pesticides in the United States, introduced initiatives to help pesticide applicators minimize off-target drift. Currently, the Office is evaluating new regulations for pesticide drift labeling and developing voluntary best management practices to aid in reducing drift, as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA 2010). Such practices can effectively reduce crop production impacts to air quality and may include deployment of windbreaks, shelterbelts, reduced tillage, and cover crops that promote soil protection on highly erodible lands (USDA-ERS 2009).

3.4 Biological Resources

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity (also known as biological diversity) compared with adjacent natural areas. Biodiversity refers to the variety of biological species and the dynamics among them across the landscape and over time. Biodiversity of the agricultural field and adjacent regions is a measure of available biological resources, which may provide needed ecological services for the production of the cotton crop. The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri 1999).

Modern conservation practices incorporated in cotton cultivation have brought a positive impact to animal and plant communities through reduced tillage, more carefully controlled and targeted chemical placement (fertilizers and pesticides), and better control of irrigation systems (Scherr and McNeely 2008). Conservation tillage practices that leave greater amounts of crop residue serve to increase the diversity and density of bird and mammal populations (Towery and Werblow 2010; Harper 2017). Increased residue also provides habitat for insects and other arthropods, which provides food for birds and other animals and promotes survival of beneficial insect predators (Towery and Werblow 2010). The increased use of conservation tillage practices has benefitted birds, mammals, and other wildlife through improved water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Sharpe 2010; Towery and Werblow 2010).

The biological resources described in this section include animals, plants, and soil microorganisms. This summary provides the foundation to assess the potential impact to plant and animal communities. Threatened and endangered species are discussed in *Chapter 6 – Threatened and Endangered Species*. Insects considered pests of cotton are discussed in *Section 3.2.4 – Pest Management*.

3.4.1 Animal Communities

Animal communities in this discussion include wildlife species and their habitats. Wildlife refers to native and introduced species of mammals, birds, reptiles, amphibians, fish, and invertebrates, occurring in both terrestrial and aquatic habitats. Wildlife may feed on cotton plants in the field and/or use the habitat surrounding cultivated fields for nesting and refuge. Mammals and birds may occasionally consume cottonseed; invertebrates can feed on the plant during the entire growing season. The environment surrounding cotton fields may serve as important food sources, shelter, nesting, or other needs for these species. Cotton fields may be bordered by other cotton fields by other agricultural crops, woods, pasture/grassland, or aquatic environments.

3.4.1.1 Vertebrates

Mammals and birds may use cotton fields and the surrounding vegetation for food and habitat throughout the year. Certain mammals are adapted to live in disturbed agricultural areas including squirrels, deer, and a variety of rodents. Native habitats may border agricultural lands and may harbor animals that are not well adapted to disturbance. Actual composition of the mammal community that may be present in a given cotton production area varies by region. Several types of mammals are present across cotton growing regions, including mice, deer, coyote, fox, squirrel, bobcat, rabbit, bats, black bear, chipmunk, armadillos, skunk, and gopher; as well as some more localized, such as ringtail cat, armadillo, and ocelot in the Texas cotton-producing region and pronghorn antelope, elk, cougar, kit fox, kangaroo squirrels, and pika in the more Western cotton-producing areas. While most mammals, including feral pigs and raccoons, do not tend to utilize cotton plants directly for food due to the lack of palatability of cottonseed, deer will eat it readily (e.g., Taylor et al. 2013). While cottonseed is often used to supplement cattle feed and certain other livestock if gossypol consumption is limited, gossypol can harm vertebrates such as chicks, swine, and young ruminants (Ely and Guthrie 2012; Heuzé et al. 2016).

Agricultural fields have the potential to provide food, water, and habitat for certain kinds of birds, but each landowner’s farming practices and the crop type determines the value of these lands to wildlife. Many bird species have been documented in and around cotton fields. Orioles are known to prey on boll weevils directly from cotton plants, and crows, mockingbirds, and cardinals will eat cotton worm (Beal et al. 1941).

Reptiles in the action area tend to be localized, including box turtles, garter snakes and rattle snakes in the eastern reaches, Texas horned lizard in the Texas panhandle area, alligators along the southeast Texas producing area, and giant garter snake in California. Some reptiles and all amphibians require proximity to aquatic habitats. Amphibians in the affected environment, such as frogs, toads, and salamanders, would be limited by access to these habitats and the availability of moist sheltering sites. Fish in water bodies adjacent to or downstream from cotton producing areas also vary by region.

3.4.1.2 Invertebrates

Many kinds of terrestrial invertebrates live in cotton-producing regions of the United States, ranging from mollusks such as land snails, to cockroaches, millipedes, isopods, and spiders. As with other taxa, the community composition of invertebrates present in the vicinity of cotton production fields will vary by location.

Invertebrates, including many insects, can feed on cotton plants or prey upon other insects living on cotton plants, as well as in the vegetation surrounding cotton fields. More than 1,326 species of insects have been reported in commercial cotton fields worldwide, but only a small proportion are pests (GTR 2002; Knutson and Ruberson 2005). Insect injury to the cotton crop can impact yield, plant maturity, and seed quality (see also *Section 3.2.4 – Pest Management*). Consequently, insect pests are managed during the growth and development of cotton to preserve cotton yield (Stewart and Catchot 2007).

Insects and other invertebrates can also be beneficial to cotton production, providing services such as nutrient cycling and predation on plant pests. Table 3-11 lists the major beneficial arthropods in cotton fields. Beneficial insects include a wide variety of predators (Table 3-12), which catch and eat smaller insects and parasitic insects that live on or in the body of other insects during at least one stage of their life cycle (USDA-NRCS 2014). Other beneficial insects function as pollinators. Major pollinators of *G. hirsutum* are bumble bees (*Bombus* spp.), black bees (*Melissodes* spp.), and honey bees (*Apis mellifera*) (Stewart and Catchot 2007; USDA-NRCS 2014). Other beneficial invertebrate organisms, including earthworms, termites, ants, beetles, millipedes, and others contribute to the decay of organic matter and the cycling of soil nutrients (Stewart and Catchot 2007; Ruiz et al. 2008).

Table 3-11. Major Beneficial Arthropods in Cotton

Beneficial Species or family	Role, Targeted Stage, or Species
Bumble bees (*Bombus* spp.) Black bees (*Melissodes* spp.) Honey bee (*Apis mellifera)*	Pollinators
Predators	
Ants (Formicidae)	Bollworm eggs and larvae
Ambush and assassin bugs (Reduviidae)	Aphids, bollworm eggs, larvae

Table 3-11. Major Beneficial Arthropods in Cotton

Beneficial Species or family	Role, Targeted Stage, or Species
Bigeyed bugs (*Geocoris* spp.)	Aphids, bollworm eggs, larvae
Pirate bugs (Anthocoridae)	Aphids, bollworm eggs, larvae, thrips, whiteflies, spider mites
Damsel bugs (Nabidae)	Aphids, bollworm eggs, larvae
Lacewing larvae (Chyrsopidae)	Aphids, bollworm eggs, larvae
Ladybird beetles (Coccinellidae)	Aphids, spider mites, bollworm eggs, budworm eggs
Ant, Fire (*Solenopsis* spp.)	Immature boll weevils, bollworm eggs, budworm eggs
Cotton fleahopper	Bollworm eggs, budworm eggs
Spiders	
Parasitoids	
Parasitic wasps *(Trichogramma* spp.)	Bollworm eggs
Parasitic wasps (*Cardiochiles* spp.)	Budworm eggs

Source: (Bohmfalk et al. 2011; USDA-NRCS 2014)

Table 3-12. Beneficial Insects that Prey on Pest Species of Cotton Plants

Pest Species	Natural Enemies (Beneficial Predator Insects)
Thrips (Thysanoptera)	Minute pirate bug (N,A), Insidious flower bug (N,A)
Lygus Bugs/ Fleahoppers *(Lygus hesperus)*	Big-eyed bug (N,A), Leafhopper assassin bug (N,A), Spined assassin bug (N,A), Jumping spiders (N,A), Lynx spiders (N,A), Celer crab spider (N,A), Minute pirate bug (N,A), Insidious flower bug (N,A), Damsel bugs (N,A), Spined soldier bug (N,A), Fire ants (N,A), *Anaphes iole* (E)
Cotton Aphid *(Aphis gossypii)*	Seven-spotted lady beetle (N,A), Harmonia or Asian lady beetle (N,A), Convergent lady beetle (N,A), Pink spotted lady beetle (N,A), Scymnus lady beetle (N,A), Green lacewings (N,A), Brown lacewings (N,A), Hover flies (N,A), *Lysiphlebus testaceipes* (N,A), Cotton aphid fungus
Boll Weevil *(Anthonomus grandis)*	Fire ants (L), Leafhopper assassin bug (A), Spined assassin bug (A), Jumping spiders (A), *Bracon mellitor* (L), *Catolaccus grandis* (L)
Tobacco Budworm *(Heliothis virescens)*	Seven-spotted lady beetle (E,L), Harmonia lady beetle (E,L), Convergent lady beetle (E,L), Pink spotted lady beetle (E,L), Scymnus lady beetle (E), Green lacewings (E,L), Brown lacewings (E,L), Big-eyed bugs (E,L), Leafhopper assassin bug (L), Spined assassin bug (L), Jumping spiders (E,L), Lynx spiders (L), Celer crab spider (L), Minute pirate bug (E,L), Insidious flower bug (E,L), Damsel bugs (E,L), Spined soldier bug (E,L), Fire ants (E,L), Collops beetle (E,L), Earwigs (E,L), Ground beetles (E,L), *Trichogramma* (E), *Archytas* (L), Other tachinid flies (L), *Cotesia marginiventris* (L), *Cardiochiles nigriceps* (L), *Chelonus insularis* (E), *Microplitis croceipes* (L
Cotton Bollworm *(Helicoverpa zea)*	Seven-spotted lady beetle (E,L), Harmonia lady beetle (E,L), Convergent lady beetle (E,L), Pink spotted lady beetle (E,L), Scymnus lady beetle (E), Green lacewings (E,L), Brown lacewings (E,L), Bigeyed bugs (E,L), Leafhopper assassin bug (L), Spined assassin bug (L), Jumping spiders (E,L), Lynx spiders (L), Celer crab spider (L), Minute pirate bug (E,L), Insidious flower bug (E,L), Damsel bugs (E,L), Spined soldier bug (E,L), Fire ants (E,L), Collops beetle (E,L), Earwigs (E,L),

Table 3-12. Beneficial Insects that Prey on Pest Species of Cotton Plants

Pest Species	Natural Enemies (Beneficial Predator Insects)
	Ground beetles (E,L), *Trichogramma* (E), *Archytas* (L), Other tachinid flies (L), *Cotesia marginiventris* (L), *Chelonus insularis* (E), *Microplitis croceipes* (L)
Pink Bollworm *(Pectinophora gossypiella)*	*Trichogrammatoidea bactrae* (E)
Beet Armyworm/ Fall Armyworm *(Spodoptera exigua)*	Seven-spotted lady beetle (E,L), Harmonia lady beetle (E,L), Convergent lady beetle (E,L), Pink spotted lady beetle (E,L), Scymnus lady beetle (E,) Green lacewings (E,L), Brown lacewings (E,L), Big-eyed bugs (E,L), Leafhopper assassin bug (L), Spined assassin bug (L), Jumping spiders (L), Lynx spiders (L), Celer crab spider (L), Minute pirate bug (E,L), Insidious flower bug (E,L), Damsel bugs (E,L), Spined soldier bug (L), Fire ants (E,L), Collops beetle (E), Earwigs (E), Ground beetles (E,L), *Archytas* (L), Other tachinid flies (L), *Cotesia marginiventris* (L), *Meteorus* (L), *Chelonus insularis* (E), Nuclear polyhedrosis virus (L)
Soybean Looper/ Cabbage Looper (*Copidosoma* is specific to soybean looper) *(Acrosternum hilare)*	Seven-spotted lady beetle (E,L), Harmonia lady beetle (E,L), Convergent lady beetle (E,L), Pink spotted lady beetle (E,L), Scymnus lady beetle (E), Green lacewings (E,L), Brown lacewings (E,L), Big-eyed bugs (E,L), Leafhopper assassin bug (L), Spined assassin bug (L), Jumping spiders (L), Lynx spiders (L), Celer crab spider (L), Minute pirate bug (E,L), Insidious flower bug (E,L), Damsel bugs (E,L), Spined soldier bug (L), Fire ants (E,L), Collops beetle (E), Earwigs (E), Ground beetles (E,L), *Trichogramma* (E), *Cotesia marginiventris* (L), *Meteorus* (L), *Copidosoma* (E), Nuclear polyhedrosis virus (L)
European Corn Borer *(Ostrinia nubilalis)*	*Macrocentrus grandii* (L)
Stink Bugs *(Halyomorpha halys)*	*Telenomus wasps* (E), *Trissolcus* wasps (E)
Spider Mites *(Tetranychus urticae)*	Six-spotted thrips (E), Western predatory mite (E,N,A), Stethorus (E,N,A), Minute pirate bug (E,N,A), Insidious flower bug (E,N,A), Green lacewings (E,N,A)
Whiteflies *(Bemisia argentifolii)*	Minute pirate bug (N,A), Green lacewings (N,A), Collops beetles (N,A), Big-eyed bugs (N,A), Whitefly parasites (N), Convergent lady beetles

Source: (Knutson and Ruberson 2005; USDA-NRCS 2014)

Notes: Parenthetical letters designate life stages of the pest attacked by the natural enemy: (E) = eggs, (N) = nymphs, (L) = larvae, (A) = adults

3.4.1.3 Aquatic Species

Aquatic ecosystems potentially impacted by agricultural activities include freshwater and marine systems adjacent to, nearby, or downstream from cotton fields. These include impounded bodies, such as ponds, lakes, and reservoirs, streams and rivers, and marine environments such as the Gulf of Mexico. In conjunction with sediment or airborne soil particulates from soil erosion, aquatic species may be exposed to nutrients and pesticides from agricultural runoff or particulate deposits. These species would include freshwater and estuarine/marine fish and invertebrates, amphibians, as well as marine mammals. Although some ecological research has shown that farming practices can be detrimental to stream health (Genito et al. 2002), some research has demonstrated that, compared to nearby urbanized areas, agricultural lands can also support diverse aquatic invertebrate communities (Lenat and Crawford 1994; Wang et al. 2001; Stepenuck et al. 2002).

3.4.2 Plant Communities

The landscape context surrounding a cotton field varies depending on the region. In certain areas, cotton fields may be bordered by other cotton fields (or another crop) or surrounded by woodlands, rangelands, and pasture or grassland areas. In some cases, areas surrounding cotton fields may include other land uses besides pure agricultural cropland. The plant communities in these surrounding land cover types may be natural, managed (such as to control soil and wind erosion), or a combination. They may provide wildlife habitat. Surrounding plants may be impacted, both positively and negatively, by agricultural operations. Fertilizers and water may run off into adjacent lands, resulting in increased plant growth outside the field margins.

The affected environment for growing cotton plants can generally be considered the agroecosystem (managed agricultural fields), plus some area extending beyond planted cotton. Plants other than the intended crop plant that grow in cotton fields are considered weeds and are discussed in *Section* 3.2.5 – *Weed Management and Herbicide Resistance in Weeds*. Weeds can also include volunteer plants from other crops, such as those crops that are grown in rotation with cotton. Cotton agronomic performance can be reduced by weed competition for water, nutrients, and light, and these plants within the planted area receive the greatest impacts of agricultural practices.

3.4.3 Soil Microorganisms

The inorganic and organic matter comprising soil is home to a great variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS 2004). These organisms are responsible for a wide range of activities that impact soil health and plant growth. Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, and nutrient cycling (Hesammi et al. 2014). These microorganisms also suppress soil-borne plant diseases and promote plant growth (Compant et al. 2005).

The main factors affecting microbial diversity and abundance include soil type (texture, structure, organic matter, aggregate stability, pH, moisture capacity, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, application of herbicide and fertilizer, and irrigation) (Garbeva et al. 2004). Fertilization and cultivation may also have profound effects on soil microbial populations, species composition, colonization, and associated biochemical processes (Steiner et al. 2007). Consequently, significant variation in microbial populations is expected in agricultural fields.

Decomposers, such as bacteria, actinomycetes (filamentous bacteria), and saprophytic fungi, degrade plant and animal remains, organic materials, and some pesticides (USDA-NRCS 2004).

Other organisms, such as protozoans, mites, and nematodes, consume the decomposer microbes and release macro- and micronutrients, making them available for plant usage.

Microbial diversity in the rhizosphere (surrounding the roots) may be extensive and differs from the microbial community in the bulk soil. Plant roots, including those of cotton, release a variety of compounds into the soil, creating a unique environment for microorganisms in the rhizosphere (Garbeva et al. 2004). Mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes have co-evolved with plants and supply nutrients to and obtain food from their plant hosts in a mutually beneficial relationship (USDA-NRCS 2004).

3.4.4 Biodiversity

Agricultural lands, including cotton fields, are frequently disturbed and impacted by crop production activities, including tillage, bed preparation, mechanized planting, planting of a monoculture crop, and application of fertilizers and pesticides. As a result, these areas are associated with simplified or lower levels of biodiversity compared to adjacent natural areas (Altieri 1999; Lovett et al. 2003). Biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management, including selection and use of insecticides and herbicides; and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri 1999). Additional enhancement strategies include intercropping (planting of two or more crops together in the same field at the same time), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically to incorporate nutrients and organic matter into the soil), addition of organic matter (compost, green manure, animal manure, etc.), and establishing hedgerows and windbreaks (Altieri 1999).

While biodiversity will be inherently limited in cropland, growers, as well as federal and state agencies/programs, well recognize the need for environmental stewardship and maintenance of some degree of cropland biodiversity, which is essential to sustainable farming. A variety of federally supported programs, such as the USDA funded Sustainable Agriculture Research and Education Program (SARE), and partnership programs among the EPA and the agricultural community, support sustainable agricultural practices that are intended to protect the environment, conserve natural resources, and promote cropland biodiversity (i.e.,(US-EPA 2017b; USDA-NIFA 2017).

3.5 Human Health and Worker Safety

Human health considerations associated with GE crops are those related to (1) the safety and nutritional value of GE crops and their products for consumers (e.g., cottonseed oil), and (2) the potential health effects of pesticides that may be used in association with GE crops. As for food safety, consumer health concerns center on the potential toxicity or allergenicity of the introduced genes/proteins, the potential for altered levels of existing allergens in plants, or the expression of new antigenic proteins. Consumers may also be concerned about the potential consumption of pesticides on/in foods derived from GE crops. Occupational exposure to pesticides is also a concern.

The following safety assessment summary of GE crop plants includes characterization of the physicochemical and functional properties of the introduced gene(s) and gene products, determination of the safety of the gene products (e.g., proteins, enzymes), and potential health effects of food derived from the GE crop plant.

3.5.1 Food Safety

Cottonseed oil for human consumption is used mainly in processed foods and as a salad and cooking oil. Because raw cottonseed oil contains gossypol and cyclopropenoid fatty acids (CPFAs), naturally occurring compounds that can be toxic to humans and non-ruminant animals at high doses (Scarpelli 1974; Poore and Rogers 1998; Dowd et al. 2010), only highly refined cottonseed oil is used for food purposes. The refining process substantially reduces the levels of gossypol and CPFAs, as well as other undesired compounds (AOCS 1990).

The FDA is responsible for ensuring the safety of plant-derived foods.[15] The FDA created a voluntary plant biotechnology consultation process in the 1990's to work cooperatively with GE plant developers to ensure food made from GE plant varieties are safe. In such a consultation, a developer who intends to commercialize food or feed derived from a GE plant meets with the FDA to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the food product(s). The FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. As part of FDA's consultation process, Bayer submitted a Premarket Biotechnology Notification to the FDA on April 17, 2017 to consult on the safety of products derived from GHB811 cotton for human uses and consumption.

3.5.2 Pesticides Used in Cotton Production

Before a pesticide can be used on a food crop, the Food Quality Protection Act requires the EPA to establish maximum contaminant limits, more commonly referred to as tolerances, for pesticide residues in or on food, or to establish an exemption for a tolerance (21 U.S. Code § 346a). The EPA establishes pesticide tolerance limits to ensure the safety of food for human consumption (US-EPA 2017c). If pesticide residues are found above the tolerance limit, the commodity will be subject to seizure by the government.

The USDA and the FDA enforce tolerances to ensure that the nation's food supply is maintained safely at all times. The USDA enforces tolerances established for meat, poultry, and some egg products, while the FDA enforces tolerances established for other foods. The USDA's Pesticide Data Program (PDP) is a national pesticide residue monitoring program and produces the most comprehensive pesticide residue database in the United States. The Monitoring Programs Division administers PDP activities, including the sampling, testing, and reporting of pesticide

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[15] Under the Federal Food, Drug, and Cosmetic Act, food is defined as "food or drink for man or other animals."

residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities highly consumed by infants and children (USDA-AMS 2017a). The program is implemented through cooperation with State agriculture departments and other Federal agencies. PDP data:

- enable the EPA to assess dietary exposure;
- facilitate the global marketing of U.S. agricultural products; and
- provide guidance for the FDA and other governmental agencies to make informed decisions.

Pesticide tolerances for glyphosate have been established by the EPA for cotton products (40 CFR §180.364), but not for HPPD inhibitors such as isoxaflutole because they have not been registered by EPA for use on cotton. Bayer plans to submit an herbicide label expansion request to the EPA for the use of and HPPD inhibitor, such as isoxaflutole, on GHB811 cotton (Bayer 2017b).

The EPA also sets limits for potential drinking water contaminants that need to be regulated in order to protect public health (40 CFR part 141). These contaminant limits are required by the Safe Drinking Water Act (SDWA). The EPA works with States, Tribes, and many other partners to implement SDWA standards.

The EPA conducts periodic pesticide reregistration reviews for each pesticide every 15 years, as required by FIFRA, to ensure that each continues to meet the statutory standard of no unreasonable adverse effects. As part of this process, the EPA is currently reviewing glyphosate and HPPD inhibitors, including isoxaflutole (US-EPA 2017d, e).

3.5.3 Worker Safety

Agriculture is one of the most hazardous industries in the United States because workers are exposed to risks from operating farm machinery and from applying chemical pesticides and fertilizers. Several Occupational Safety and Health Administration standards have been established to protect agriculture workers under the general Occupational Safety and Health Standards (29 CFR part 1910) and the Occupational Safety and Health Standards for Agriculture (29 CFR part 1928). Additional protections are provided through the National Institute of Occupational Safety and Health, which in 1990 began development of an extensive agricultural safety and health program to address the high risks of injuries and illnesses experienced by workers and families in agriculture.

To limit pesticide exposure risks, the EPA issued the Agricultural Worker Protection Standard (WPS) (40 CFR parts 156 and 170) in 1992. The WPS is intended to minimize risks from pesticide poisonings and related injuries. In November 2015, the EPA issued revisions to the WPS regulations to enhance the protections provided to agricultural workers, pesticide handlers, and other persons by strengthening elements such as training, information about pesticide safety and hazard communication, use of personal protective equipment, and provision of supplies for routine washing and emergency decontamination (80 FR 211, November 2, 2015, p. 67495). The EPA expects the revised WPS to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers, vulnerable groups (such as minority and low-income populations, child farmworkers, and farmworker families), and other persons who may be on or near agricultural establishments, and to mitigate exposures that do occur.

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

3.6 Animal Feed

Animal feed derived from cotton includes whole cottonseed, cottonseed oil, and cotton meal derived from seeds. Cottonseed and cotton meal represent a good source of protein, fiber, and energy for ruminants (cattle, sheep, goats) in cotton-producing areas such as India, China, and the United States, where they are used as partial substitute for soybean meal. These constituents can also serve well as feed for monogastric animals (swine, poultry, horses) if limits on gossypol consumption are maintained (Heuzé et al. 2016). Because most non-ruminant animals can be adversely affected by high levels of gossypol intake, rations of cottonseed meal intended for these animals must be limited to tolerable levels.

As with human foods, the FDA regulates animal feed safety under the FFDCA and the Food Safety Modernization Act. It is the responsibility of feed manufacturers to ensure that their products are safe for animal consumption. Bayer submitted a Premarket Biotechnology Notification for GHB811 cotton to the FDA on April 17, 2017, to consult on the safety of animal feed products derived from GHB811 cotton.

3.7 Socioeconomics

3.7.1 Domestic Economic Environment

Conventional and GE Cotton Production

Cotton yields five products of commercial value: fiber, linters (fine, silky fibers that cling to the seed after ginning), hulls, cottonseed oil, and meal. Cotton fiber is one of the most commercially valuable textile fibers in the world. In the United States, it typically accounts for approximately 85% of the value of harvested cotton. The United States is the world's third-largest cotton fiber producer, after China and India, and the leading cotton exporter. The average U.S. crop moving from the field through cotton gins, warehouses, oilseed mills, and textile mills to the consumer, accounts for more than $35 billion annually in products and services (NCCA 2017).

Consequently, the cotton industry is a vital part of economies in the 17 major cotton-producing states (NCCA 2017).

After fiber, in terms of economic value, oil is the most valuable product, followed by meal, which itself is worth more than the combined value of hulls and linters. Linters serve as a good source of cellulose and are used to produce a variety of products such as plastics, rocket propellants, rayon, cosmetics, photography and X-ray film, and paper products (NCPA 2018).

Domestic and global vegetable oil markets and markets for livestock feed ingredients all play major roles in determining the value of cottonseed. For every 100 pounds of fiber produced by cotton plants, there is about 162 pounds of cottonseed. Annual cottonseed production typically comes to about 6.5 billion tons, of which about two-thirds is fed whole to livestock. The remaining seed is crushed, producing an oil and high protein meal for livestock, dairy, and poultry feed. The oil is further processed to produce food grade cooking oil, which is used in salad dressings, shortenings, margarine, and some canned fish products. Limited quantities of the oil are used in soaps, pharmaceuticals, cosmetics, textile finishes, and other products (NCCA 2017).

During the past decade, annual cotton production in the United States has varied from approximately 12 -19 million bales (480 pounds/bale), and net value has ranged from around $3.0 billion to $7 billion, annually. Upland cotton acreage harvested in 2017 increased 30% from a year earlier to 11.2 million acres; American Pima acreage also increased to 242,000 acres or about 28% from 2016 (USDA-NASS 2017b).

Weed Management Costs

Concurrent with the development of HR weed populations has been an increase in production costs to manage them. A 2012 survey of 2,500 cotton farmers in 13 southern cotton-producing states was conducted to assess the temporal and geographic extent of weed resistance to herbicides in cotton production, appraise changes in production practices after the emergence of HR weeds, evaluate the effectiveness of those changes in managing resistant weeds, and ascertain the influence of HR weeds on cotton weed control costs (Zhou et al. 2015). More than two-thirds of the farmers surveyed experienced HR weeds on their farms. Pigweed was the dominant weed problem, followed by horseweed, ragweed, and other non-specific weeds. Farmers indicated that they used various combinations of labor, mechanical/chemical, and cultural practices to manage weed resistance on their farms: 90% indicated they hand hoed or pulled weeds in field, 54% increased field scouting, 69% changed in-season herbicide program/chemistry, 21% used fall tillage after harvest to kill growing weeds, 12% used fall residual herbicide programs, 47% controlled weeds in field boarders/ditches, 36% used winter cover crop to suppress weeds, and 35% used more crop rotations (Zhou et al. 2015). Cotton producers extensively relied on mechanical/chemical methods to control weed resistance, which made up 42% of those surveyed. The chemical practice used by the largest number of farmers, 69% of those surveyed, was a change in in-season herbicide program/chemistry programs, specifically, alternating MOAs. Most farmers reported an increase in weed control costs after the emergence of HR weeds. The percentage of farmers surveyed who indicated they had total weed control costs ≥$50 per acre nearly doubled after the emergence of HR weeds on their farms (Zhou et al. 2015).

Sosnoskie and Culpepper (2014) similarly found that the increased presence of glyphosate resistant (GR) weeds, especially Palmer amaranth, generated several new costs for growers. This problem weed started becoming present in Georgia crops beginning in the period 2000-2005, and growers doubled applications of Palmer-specific herbicides by 2006- 2010. Because of inadequate chemical control, growers were forced to hand weed in 52% of cotton acres. Growers made additional use of paraquat, glufosinate, and residual herbicides to control Palmer amaranth. To incorporate additional preplant herbicides, 20%t of acres required a tillage pass. Growers increased harrowing (in crop tillage) to 44% t of acres. The study found that about 19% of crop acreage required deep tillage every three years, which is contrary to typical constraints placed on no-till cotton production.

Weed management in cotton differs from that in corn and soybean. Cotton is a poor competitor against many of the weeds that infest the southern and southwestern United States. Following planting, cotton requires about eight weeks of weed-free growth to achieve maximum yields. Good yields require greater than 95% weed control; excellent yields require 99% or better control. Consequently, near optimal control is needed to avert difficulties with picking, removing excess trash in the harvested lint, and preventing a recurring cycle of heavy weed seed fall that promotes high populations of weeds the following spring (Cotton-Incorporated 2017).

Lambert et al. (2017) examined the weed management costs (WMCs) in cotton production in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Louisiana, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. For 2012, the aggregate costs of managing herbicide resistance ranged between $25 and $53 million, depending on the types of management practices implemented. Post-resistance WMCs for surveyed cotton farmers ranged between $25.37 and $53.19 million. Average costs of managing weeds increased by $98/ha ($40/acre) following the establishment of HR weeds. Post-resistance changes in WMC ranged between $85/ha ($34/acre) and $138/ha ($56/acre), depending on the combination of adopted practices. WMCs increased by $88/ha ($36/acre) when cost-neutral practices were adopted (Lambert et al. 2017).

Interestingly, while HR weeds have been on the rise, since 2004 (the year serious GR Palmer amaranth problems were first recognized), U.S. cotton yields have exceeded the long-term trend seven of the following ten 10 years (Kniss 2013). Thus, HR weeds have apparently not had significant adverse impacts on cotton crop yields, as is often implied in reviews of HR weeds.

In summary, while overall national yields have increased, there is ample evidence that farmers in the South have had to adapt to HR weed populations by using other herbicides, re-introducing tillage, or using cover crops. These additional weed control practices cost money, and some growers with HR weeds may have seen a reduction in their net economic return.

Organic Cotton Production

Organic cotton production has steadily increased over the last decade. Approximately, 10,335 bales of organic upland and pima cotton fiber were harvested in 2013 (OTA 2015) from an estimated harvested 9,262 acres (15,685 acres were planted) (OTA 2015). This represents a 16% increase in organic fiber bale production over the prior year's 8,867 bales harvested from 9,842 acres (14,787 acres planted) (OTA 2015). The Texas Organic Cotton Marketing Cooperative, based in the West Texas High Plains, grew 85% of the organic cotton in the United States in 2016. Organic cotton – mostly Pima – is also grown in New Mexico and minor amounts in California and North Carolina (OTA 2015). In recent years, small and sporadic acreages of organic cotton have been cultivated in Missouri, Illinois, Kansas, Tennessee, and Colorado (USDA-ERS 2010).

Organic fiber sales in the United States totaled $1.4 billion in 2016, a 9.2% increase from 2015 (OTA 2018). The organic fiber and textiles category continues to rank as the largest non-food organic category in the U.S. market. The 2017 OTA survey showed that organic fiber sales currently account for almost 40% of the $3.9 billion organic non-food market (OTA 2018).

In 2015, U.S. organic cotton growers reported receiving $1.38 per pound for organic upland cotton, with prices reaching as high as $2.20 for organic Pima cotton (OTA 2018). This compares to an average price for conventional upland cotton of 61.20 cents per pound in the 2014-2015 marketing year (MY), and 69.70 cents in the 2016-2017 MY (USDA-AMS 2017b). In 2016, U.S. organic cottonseed prices ranged from $500 to $600 per ton. This compares to $225 to $300 per ton for conventional cotton (USDA-AMS 2017a).

Growing organic cotton in the United States is a highly specialized and problematic endeavor. A few isolated regions of the United States have conditions that make it possible: well-drained soil, a long growing season, moderate rainfall, and a late freeze that minimizes pests and defoliates the plants for harvest. For these reasons, in conjunction with the increasing difficulty of weed control, continual labor shortage, and limited commercial availability of organic cotton seed, it is expected that increases in U.S. organic cotton production during the next several years will be limited (TE 2016).

A primary factor limiting yields in organic cotton is effective weed control. In wet regions or years, early season weeds can choke out an emerging cotton crop. Later in the season, weeds can adversely impact yields and quality. Mechanical weeding is standard practice for organic farmers. A number of factors also limit the availability of seasonal labor in cotton-growing regions. Surveyed cotton growers–particularly those new to farming organic cotton–have expressed concerns that the lack of available labor is a hindrance to expanding their production. Commercial availability of organic seed also remains a major hurdle for organic cotton producers. GE seeds have become dominant in the marketplace. Among major seed companies, non-GE and non-treated cottonseed offerings are limited, and there has not been significant effort dedicated to improving cottonseed by traditional breeding techniques (OTA 2014). Most surveyed cotton farmers report using at least a portion of their own saved cottonseed from year to year. Herbicide drift is another challenge cited by the organic cotton-growing community. Finally, weather conditions can have marked impacts on cotton production in general. For example, yields and quality for the 2013 organic cotton crop suffered from the impacts of severe wind and hail incidents.

3.7.2 International Trade

U.S. cotton exports make a significant contribution to the U.S. economy. Annual values of U.S. cotton sold overseas have averaged more than $2 billion. Currently, the United States contributes, on average, about 10.5 million bales to the world's cotton exports,[16] accounting for about 37% of the total world export market. The largest customers for U.S. cotton are Asia and Mexico (NCCA 2017). Exports to the Indian subcontinent also rose sharply during market year (MY) 2016/17, with India, Pakistan, and Bangladesh combined representing the second-largest U.S. trading partner.

The United States ended MY 2016/17 with cotton exports totaling 14.9 million bales, including 614,000 bales of extra-long staple cotton and 14.3 million bales of upland cotton. This represents the highest export since 2005/06, when the United States exported 17.7 million bales. Both rising U.S. crop estimates and rising global consumption helped account for this increase (USDA-FAS 2018).

Organic cotton production in the United States currently represents approximately 0.4% of global cotton production. As of 2017, 19 countries produce organic cotton, although the top five countries (India, China, Turkey, Kyrgyzstan and United States) account for more than 92% of production. India alone accounts for 67% (TE 2016). For 2014 to 2015, approximately 112,488 metric tons (2.47 million pounds) of organic cotton were grown by 193,840 farmers on 350,033 hectares (864, 950 acres) in 19 countries. These included (in order by rank: India (66.9%), China (11.69%), Turkey (6.49%), Kyrgyzstan (4.93%), United States (2.16%), Egypt (1.91%), Tanzania (1.91%), Burkina Faso (0.95%), Tajikistan (0.89%), Uganda (0.71%), Peru (0.49%), Mali (0.47%), Benin (0.34%), Ethiopia (0.13%), Brazil (0.02%), Israel (0.01%), Senegal (0.01%), Madagascar (0.004%), and Colombia (0.001%), with an additional 85,671 hectares in the process of conversion to organic between 2015-2016 and 2017-2018 (TE 2016).

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[16] 1 bale of cotton = 500 lbs

4 ENVIRONMENTAL CONSEQUENCES

This chapter identifies the possible environmental effects associated with the alternatives on the affected environment (as described in *Chapter 3 Affected Environment*), considers the likelihood that they will occur, and evaluates their potential to cause significant impacts if they do occur. In this chapter, APHIS only examines the effects—both direct and indirect—of its decision regarding the regulatory status of GHB811 cotton on different aspects of the human environment. For the purposes of this EA, those aspects are: cotton production practices, the physical environment, biological resources, public health, animal feed, and socioeconomic issues.

Under the No Action Alternative, APHIS would not approve the petition for nonregulated status for GHB811 cotton and GHB811 cotton would remain regulated. This alternative represents the status quo, which refers to the situation that would occur if APHIS denies the petition. Under the Preferred Alternative, APHIS would approve the petition for nonregulated status for GHB811 cotton.

This chapter describes the effects of current cotton production on each resource area of the affected environment and how such effects are anticipated to occur if APHIS selects the No Action Alternative. It then discusses the possible effects of the Preferred Alternative on each resource area in the affected environment. This analysis provides the opportunity to make meaningful comparisons between the No Action Alternative and the Preferred Alternative.

4.1 Land Use and Acreage

No Action Alternative: Land Use and Acreage

Denial of the petition would have no effect on the acreage or areas utilized for cotton crop production. The USDA expects the acreage planted to upland cotton to fluctuate over the next few years and to stabilize at 10 million acres during the period 2019 to 2026 as a result of the projected increase in export over the next decade along with slow growth in domestic mills (USDA-OCE 2017).

Cotton growers have a variety of cotton cultivars available for planting. Growers select cultivars based on their yield, quality, pest and disease resistance, herbicide tolerance, and other traits. Under the No Action alternative, GHB811 cotton would not be available to growers. This is unlikely to affect U.S. growers’ choice to plant cotton, so is not expected to change overall U.S. cotton acreage.

Preferred Alternative: Land Use and Acreage

Under the Preferred Alternative, which would correspond to the decision to approve the petition, there are no expected direct or indirect impacts on land use and cotton acreage since the drivers of land use for cotton production center on the market price of cotton and the suitability of the land for cotton production. A decision to approve the petition will not affect these factors. Under the Preferred Alternative, APHIS does not anticipate that the availability of GHB811 cotton will change the acreage of GE cotton compared to acreage under the No Action Alternative.

4.2 Agronomic Practices in Cotton Production

No Action Alternative: Agronomic Practices

Under the No Action Alternative, APHIS would continue to regulate GHB811 cotton. Growers would continue to plant GE and non-GE cotton varieties. Agronomic practices such as tillage, crop rotation, fertilization, and weed and pest control, including pesticide use, would continue along current trends. Growers will select pesticides and other pest control practices based on weed, insect and disease pressures and other factors.

As discussed in Section 3.2.5 – *Weed Management and Herbicide Resistant Weeds*, the continued evolution, spread, and persistence of HR weeds is a major concern for cotton growers. For example, GR Palmer amaranth is present in all cotton-producing counties in Georgia. Herbicide costs have more than doubled and, still, herbicides alone are not able to effectively control GR Palmer amaranth (Sosnoskie and Culpepper 2014). While, no-till practices are still used in many areas, the presence of HR weeds has necessitated the inclusion of tillage and even hand weeding in some areas (Arbuckle and Lasley 2013; Sosnoskie and Culpepper 2014). GR Palmer amaranth has forced many Georgia cotton growers to return to tillage, with 43% of crops tilled during 2006-2010 compared to 36% between 2000 and 2005 (Sosnoskie and Culpepper 2014). Deep-tillage to bury weed seed is practiced every three years on 20% of acreage. In Georgia, heavily infested fields are being hand-weeded at a cost of up to $57 per hectare across, 52% of the state’s cotton acreage (Sosnoskie and Culpepper 2014). In-crop cultivation is frequently practiced (42% of acres), tillage is used to incorporate pre-plant herbicides (20% acres) and deep-turning is more frequent (19% of acres every three years) (Sosnoskie and Culpepper 2014).

Compared to the past, growers rely on residual herbicides more (Sosnoskie and Culpepper 2014). They also choose to apply multiple herbicides more frequently during different crop development stages (Shepard 2015).

Existing populations of resistant weeds will likely persist and additional new weed populations with multiple herbicide resistance will likely emerge. The continual emergence of HR weeds will likely require cotton growers to continue modifying crop production practices. Herbicide use is likely to increase in some cropping systems to manage HR weeds (Owen and Zelaya 2005a; Culpepper et al. 2008; Kniss 2013). Herbicide use, in terms of both area-treatments (roughly defined as the number of times one herbicide was applied to one field) and lbs a.i./acre has increased over the last decade. Kniss reports a steady, linear trend for increasing number of herbicide area-treatments for all corn, soybean, cotton, wheat, and rice (Kniss 2013, 2017). The quantity (lbs a.i./acre) of herbicides applied to these crops has likewise increased (Kniss 2017). This increase in herbicide use is attributed in part to the emergence of weed populations resistant to various herbicide MOAs over the last decade, and the difficulty in managing them.

Although glyphosate still controls large numbers of weeds, growers have been applying herbicides with different modes-of-action (MOAs) on cotton fields planted with GE cotton to control GR weeds and to manage the development of HR weeds. Between 2009 and 2011, the use of non-glyphosate herbicides (none of which were HPPD inhibitors) on GR cotton increased for pre-emergent (113%) and post-emergent (220%) applications (Culpepper 2015). From 2008 to 2011, there was a similar trend for such treatments on GR soybeans (177% increase for pre-emergent and 345% for post-emergent applications), a crop commonly grown in rotation with cotton. In Georgia, the presence of GR Palmer amaranth has increased the lbs a.i./acre of herbicide applied to cotton by a factor of 2.5 compared to the amount used prior to emergence of glyphosate resistant weeds (Culpepper 2015). Given these trends, under the No Action Alternative, increased use of other herbicides such as chloroacetamides, glufosinate, ALS inhibitors, PPO inhibitors, and PSII inhibitors would be expected.

In an attempt to reduce tillage that might otherwise be used to manage HR weeds, the USDA-NRCS offers farmers technical and financial assistance to manage HR weeds, while maintaining conservation stewardship through two programs. The Conservation Stewardship Program[17] (CSP) is the largest conservation program in the United States with over 70 million acres of agricultural and forest land enrolled in CSP. The Environmental Quality Incentives Program[18] (EQIP) provides financial and technical assistance to agricultural producers through contracts that address natural resource concerns and for opportunities to improve soil, water, plant, animal, air and related resources on agricultural land and non-industrial private forestland. Among the practices that qualify for financial incentives and technical assistance that do not require additional tillage to control weeds are the use of cover cropping and crop rotation, both of which have been shown to be effective in the management of weeds, pests, and diseases.

Preferred Alternative: Agronomic Practices

Approval of the petition would provide growers the option to produce GHB811 cotton, subject to Bayer consultation with the FDA and the EPA registration of isoxaflutole for use on this cotton variety. For any herbicide registered for use on GHB811 cotton, growers are required by law to use them in strict accordance with the EPA label requirements.

The agronomic practices and inputs used to grow GHB811 cotton, such as tillage, crop rotation, fertilizers, and pesticides, would be the same as those currently used for other conventional and GE cotton varieties, except for the potential added availability for use of isoxaflutole on GHB811 cotton. GHB811 cotton would be the first HPPD resistant cotton available to growers. Growers would continue to manage weeds, including HR weeds, using a combination of chemical, mechanical, and cultural weed control methods that are available to them now as described for the No Action Alternative, but would have the additional MOA provided by

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[17] CSP: https://www.nrcs.usda.gov/wps/portal/nrcs/main/national/programs/financial/csp/

[18] EQIP: https://www.nrcs.usda.gov/wps/portal/nrcs/main/national/programs/financial/eqip/

isoxaflutole (an HPPD inhibitor). Potential use of isoxaflutole on GHB811 cotton could influence growers' crop rotation schemes since other crops are sensitive to isoxaflutole.

The primary purpose of GHB811 cotton is to help manage weeds and HR weeds. Bayer intends to cross GHB811 cotton with other lines of cotton to produce seeds of stacked-trait varieties resistant to multiple herbicide MOAs: isoxaflutole, glyphosate, and glufosinate-based herbicides. As a stacked trait cotton with resistance to 3 herbicide MOAs, GHB811 cotton varieties may help facilitate effective weed and weed resistance management. Such varieties would allow growers to use multiple herbicide MOAs in tank mixtures for management of weeds, reducing the selection pressure on naturally resistant weeds, and likelihood that HR weed populations will evolve.

The conditions that could select for the development of weed populations that are resistant to glyphosate, HPPD inhibitors, and glufosinate based herbicides will occur at some level under both the Preferred and No Action Alternatives. However, because these herbicides have different MOA's and could be used in combination with one another (e.g. in tank mixes) on GHB811 cotton, as well as in rotations, the rate of development of new HR weed populations, as well as the overall number of HR weed populations, is expected to be less than cotton cropping systems utilizing one or two MOAs. This is because weeds would have to become resistant to multiple MOA's rather than a single MOA, and successfully reproduce. Over time, GHB811 cotton, as part of an effective IWM program, may help growers slow the development of HR weed populations, and in some cases, reduce existing populations of glyphosate resistant weeds. The efficacy of a GHB811 cropping system in controlling weeds will largely depend on the extent that IWM tactics are used.

Evans et al. (2015) concluded that while herbicide mixing could delay the development of glyphosate resistance or other herbicide resistance weed traits, they are unlikely to prevent them. In other words, stacked-trait varieties may delay evolution of resistance, but do not prevent it (Evans et al. 2015). The effectiveness of stacked-trait varieties depends on management decisions affecting how the herbicides are used. Weed management programs based on the stacking of transgenes to control development herbicide resistance must include alternative tactics; a diversity of management strategies (IWM) is of key importance to sustain the efficacy of stacked-trait varieties and herbicides (Gressel et al. 2017).

To the extent GHB811 cotton is adopted, the total amount (lbs/acre/yr) of isoxaflutole in cotton would increase, use of glufosinate may also increase, while the use of some other herbicides may decline. Glyphosate-based herbicides are currently used widely in cotton; the amount of these herbicides used would likely remain about the same. These potential changes in use are further discussed in Chapter 5.

4.3 Physical Environment

4.3.1 Water Resources

No Action Alternative: Water Resources

Under the No Action Alternative, GHB811 cotton would continue to be regulated by USDA. Growers would continue to cultivate the GE and the non-GE cotton varieties currently available (as well as any others that become available), employing the agronomic practices and inputs typically associated with these varieties. Current acreage for cotton production and agronomic practices, including crop rotation, irrigation, tillage, nutrient management, and pest and weed control, would not be expected to change from current practices as a result of the No Action decision. Consequently, APHIS does not expect that there will be changes to water quality or uses beyond current trends and normal variations.

Cotton is expected to remain an economically important crop in the United States. The number of U.S. acres planted to cotton are expected to fluctuate within the limits that have been seen in the past typically and remain among locations of cotton production within current regions. Current agronomic practices associated with cotton production can impact water quality or quantity. Tillage, the identity and amount of agricultural inputs, and the rate and timing of irrigation, can impact water resources. These activities are expected to fluctuate within typical limits. Under the No Action Alternative, growers would have fewer weed and pest management options than they would have under the Preferred Alternative. This could, in part, affect their choices concerning how many acres to plant to cotton, which could relate to available and predicted water resources.

Conservation tillage and no-till practices are commonly used in GE cotton production to help reduce agricultural runoff and provide other benefits. Currently about 64% of U.S. cotton growers use conservation tillage (Cotton-Incorporated 2015). The widespread adoption of these practices has resulted in a 68% reduction in soil loss per pound of cotton produced (a measure of soil erosion) on U.S. cotton acreage over the past 30 years (FTM 2016). However, because of increasing HR weed problems, conservation and no-till practices are being used less in many of areas of the Southeast while more aggressive tillage is implemented to help control HR weed populations (Smith 2010; Hollis 2015). In the face of challenges in managing HR weeds, producers tend to increase their use of tillage practices, which can lead to erosion and increased run-off. In addition, some growers may apply herbicides more frequently and at higher rates to control HR weed populations (Benbrook 2012; Kniss 2012). Increases in tillage typically correspond to greater soil erosion and NPS run-off risks to nearby water bodies. Therefore, if increased tillage is used to control increasing HR weed populations, greater soil erosion and run-off could occur.

Because certain agricultural practices can contribute to both NPS and point source water pollution and reduce water quality and availability, various national and regional efforts have been instituted to reduce contaminants in run-off from agricultural sources, as well as other sources (US-EPA 2017j; USDA-NRCS 2017).

As discussed in Section *3.4.1 – Water Resources*, water resources have increasing demands being placed on them for agricultural, built landscape, and industrial uses. Under the No Action Alternative, the quantity of water available for agricultural use is expected to be restricted as demand for water increases in some areas of the Southern United States. Consequently, pressure for the conservation of existing surface water and groundwater resources is expected to increase.

Preferred Alternative: Water Resources

The primary purpose of GHB811 cotton is to help manage weeds and HR weeds. As a stacked-trait cotton resistant to 3 different herbicide MOAs, GHB811 cotton varieties may provide for effective weed and weed resistance management. The rate of development of new HR weed populations, as well as the overall number of HR weed populations, could be lessened in this cropping system, relative to cropping systems using only 1 or 2 MOAs (Evans et al. 2015). However, this is highly dependent on the efficacy of the IWM program employed with GHB811 cotton varieties (Evans et al. 2015; Gressel et al. 2017). In general, under the Preferred Alternative, the potential effects of GHB811 cotton production on water quality are expected to be similar to those under the No Action Alternative. However, as described for the No Action Alternative, HR weeds have forced cotton growers in some areas to include or intensify tillage to control weeds in order to sustain maximum yields and profitable returns. Conventional tillage is becoming a more common practice among cotton growers in Southern states because of the development of HR weeds (Hollis 2015). 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. Relative to the types of tillage currently used, any reduction in tillage under the Preferred Alternative would likely benefit water resources. To the extent GHB811 cotton facilitates effective management of weeds, management of development of HR weed populations, and use of conservation and no-till practices, potential impacts on water quality are expected to limited, no more and possibly less than the level that would occur under the No Action Alternative. This would result from limiting herbicide inputs and agricultural run-off. In the long term, however, unless growers implement IWM practices in cultivation of GHB811 cotton varieties, any further development of HR weed populations would likely entail increased tillage in some areas, as well as increased herbicide inputs, which present risks to water quality (as described in the No Action Alternative).

Regardless of the determination APHIS makes for the petition, fertilizer and pesticide use in cotton production has, and will continue to have, the potential to adversely impact water quality. The various national, state, and regional efforts underway to mitigate the potential impacts of agriculture on water quality are expected to continue. However, much of the future success of these efforts will depend on grower practices, such as adoption of conservation measures.

The EPA regulates the use of herbicides under FIFRA and is making a separate decision which may or may not allow isoxaflutole use on GHB811 cotton. Isoxaflutole is classified as a restricted use pesticide because of its potential impacts on surface and groundwater. Chemicals classified as restricted use pesticides are not available for purchase and use by the general public without appropriate licenses due to their potential to have unreasonable adverse effects on the environment, applicators, or the general public unless applied by trained and certified applicators (or those under the supervision of certified applicators). The potential impacts of isoxaflutole use on surface and groundwater are discussed in more detail under *Section 4.4.2 – Plant Communities,* and *Section 4.5 – Human Health*.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

Under the No Action Alternative, soil conservation practices would be expected to continue to be available to growers, including the use of conservation and no-till practices. Under the No Action Alternative, GHB811 cotton would not be available. Current cotton management practices that benefit soil quality and reduce erosion, such as crop rotation, contouring, reduced and no tillage, cover crops and windbreaks, and other practices would continue to be available to growers.

Impacts on soils would derive from grower weed management and tillage choices in cultivation of cotton. For all cropping systems, GE and non-GE (to include organic), soil erosion has been and will remain a key issue in parts of the United States. While erosion can occur through natural processes, the characteristics of which depend on a number of factors. Soil type, local terrain and ecology, weather, tillage, crop rotation, and cover crop management practices all influence the erosional capacity of soils and soil fertility. Conservation tillage systems, including no-till, are highly advised for commercial cropping systems as they contribute to higher soil quality and reduced erosion, as compared with conventional tillage.

Under the No Action Alternative, HR weeds would remain a concern in the Southeast and other regions and the continued expansion of resistant weeds into new regions would require modifications of crop management practices to address these weeds, such as increasing tillage, which can affect soils. Crop management changes may also include the use of multiple MOAs in herbicide applications on cotton and making adjustments to crop rotation (Owen et al. 2011). Growers in the Southeast, who already experience impacts of HR weed infestations, are by necessity having to diversify their overall weed management strategies (Smith 2010). Many growers who have adopted no-till production are now resorting to increased tillage in their management programs, which reduces the benefits of no-till production (Smith 2010).[19] Growers in Arkansas, California, Georgia, Louisiana, Mississippi, Missouri, and Texas, are using more tillage to manage weeds. Some of the adjustments may have the potential to impact soil quality, erosion, and soil moisture retention. Crop plant residue management, which relies on

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[19] See also: http://www.southwestfarmpress.com/cotton/resistant-weeds-alter-cotton-production-practices.

intensive tillage and leaves low amounts of crop residue on the surface, results in greater losses of soil organic matter (USDA-NRCS 1996).

Several factors can influence soil microbial communities (see *Section 3.4.3 – Soil Microorganisms*), including herbicide applications (Garbeva et al. 2004). Under the No Action Alternative, growers will continue to use herbicides, which can affect soil quality through their effects on soil microbial communities. Additional herbicides may be used by certain growers to control HR weeds (Owen 2011; Vencill et al. 2012). The environmental risks of herbicide usage continue to be assessed by the EPA in the pesticide registration process, and are regularly reevaluated by the EPA for each pesticide to maintain its registered status under FIFRA.

Preferred Alternative: Soil Quality

The potential impacts of cotton production on soil quality are not expected to significantly differ under the Preferred Alternative. Because GHB811 cotton has been found to be compositionally, agronomically, and phenotypically equivalent to other non-GE and GE commercially cultivated cotton (Bayer 2017b), the potential for impacts associated with agronomic practices and inputs with the possible exception of those from isoxaflutole, which could limit options for rotation crops, would not be any different for GHB811 cotton production.

As discussed above, cotton growers have had to increase tillage to manage HR weed populations in the southeastern United States (Smith 2010). Where stacked-trait GHB811 cotton varieties, as part of an IWM program, are effective in managing existing resistant weed populations and allaying the rate of development of resistant populations, conservation and no-till practices could potentially be sustained and, in some instances, restored. To the extent GHB811 cotton facilitates effective weed management, and use of conservation and no-till practices, benefits to soil quality via retention of organic matter, and limited soil run-off, would be expected.

4.3.3 Air Quality

No Action Alternative: Air Quality

The emission sources associated with cotton production would be unaffected by a decision to deny the petition. Emissions from farm equipment, particulates from tillage operations, and contaminants from pesticide applications would continue to affect air quality along current trends. Federal, state, and local efforts to reduce emissions would likewise continue to drive decisions that affect air quality under either alternative.

The trend of increasing tillage practices in some areas of the South would likely continue under the No Action Alternative. Tillage activities affect air quality by releasing particulate matter and emitting NAAQS pollutants. Under the No Action Alternative, these potential emissions may cause some transient impacts to local air quality.

Preferred Alternative: Air Quality

A determination of nonregulated status of GHB811 cotton would have no effect on emission sources associated with cotton cultivation. However, GHB811 cotton could potentially help mitigate impacts on air quality via improvements in weed management options, which could facilitate use of conservation and no-till practices. To the extent of GHB811 cotton, as a weed management tool, helps sustain, or in some cases facilitate a return to, conservation and no-till practices in cotton, benefits to air quality would be expected compared to current trajectory under the No Action Alternatives.

Glyphosate, isoxaflutole, and glufosinate, herbicides proposed for use with GHB811 cotton, are characterized as having low-volatility (NPIC 2018; PPDB 2018b, a). Consequently, use of these with GHB811 cotton is not expected to present a significant risk to air quality any more than would already occur under the No Action Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

Animal species in cotton production fields and adjacent environments are potentially directly affected by fertilizers, pesticides, engine emissions, noise and erosion. They are affected indirectly from the effects of habitat loss and fragmentation from conversion of natural lands to agricultural fields including the corresponding typical increase in surrounding edge habitat.

No Action Alternative: Animal Communities

Under the No Action Alternative, terrestrial and aquatic species would continue to be affected by current land use and agronomic practices and inputs associated with cotton production no differently than they are now. These include exposure to practices associated with the types of cotton currently being grown (96% of which are GE; USDA-ERS 2017c), including tillage, planting and harvesting, pesticide and fertilizer applications, and the use of agricultural equipment.

Growers would continue to choose certain pesticides based on weed, insect, and disease pressures. Agricultural production of nonregulated HR GE and non-GE cotton would continue to utilize EPA-registered pesticides. The risks of pesticide use on wildlife and wildlife habitat are assessed by the EPA during the pesticide registration process and are regularly reevaluated by the EPA for each pesticide to maintain its registered status under FIFRA. Off-site impacts are diminished when pesticides are applied in accordance with label instructions. The EPA's process ensures that each registered pesticide continues to meet the highest standards of safety to protect human health and the environment. These standards would maintain the current range of potential impacts from the No Action Alternative on non-target terrestrial and aquatic species.

Due to the continued emergence of HR weeds, certain growers in some cropping systems may increase herbicide use to mitigate the impacts of HR weeds on crop yield (Kniss 2012). In addition, if more aggressive tillage practices are implemented as a means of weed suppression, it could possibly diminish the benefits to wildlife provided by conservation tillage practices.

Preferred Alternative: Animal Communities

Under the Preferred Alternative, the direct and indirect impacts on animals would be similar to those under the No Action Alternative. The only difference in potential risks to animals, relative to cotton production, would be those potentially presented by isoxaflutole and the *2mepsps* and *hppdPfW336-1Pa* transgenes and their gene products. Use of isoxaflutole would be new in cotton production.

Several studies have examined the toxicity of isoxaflutole to wildlife. Based on studies conducted with mallard duck and bobwhite quail, isoxaflutole and its degradants are considered practically non-toxic to avian species on an acute basis (LD50 > 2,150 mg/kg) [20] and slightly toxic on a sub-acute basis (5-day LD50 > 4,255 ppm). Isoxaflutole is practically non-toxic to rats (LD50 > 5,000 mg/kg) and honey bees (LD50 > 100 ug/bee) (US-EPA 1998a). In freshwater aquatic organisms, isoxaflutole is moderately toxic to rainbow trout (96-hour LC50 > 1.7 ppm) and bluegill sunfish (96-hour LC50 > 4.5 ppm).[21] It is also moderately toxic to *Daphnia magna* (48-hour EC50 >1.5 ppm) (US-EPA 1998a).[22] In brackish and marine organisms, isoxaflutole is highly toxic to mysid shrimp (96-hour LC50/EC50 = 0.018 ppm), moderately toxic to the eastern oyster (96-hour LC50/EC50 = 3.3 ppm), and moderately toxic to the sheepshead minnow (96-hour LC50 > 6.4 ppm) (US-EPA 1998a).

Bayer previously consulted with the FDA on the marketing of GHB614 cotton, which is comprised of the *2mepsps* gene and corresponding 2mEPSPS protein. The FDA had no concerns regarding cottonseed and cottonseed-derived products from GHB614 cotton (US-FDA 2008). Similarly, the FDA consulted with Bayer on GE FG72 soybean, which has dual resistance to glyphosate and isoxaflutole and is comprised of both the *2mepsps* and *hppdPfW336-1Pa* genes. The FDA had no concerns regarding food and feed derived from FG72 soybean (US-FDA 2012).

The *epsps* gene and enzyme product have well understood biological activities. The plant-trait combination of *epsps* with various crops (corn, canola, cotton, soybean) has been extensively reviewed for potential adverse human health effects (ILSI-CERA 2011). The EPSPS enzyme occurs naturally in plants and microorganisms; wildlife are potentially exposed to EPSPS through environmental sources on a daily basis worldwide. The *2mepsps* coding sequence in GHB811 cotton was cloned from corn (*Zea mays*). Previous evaluations of *epsps* genes and their enzyme products (EPSPS enzymes) have shown that they do not share amino acid sequence similarity to known toxins and are unlikely to serve as human allergens (ILSI-CERA 2011). Due to the negligible risk EPSPS proteins pose, the EPA has issued permanent exemptions from food

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[20] LD_{50} – Lethal dose for 50% of a population:

[21] LC_{50} – Lethal concentration for 50% of population.

[22] EC_{50} – The effective concentration at which a respsone is observed in at least 50% of a population.

and feed tolerance limits for CP4 EPSPS (derived from *Agrobacterium* spp.) in all crops in the United States (US-EPA 2007). It is therefore unlikely the 2mEPSPS in GHB811 cotton (derived from corn) presents any risk to wildlife.

The *hppdPfW336-1Pa* gene in GHB811 cotton encodes for the HPPD W336 protein. HPPD enzymes, a group of biochemically and structurally related proteins, are ubiquitous in commonly consumed food plants and animals. HPPD is ubiquitous in nature, found in taxa from all kingdoms: bacteria, fungi, plants, and animals. For example, HPPD amino acid sequences have been identified in bacteria such as *Streptomyces avermitilis* (Denoya et al. 1994), plants such as *Arabidopsis thaliana* (Garcia et al. 1999), and humans (Ruetschi et al. 1993).

It is unlikely that the *2mepsps* and *hppdPfW336* genes and their products that occur in GHB811 cottonseed present any risk to animals. Data submitted by Bayer indicate that GHB811 cotton is essentially equivalent to non-transgenic cotton based on its compositional analysis.

4.4.2 Plant Communities

No Action Alternative: Plant Communities

Denial of the petition, which would correspond to the No Action Alternative, would have no effect on plants. As a regulated article, GHB811 cotton may undergo APHIS authorized field testing. During field testing, herbicides may be used to control weeds in GHB811 cotton crops, and this would have no lasting effect on plant communities in and around the authorized field test site. Any herbicide used must be registered with the EPA and applied according to the EPA label requirements. There are no reasonably foreseeable adverse impacts on plant communities that could result from the field testing of GHB811 cotton.

Preferred Alternative: Plant Communities

Because the agronomic practices and inputs that will be used for GHB811 cotton production will be similar to those for the No Action Alternative except for applications of isoxaflutole, the potential impacts on vegetation close to cotton fields are virtually the same under both the Preferred and No Action Alternatives. The agronomic and phenotypic characteristics of GHB811 cotton have been evaluated in field trials. GHB811 cotton has been shown to be phenotypically and agronomically similar to other commercially grown cotton varieties. However, isoxaflutole is highly toxic to terrestrial plants (EC25 = 1 X 10-5 pounds a.i./acre), which is one reason it is a restricted use herbicide (US-EPA 1997, 2001c). Due to the low vapor pressure of this herbicide, and due to the fact that it is only to be applied using ground equipment, risk to non-target plant species from drift and volatilization is not expected from isoxaflutole (US-EPA 1998a).

Isoxaflutole and Potential Impacts on Plants

Isoxaflutole is readily degraded by light though a process called photolysis, and soil microbes, into two degradation products: diketonitriles identified as RPA 202248 and RPA 203328 (US-EPA 1998a). Both degradates are highly soluble in water and can persist and accumulate in surface water and groundwater (US-EPA 2001a, b; DATCP 2002). Isoxaflutole has a photolytic half-life in water of 6.7 days. The degradation product RPA 202248 is stable in water, with a half-life of about 60 days in aerobic soils. The degradation product RPA 203328 is also stable in water but has a much longer half-life in soils, 977 days (US-EPA 1998a).

The EPA issued a conditional registration in September 1998 (US-EPA 1998b) due to concerns regarding possible water contamination, and effect non-target plants, including vegetable crops. Subsequent to the 1998 conditional registration, the EPA required several small-scale studies to find out whether isoxaflutole would contaminate surface and groundwater (US-EPA 1997, 2001c, b). The results of these studies indicated that use of surface or groundwater contaminated with isoxaflutole or its degradates could damage sensitive crops (US-EPA 2001c, b). Consequently, isoxaflutole has been conditionally registered since 1999; it is a Restricted Use Pesticide (US-EPA 2011b, d).

Current EPA label requirements restrict isoxaflutole use in certain soil types and in certain areas to prevent leaching into groundwater and run-off to surface waters (Bayer 2013, 2017c). Further restrictions include prohibition of applications made from aircraft or through irrigation systems, and a requirement that ground-based treatments can only be made by spray applications and certified pesticide applicators. Because of these concerns, certain states, such as Wisconsin, likewise restrict the use of isoxaflutole in agriculture.

Volunteer GHB811 Cotton

In the event GHB811 cotton presents as a volunteer, the risks to wild plants and agricultural productivity from volunteer cotton are low because volunteer cotton is easily managed (Morgan et al. 2011). Except for glyphosate and HPPD inhibitor based herbicides, GHB811 cotton is expected to be sensitive to the same herbicides as other cotton varieties, so volunteers could be effectively controlled by herbicides with other MOAs. Herbicides with such MOAs as ALS inhibitors, chloroacetamide, PPO inhibitor, Photosystem I (PSI) disruption, Photosystem II (PSII) inhibitor, synthetic auxin, and tubulin inhibitor classes, could be used on volunteer early stage cotton. Agronomic practices such as appropriate variety selections, crop rotation, and rotation of herbicides with different MOAs could also be used to avoid or manage volunteer cotton resistance to one or a few herbicides.

Invasiveness and Weediness of GHB811 Cotton

Agronomic studies conducted by Bayer tested the weediness potential of GHB811 cotton and found that it is no different than conventional cotton in this regard. No differences were detected between GHB811 cotton and non-GE cotton in growth, reproduction, or interactions with pests and diseases, other than the intended effect of HPPD and glyphosate resistance (Bayer 2017b).

Two cultivated (*G. hirsutum*, upland cotton and *G. barbadense*, Pima or Egyptian cotton) and two wild species of cotton (*G. thurberi* and *G. tomentosum*) grow in the United States and its territories. Available evidence indicates that there is a low potential for introgression of transgenic material from GHB811 cotton to *G. tomentosum* or to native or naturalized *G.*

barbadense. There is no evidence that any of the genetic elements used in GHB811 cotton would increase the rate of outcrossing or gene introgression of GHB811 cotton relative to non-transformed cotton.

G. hirsutum is the most widely cultivated species, comprising 97% of the U.S. cotton planted. *G. barbadense* is grown in Arizona, California, New Mexico, and Texas, but no longer widely grown as an agricultural commodity in Hawaii. Naturalized populations of *G. barbadense* grow in Puerto Rico, the Virgin Islands and most of the major Hawaiian Islands. The two wild species of cotton native to the United States, *G. thurberi* and *G. tomentosum*, grow in Arizona and Hawaii respectively. *G. hirsutum* is tetraploid and incompatible with diploid species such as *G. thurberi*. Plants from these two groups do not normally hybridize and produce fertile offspring in natural settings, and experimental crosses are difficult. In contrast, *G. hirsutum* is sexually compatible with the tetraploids *G. barbadense* and *G. tomentosum* and can form viable and fertile progeny with both species (USDA-APHIS 2018). Thus, unassisted outcrossing and gene introgression could potentially occur in areas where these species are co-located.

Except for the wild and cultivated cotton species discussed above, choosing the Preferred Alternative would not result in changes to the plant communities in or around cotton fields. Therefore, there are no changes in potential impacts to plant communities under the Preferred Alternative when compared to the No Action Alternative.

4.4.3 Soil Microorganisms

No Action Alternative: Soil Microorganisms

Possible impacts to soil microbiota would not change under the No Action Alternative. Agricultural practices and inputs, such as tillage and pesticide applications, are known to impact soil microbial populations, species composition, colonization, and associated biochemical processes. The practices and inputs currently used in cotton production are unlikely to change under the No Action Alternative. Limited cultivation of GHB811 cotton in field trials as a regulated article is not expected to have any lasting adverse impacts on soil microbial communities.

Preferred Alternative: Soil Microorganisms

The potential impacts on soil microbiota under the Preferred Alternative are no different than those under the No Action Alternative. One factor that influences a grower’s selection of agricultural practices is weed management. There is a trend among growers toward increased use of differing herbicides to control HR weeds in different cropping systems (Owen 2011; Heap 2017). These trends are expected to be similar under the No Action and the Preferred Alternatives.

Glyphosate resistance is conferred through a gene (*epsps*) that is naturally produced by plants, bacteria, and soil bacterium (Funke et al. 2006). The *2mepsps* gene that encodes for the 2mEPSPS protein in GHB811 cotton is derived from corn (*Zea mays*). Literature reviews of the *epsps* gene and gene product (enzyme), which encompass data from peer-reviewed research and regulatory assessments, concluded that for the species and environments that were evaluated, the expression of EPSPS in GE plants has not been found to have negative impacts on other organisms in the environment (ILSI-CERA 2011). Due to the negligible risk posed by EPSPS, the EPA has exempted EPSPS from food tolerance limits from products derived from GE plants that express the EPSPS trait (US-EPA 2007).

The *hppdPfW336-1Pa gene* encodes for the HPPD W336 protein. The *hppdPfW336-1Pa* coding sequence was developed by introducing a single point mutation to the wild type *hppd* gene derived from *Pseudomonas fluorescens*, which naturally occurs in soils.

GHB811 cotton has been determined to be agronomically and compositionally similar to other nonregulated cotton varieties. Based on the data presented by Bayer, the cultivation of GHB811 cotton is not expected to impact microbial populations and associated biochemical processes in soil any differently than those GE HR varieties currently cultivated.

4.4.4 Biodiversity

No Action Alternative: Biodiversity

The impacts of commercial cotton production on biodiversity within and surrounding crop fields, whether traditional or GE varieties, would not change under the No Action Alternative. GHB811 cotton would continue to be regulated and may continue to undergo APHIS permitted authorized field trials. The agronomic practices and inputs used during field trials, such as planting, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment would have limited short-term impacts on wildlife in the area of the field test. Given the limited acreage and transient nature of field trials (from one to several years), impacts on biodiversity in the areas where GHB811 cotton may be field tested are unlikely.

Preferred Alternative: Biodiversity

Approval of the petition, and subsequent commercial production of GHB811 cotton, would impact biodiversity in and around GHB811 cotton crops no differently than that of current conventional and GE cotton cropping systems. Other than its HR traits, GHB811 cotton is agronomically and phenotypically equivalent to non-GE cotton. As previously discussed in this section, the trait genes and their gene products, which occur naturally in soils and soil organisms, are unlikely to present any risk to soil biota, wildlife, or plant communities. Glyphosate, glufosinate, and an HPPD inhibitor, such as isoxaflutole, which would be used with GHB811 cotton, have been reviewed by the EPA as to potential ecological impacts, and registered for use in commercial crop production.

4.4.5 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Denial of the petition would have no effect on matters concerning gene flow and weediness associated with commercial cotton production. As discussed above, the United States and its territories has two cultivated (*G. hirsutum*, upland cotton and *G. barbadense*, Pima or Egyptian cotton) and two wild species of cotton (*G. thurberi* and *G. tomentosum*). The potential for introgression of transgenic material from *G. hirsutum* to *G. tomentosum,* or to native or naturalized *G. barbadense*, is considered low. Naturalized populations of *G. barbadense* grow in Puerto Rico, the Virgin Islands, and most of the major Hawaiian Islands. The two wild species of cotton native to the United States, *G. thurberi* and *G. tomentosum*, grow in Arizona and Hawaii respectively. *G. hirsutum* is incompatible with *G. thurberi*; plants from these two groups do not normally hybridize and produce fertile offspring. *G. hirsutum* is, however, sexually compatible with *G. barbadense* and *G. tomentosum* and can form viable and fertile progeny with both species (USDA-APHIS 2018). Thus, unassisted outcrossing and gene introgression could potentially occur in areas where these species are co-located.

Outcrossing rates reported for upland cotton can vary depending on location but are relatively low, even at short distances from neighboring fields in commercial settings (Van Deynze et al. 2011). Generally, gene flow is less than 1% at distances beyond 10 m but can be detected at very low levels (<0.05%) at distances up to 1625 m (1 mile) (Llewellyn et al. 2007; Van Deynze et al. 2011). In general, buffers of 20 m of conventional cotton surrounding GE fields, if needed, prove to be highly effective in isolating GE cotton crops, unless bee or other pollinator numbers are unusually high (Llewellyn et al. 2007).

Preferred Alternative: Gene Flow and Weediness

Available evidence indicates that there is a low potential for introgression of transgenic material from GHB811 cotton into wild *G. tomentosum* or native or naturalized *G. barbadense* (USDA-APHIS 2018). There is no evidence that any of the genetic elements used in GHB811 cotton would increase the rate of outcrossing or gene introgression, relative to non-transformed cotton. While outcrossing is possible, significant impacts on wild cotton populations are unlikely to occur based on the following factors.

G. hirsutum (GHB811 cotton) is incompatible with *G. thurberi*; plants from these two groups do not normally hybridize and produce fertile offspring. *G. hirsutum* is however sexually compatible with *G. barbadense* and *G. tomentosum* and can form viable and fertile progeny with both species. Thus, unassisted outcrossing and gene introgression could potentially occur in areas where these species are co-located. Naturalized populations of *G. barbadense* occur in Puerto Rico, the Virgin Islands, and the Hawaiian Islands, Introgression of GHB811 cotton genes into *G. tomentosum* in Hawaii is likely to be rare, both because of barriers to introgression and because there is no commercial cotton production on these islands. Should outcrossing nonetheless occur, transfer of the transgenes present in GHB811 cotton would not be expected to confer a selective advantage on the hybrid progeny, and hybrid breakdown[23] would be expected to eliminate introgressed genes from the *G. tomentosum* population (USDA-APHIS 2018). Thus, the transgenes present in GHB811 cotton are unlikely to increase the rate of successful transgene

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[23] "Hybrid breakdown" is the poor viability or lethality in F1 hybrids between species.

introgression from GHB811 cotton to *G. tomentosum*. The low level of introgression from *G. hirsutum* to native or naturalized *G. barbadense* observed in the Caribbean and hybrid breakdown suggests that transgene introgression from GHB811 cotton to native or naturalized *G. barbadense* can occur but is likely to be rare (USDA-APHIS 2018). In the absence of herbicide treatment, the transgenic material in GHB811 cotton is unlikely to confer a selective advantage on any hybrid progeny that may result from outcrossing. Thus, the transgenes present in GHB811 cotton are unlikely to increase the rate of successful transgene introgression from GHB811 cotton into native or naturalized *G. barbadense* populations relative to the rate of gene introgression from conventional cultivars.

4.5 Human Health

The assessment of potential human health effects from GHB811 cotton considers two aspects of the crop: (1) the potential health effects associated with the introduced *2mepsps* and *hppdPfW336* genes and their products and (2) associated pesticides used in GHB811 cotton production.

No Action Alternative: Human Health

Denial of the petition would have no direct or indirect effects on human health or welfare. GHB811 cotton would remain a regulated article and field testing or movement of GHB811 cotton would be conducted under APHIS permits or notifications. GE and non-GE cotton would continue to be cultivated for products for human consumption (i.e., oil, feed, and fiber). Oilseed and cotton supplies for the general public would be unaffected.

Preferred Alternative: Human Health

Approval of the petition would not be expected to present any risks to human health that differ from the No Action Alternative. GHB811 cotton does not differ compositionally from other cotton varieties currently in production and is therefore not expected to pose any public health risks associated with dermal contact with cotton fiber, such as in clothing produced with GHB811 cotton. The only potential human health risks are those associated with pesticide use. This would be the first GE cotton resistant to HPPD inhibiting herbicides (which include isoxaflutole). As reviewed below, it is highly improbable that the *2mepsps* and *hppdPfW336* genes and their products present any risk to human health.

Safety of GHB811 cotton: 2mEPSPS and hppdPfW336-1Pa genes and respective EPSPS and HPPD W336 proteins

APHIS considers the voluntary FDA consultation process in evaluating potential impacts on human health. Bayer submitted a Premarket Biotechnology Notification to the FDA on April 17, 2017. Bayer will submit an application to the EPA requesting the use of an HPPD inhibitor herbicides with GHB811 cotton.

Bayer previously consulted with the FDA on the marketing of GHB614 cotton, which comprises the same *2mepsps* gene introduced into GHB811 cotton. The FDA stated on conclusion of the consultation that they had no further questions concerning cottonseed and cottonseed products derived from GHB614 cotton (US-FDA 2008). Similarly, the FDA consulted on GE FG72 soybean, comprised of both the *2mepsps* and *hppdPfW336-1Pa* genes. The FDA stated on conclusion of the consultation that they had no further questions concerning products derived from FG72 soybean (US-FDA 2012).

In addition to FDA consultation, foods derived from GE plants undergo a safety evaluation among international agencies before entering foreign markets, such as reviews by the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (FAO/WHO 2017). For example, in 2015, EFSA evaluated FG72 soybean (which is comprised of HPPD W336 and 2mEPSPS) and had no concerns regarding potential human health effects from this soybean variety (EFSA 2015). Most governments incorporate Codex Alimentarius principles and guidelines established by the World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) in their review of foods derived from GE crop plants (FAO/WHO 2017).

The *epsps* gene and its enzyme product have well understood biological activities. The plant-trait combinations of *epsps* with various crops (corn, canola, cotton, soybean) have been reviewed for potential adverse environmental (ILSI-CERA 2011) and human health effects (EFSA 2017). The EPSPS enzyme occurs naturally in plants and microorganisms and humans are potentially exposed to EPSPS through environmental sources on a daily basis, worldwide. The *2mepsps* coding sequence in GHB811 cotton was developed by introducing two point mutations to the wild-type *epsps* gene cloned from corn (*Zea mays*). Previous evaluations of *epsps* genes and their EPSPS enzyme products have shown that the EPSPS protein does not share any amino acid sequences similar to known toxins or allergens (ILSI-CERA 2011). No forms of EPSPS have been reported to present any risk to human or animal health (US-EPA 2007; EFSA 2017). *2mEPSPS* has been previously evaluated by FDA in GE corn, soybean, and cotton. The FDA stated on conclusion of these consultations that they had no further questions concerning the products derived from these varieties (US-FDA 2017b).

The *hppdPfW336-1Pa* gene in GHB811 cotton encodes for the HPPD W336 enzyme. HPPD enzymes, a group of biochemically and structurally related proteins, are ubiquitous in nature; found in taxa from all kingdoms: bacteria, fungi, plants, and animals. For example, HPPD amino acid sequences have been identified in bacteria such as *Streptomyces avermitilis* (Denoya et al. 1994), plants such as *Arabidopsis thaliana* (Garcia et al. 1999), as well as humans (Ruetschi et al. 1993). HPPD has been characterized from a variety of food sources, such as carrot (Garcia et al. 1997), swine (Endo et al. 1992), and cattle (NCBI 2017).

In consideration of these factors, it is highly unlikely that the *2mepsps* and *hppdPfW336* genes and their products, which occur in GHB811 cottonseed, present any risk to human health. It should be noted that the *2mepsps* and *hppdPfW336* genes and their products would not normally be present in processed cottonseed oil derived from GHB811 cotton; the refining process for cottonseed oil includes heat, solvent, and alkali treatments that remove and destroy proteins. While short fragments of nucleic acids, degraded DNA, may be detected in refined oils (Hellebrand et al. 1998), it has generally been shown that refined oils do not contain proteins (e.g.,Martin-Hernandez et al. 2008). Thus, the intact *2mepsps* and *hppdPfW336* genes and their protein products would only be present in whole seed and meal.

Safety of Glyphosate

Glyphosate use consistent with current EPA label requirements presents a reasonable certainty of no harm to human health. There has been debate, however, as to the potential carcinogenicity of glyphosate. Based on current data, it is unlikely that glyphosate presents a risk to human health as a carcinogen. The International Agency for Research on Cancer (IARC) recently classified glyphosate as probably carcinogenic to humans (Group 2A) (IARC 2015). However, the EPA does not find evidence to support this classification, concluding from its own review of available scientific literature and data that there is no information that supports a carcinogenic classification for glyphosate. The EPA published its *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* in 2016, in which it concluded that, overall, animal carcinogenicity and genotoxicity studies are consistent and do not demonstrate a clear association between glyphosate exposure and carcinogenic potential (US-EPA 2016b). The Agency’s proposed classification is that glyphosate is not likely to be carcinogenic to humans at doses relevant for human health. Glyphosate is currently undergoing registration review, the EPA’s periodic review of pesticide registrations required under the law to ensure that each pesticide continues to satisfy the statutory safety standards for registration. The draft risk assessments and supporting documents will be available in glyphosate’s registration review docket EPA-HQ-OPP-2009-0361 on www.regulations.gov in 2018. The EPA will open a public comment period for the draft risk assessments, evaluate the comments received, and consider any potential risk management options for this herbicide.

The FIFRA Scientific Advisory Panel (SAP) members, an oversight panel, agreed with the EPA that, based on the evidence presented in the EPA Issue Paper (US-EPA 2016b), there is no reliable evidence of an association between glyphosate exposure and the development of any solid tumor, or between glyphosate exposure and leukemia or Hodgkin’s lymphoma (FIFRA-SAP 2016). However, some SAP members noted that the epidemiologic data are still limited and that none of the studies have considered glyphosate’s effects on manufacturing workers or others who may have relatively highly exposures. Some panel members indicated that this was a critical data gap in the EPA review of glyphosate (FIFRA-SAP 2016). The SAP also agreed with EPA that available studies do not link glyphosate exposure to multiple myeloma (MM) (FIFRA-SAP 2016). A recent prospective cohort study conducted among 54,251 U.S. agricultural workers, farmers, and their families reports that there are no associations between glyphosate use and overall cancer risk or with total lymphohematopoietic cancers, including non-Hodgkin lymphoma (NHL) and multiple myeloma (Andreotti et al. 2017).

Safety of Isoxaflutole

Isoxaflutole-containing herbicides could be used with GHB811 cotton if the EPA approves the registration for its use on this GE cotton variety. This would be the first use of isoxaflutole in cotton production, if approved by the EPA. Isoxaflutole does not present significant human health hazards (discussed below), although its physical characteristics do present risks for contamination of surface and groundwater (discussed in *Section 4.3.1 – Water Resources*, and *Section 4.4.2 – Plant Communities*).

The EPA conducted a human health risk assessment for isoxaflutole use on GE soybean (US-EPA 2011e). Isoxaflutole is a category III pesticide, which means it requires caution while using, but is not particularly harmful. The EPA has determined that isoxaflutole has low acute oral, dermal, and inhalation toxicity (characteristics that correspond to Category III); it is neither a dermal irritant, eye irritant, nor a dermal sensitizer (US-EPA 2011c). For example: the acute oral toxicity for rats is a LD50 > 5000 mg/kg; acute dermal toxicity a LD50 > 2000 mg/kg; and acute inhalation toxicity a LC50 > 5.23 mg/L (US-EPA 1998a). Although the EPA has classified isoxaflutole as a probable (B2) human carcinogen, this risk is estimated to be below EPA's established level of concern for life-time cancer risk (US-EPA 1998a, 2011c). The EPA estimates the aggregate cancer risk from isoxaflutole and its degradates in food and water for the general population to be negligible (on the order of less than 1 in a million). Isoxaflutole is carcinogenic to rats at a dose of 500 mg/kg/day, which is an experimental dose greater than what humans or wildlife would ever encounter (US-EPA 2011c). The EPA concluded that acute, chronic, and cancer aggregate exposure and risk estimates are not of significant concern (US-EPA 2011c). APHIS is not aware of any increased risks associated with the combined exposure to isoxaflutole and glyphosate (synergistic effects). Given the levels of risks associated with these compounds, it is unlikely that their combined exposure would result in an increased risk to human health.

The FDA and USDA monitor foods for pesticide residues to enforce tolerance limits and ensure protection of human health (USDA-AMS 2017a). The EPA uses the USDA Pesticide Data Program (PDP) to prepare pesticide dietary exposure assessments pursuant to the Food Quality Protection Act. Pesticide tolerance levels for glyphosate have been established by the EPA for a wide variety of commodities, including cottonseed (40 parts per million), as described in 40 CFR §180.364. The EPA recently established isoxaflutole tolerances for isoxaflutole-resistant soybean (US-EPA 2011f), but not as yet for cotton. Bayer will submit an herbicide label expansion request to the EPA for the use of isoxaflutole-based herbicides with GHB811 cotton (Bayer 2017b).

Because of concerns for the parent compound and degradates to contaminate drinking water, isoxaflutole is a Restricted Use Pesticide (US-EPA 2011c). For example, current EPA label requirements restrict use in certain soil types and in certain areas to prevent leaching into groundwater and run-off to surface waters (Bayer 2013, 2017c). Further restrictions include prohibition of applications made from aircraft or through irrigation systems, and a requirement that ground-based treatments can only be made by spray applications and certified pesticide applicators. Certain states, such as Wisconsin, likewise restrict the use of isoxaflutole in agriculture.

4.6 Worker Safety

No Action Alternative: Worker Safety

Denial of the petition for GHB811 cotton would have no effect on the safety of those working in cotton production. The hazards posed to agricultural workers, and protections provided them, would remain unaffected. The use of herbicides on cotton crops, both in terms of the types of chemistries and quantity of herbicides used on cotton crops, as well as other agronomic inputs, would be unaffected by denial of the petition. As described in *Section 3.5.3 – Worker Safety*, on November 2, 2015, the EPA revised the Worker Protection Standards (WPS) (40 CFR Part 170) to implement stronger protections for agricultural workers, handlers, and their families. Most of the revised WPS requirements became effective on January 2, 2017, with further revisions implemented as of January 2, 2018.

Preferred Alternative: Worker Safety

Occupational exposure to pesticides that would be used on GHB811 cotton can occur through inhalation and dermal contact at workplaces where these compounds are produced or used. The potential for exposure of workers to glyphosate and isoxaflutole under the Preferred Alternative is not expected to differ from that which may occur under the No Action Alternative. Certain weed control operations, such as tillage with heavy farming equipment, can lead to worker accidents. Tractors are the main cause of accidental deaths on farms (OSU 2018).

Bayer intends to request from the EPA modification of registration for a new use of isoxaflutole with GHB811 cotton. Based on its initial review, the risk to workers from short and intermediate exposure to isoxaflutole does not exceed the EPA’s level of concern (US-EPA 1998a). Isoxaflutole is more hazardous than glyphosate in part because it is classified by EPA as a probable (B2) human carcinogen. Therefore, although the risk is low, with respect to carcinogenicity, it presents a greater risk to workers than glyphosate. The EPA estimates that the aggregate cancer risk from isoxaflutole and its degradates in food and water for the general population is less than one case per million, which is below the EPA’s established level of concern for lifetime cancer risk (US-EPA 1998a, 2011c).

The EPA use requirements for pesticides are intended to mitigate any potential impact on human health and the environment. Once registered, a pesticide may not be legally used unless the use is consistent with the guidelines and application restrictions on the pesticide's label (i.e., Bayer 2013, 2017d). Used in accordance with the EPA label requirements, glyphosate, isoxaflutole, and other pesticides that may be used with GHB811 cotton are expected to present only minor health risks to workers. The EPA WPS (40 CFR Part 170) would be the same as that described for the

No Action Alternative. APHIS assumes that agricultural workers applying pesticides to GHB811 cotton will adhere to these label use and WPS requirements.

On March 1, 2011, the EPA completed a search for isoxaflutole incidents in the Agency's Incident Data System and none were identified. Based on the lack of incident cases reported, there does not appear to be worker safety concerns at this time regarding isoxaflutole use in U.S. agriculture (US-EPA 2011b, d).

Considering these factors, worker health and safety risks under both alternatives are substantially the same. A determination of nonregulated status for GHB811 cotton does not appear to present any more risk to worker safety than expected under the No Action Alternative.

4.7 Animal Health

Processing of cotton generally provides cottonseed meal, cottonseed hulls, and whole cottonseed to be utilized in the animal feed industry as sources of protein, fiber, and energy. Whole cottonseed, cottonseed meal, hulls, and cotton gin trash are used in animal feeds for cattle, sheep, goats, horses, poultry, swine, fish, and shrimp.

No Action Alternative: Animal Health

Denial of the petition would have no effect on the quality or availability of animal feed or on animal health and welfare. Under the No Action Alternative, cottonseed-based animal feed would remain available from currently cultivated conventional and GE cotton varieties. No change in the availability of these crops as a source of animal feed is expected under the No Action Alternative.

Preferred Alternative: Animal Health

As discussed for human health considerations, approval of the petition is unlikely to have any effect on animal health and welfare. The two introduced genes and their protein products in GHB811 cotton are unlikely to have any effect on the nutritional quality of animal feed derived from GHB811 cotton. Bayer previously consulted with the FDA on GE FG72 soybean, which comprises both the *2mepsps* and *hppdPfW336-1Pa* genes and their products. The FDA stated on conclusion of the consultation that they had no further questions concerning products derived from derived from FG72 soybean (US-FDA 2012). The *2mepsps* gene in GHB811 cotton was derived from corn, which is widely used for animal feed. HPPD occurs naturally in barley (Falk et al. 2002), swine (Endo et al. 1992), and cattle (NCBI 2017). It is therefore highly improbable that animal feed derived from GHB811 cotton seed would have any adverse effects on animal health and welfare. The EPA label use requirements and restrictions for herbicide formulations with isoxaflutole specifically address surface and groundwater concerns and serve to mitigate potential adverse impacts from drinking water contamination (Bayer 2013, 2017d). Based on these factors, the likelihood of adverse impacts on animal health and welfare is low.

4.8 Socioeconomics

4.8.1 Domestic Socioeconomic Environment

No Action Alternative: Domestic Socioeconomic Environment

Cotton commodities markets would be unaffected by denial of the petition. The basic costs to growers in production of cotton crops would likewise be unaffected. As reviewed in *Section 3.7 – Socioeconomics*, management of HR weeds, which are common in U.S. cotton crops, can result in increased costs to growers from the need for increased use of herbicides, tillage, hand hoeing or pulling of weeds, increased field scouting, and winter cover cropping. These costs would be unaffected by denial of the petition.

Preferred Alternative: Domestic Socioeconomic Environment

Approval of the petition and eventual commercialization of GHB811 cotton would have no effect on cotton commodities markets. The primary purpose of GHB811 cotton is to help manage weeds and HR weeds. Currently, over two-thirds of cotton farmers report HR weeds on their farms. Pigweed and horseweed were the dominant resistant weed problems, accounting for 61% and 25%, respectively (Zhou et al. 2015). Weed problems are not evenly distributed among all cotton farms; HR weed populations are a greater problem in southeastern states, such as Georgia and Arkansas, than in other regions (Kniss 2013). Management of extant HR weed populations and preventing their development can be costly to individual farmers. These costs result from the need for more frequent monitoring, increased herbicide applications, hand weeding, tillage, and the related fuel and labor costs. According to USDA-NASS data, total herbicide use on cotton increased from 1999 – 2015, from 2.06 to 3.06 pounds of active ingredient per acre (USDA-NASS 2017a).

Lambert et al. (2017) examined the weed management costs (WMCs) in cotton production in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Louisiana, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Based on their 2012 study, the average costs of managing weeds increased by $98/ha ($40/acre) following the establishment of HR weeds. Post-resistance changes in WMC ranged between $85/ha ($34/acre) and $138/ha ($56/acre), depending on the combination of adopted practices. WMCs increased by $88/ha ($36/acre) when cost-neutral practices were adopted (Lambert et al. 2017).

Since 2004, the year serious GR Palmer amaranth problems were first recognized, U.S. cotton yields have exceeded the long-term trend in seven out of 10 years (Kniss 2013). This would indicate that HR weeds have, to date, not had significant adverse impacts on national cotton crop yields, as is often implied in reviews of HR weeds (Kniss 2013). Farmers in the southern United States have adapted management practices to control HR weed populations by alternating herbicide MOAs, re-introducing tillage, and using cover crops in order to sustain yields (Kniss 2013). These additional weed control practices are costly and some growers with GR weeds may have seen a reduction in their net returns.

The need for effective management of HR weeds has been addressed in part by the development and adoption of stacked-trait varieties of GE crop plants such as GHB811 cotton. Because these varieties allow use of multiple herbicides with different MOAs, the herbicide regimes used in these cropping systems can, in theory, reduce selection for resistant weed biotypes – or rather, reduce the likelihood of survival of weeds inherently resistant to the herbicide MOA. GE crop varieties incorporating two or more HR traits are now common. Stacked-trait cotton varieties comprised less than 1% of planted acres in 2000, and as of 2017 comprised 80% of planted acres (USDA-ERS 2017b). The preference for these varieties results from the development of HR weeds and need for their management.

While stacking traits is a widely practiced strategy, due to the relatively recent introduction of these stacked types of GE crops, the efficacy of this approach and need for proper implementation of the cropping strategy is not well established (NAS 2016). There is a debate within the weed science research community about the benefit of stacking multiple HR traits and the use of multiple herbicides for resistance management. Some agronomists and weed scientists have expressed concern regarding the potential impact of these cropping systems on sustainable weed control. Critics of stacked-trait GE HR varieties assert that these cropping systems are likely to (1) increase the severity of resistant weeds (e.g., resistance to multiple herbicide MOAs), (2) facilitate a significant increase in herbicide use, with potential negative consequences for environmental quality, and (3) deter further research into integrated weed management (Mortensen et al. 2012). This position derives in part from the repeated and singular use of glyphosate on GE GR crops, which led to wide-scale selection for weeds with resistance to glyphosate.

Proponents of GE HR varieties assert that the potential for development of herbicide resistance is a problem for all crops on which herbicides are applied – not just GE crops – and that, with proper management of weeds, development of resistant weed populations can be prevented, or at least minimized. Scientists who believe stacked-trait GE HR varieties in particular are beneficial, assert that such crop varieties provide growers a broader range of options for using multiple MOAs, and rotation of MOAs as part of an IWM program (Halpin 2005; Que et al. 2010; Reddy and Nandula 2012).

Herbicide formulations with isoxaflutole offer an additional weed control option for GHB811 cotton growers to help manage problem weed species and provide an alternative MOA to help slow the spread of HR weeds. GHB811 cotton is the first GE cotton with HPPD resistance, and introduces as new herbicide MOA for use with cotton. To provide economic benefit to growers, GHB811 cotton will have to be used effectively in an IWM program incorporating practices such as herbicide MOA rotation; crop rotation; cultural and mechanical control practices; and equipment-cleaning and harvesting practices that minimize selection and spread of herbicide-resistant weeds (Owen 2011; Mortensen et al. 2012; Shaner and Beckie 2014). These practices are supported through collaborative efforts among federal and state government agencies, university extension services, and farmer organizations to develop crop-specific, cost-effective resistant-management programs that preserve effective weed control in HR crops. Fundamentally, management of and preventing the development of resistant weeds populations requires widespread implementation of IWM through regional cooperation among neighboring growers to achieve better long-term solutions for weed management.

To the extent IWM practices are implemented, there is some evidence that HR weed populations can be reduced and, in some cases, eliminated. For example, it has been shown that weed population densities can be decreased in continuous (non-rotated) GR corn cropping systems incorporating IWM strategies, although reductions in the density of high-risk weed species may take from 2 to 6 years (Gibson et al. 2015; Livingston et al. 2015).

Under both the Preferred and No Action Alternatives, management of extant HR weeds and their ongoing development will remain a concern in commercial agriculture for the foreseeable future. This applies equally to GE and conventional cropping systems. For example, there is a broad array of HR weeds in non-GE wheat, rice, and barley. If APHIS approves the petition for nonregulated status for GHB811 cotton and growers adopt these varieties but do not implement effective IWM programs, it is likely, over time, that HR weed populations in these cropping systems will increase (Mortensen et al. 2012; Shaner and Beckie 2014) in both variety and number, which could lead to further spread of HR weed populations to other fields. The same applies to current conventional and other GE cropping systems. To the extent that recommended IWM practices are implemented with GHB811 HR cotton, namely varieties resistant to 3 different MOAs, it is likely that the rate of development of HR weed populations would be reduced relative to cropping systems using only 1 or 2 MOAs (Mortensen et al. 2012; Shaner and Beckie 2014; Gibson et al. 2015). Sustainable weed management in a GHB811 cropping system will require implementation of IWM programs that effectively integrate chemical, physical, biological, and cultural methods to control weeds, and reduce selection for resistant populations. Grower reliance solely on herbicides for weed management will result in further development of resistant weed populations, including populations resistant to multiple herbicide MOAs (Evans et al. 2015; Gressel et al. 2017).

Fundamentally, prevention will always be cheaper than control or eradication of resistant weed populations. 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, herbicide application, and tillage. Effective weed management also facilitates growers maximizing net returns. Good yields require greater than 95% weed control. Excellent yields require 99% or better control (Cotton-Incorporated 2017). No evidence from the scientific literature supports the idea that stacked-trait GE crop varieties worsen HR weed problems and increase costs. However, the economic benefits of the introduction of GHB811 cotton depend greatly on: the cost of the seed and required herbicides to growers; how well and how broadly growers implement recommended IWM practices in production of GHB811 cotton; and overall efficacy of their weed management program (Frisvold and Ervin 2016; Jussaume and Dentzman 2016).

Damage to Non-target Crops and other Plants from Spray Drift

Because isoxaflutole is toxic at very low concentrations to a variety of terrestrial plants including crop plants, there may be increased risks to other crops in areas where isoxaflutole is used. Isoxaflutole is particularly toxic to cotton, or rather, those varieties that are not resistant to HPPD inhibitors. Isoxaflutole is also phytotoxic to a variety of vegetable crops (i.e., adzuki bean, soybean, alfalfa, carrot, cucumber, navy and black bean, onion, sugar beet, tomato, canola, radish) (Felix and Douglas 2005), although corn and wheat are less susceptible. For example, dry beans, sugarbeets and melons cannot be planted in fields where isoxaflutole treatments have been made within the last 18 months (US-EPA 2011d).

The primary isoxaflutole degradates, RPA 202248 and 203328, are mobile and expected to move off-site to some degree in run-off. These could also move offsite in spray drift and dusts distributed by winds (degradates can persist for several months in soils). However, the main transport mechanism is runoff. Runoff to surface water would be problematic if it were to contaminate irrigation waters (US-EPA 2011b).

Based on these factors, herbicide drift to neighboring crops could cause damage sufficient to result in monetary loss. Two forms of herbicide drift exist, particulate drift and vapor drift. Particle drift occurs with all pesticide applications and is directly associated with droplet size in combination with boom height and wind speeds. Controlling droplet size by using the proper nozzles and operating equipment at the proper pressures will minimize drift more than anything else within the operator’s control. Vapor drift is confined to volatile herbicides and arises directly from spray or evaporation of the herbicide from plant and soil surfaces, which may occur hours after the herbicide has been applied. Glyphosate is applied at later stages in crop development than other herbicides when it is used with glyphosate resistant crops, but it is not particularly prone to herbicide drift issues (Cederlund 2017). Isoxaflutole is also less prone to spray drift than are other herbicides (US-EPA 1997). However, conventional cotton is particularly susceptible to isoxaflutole and exposure to isoxaflutole as a result of drift may impact cotton yield. For isoxaflutole, spray drift exposure from ground application is assumed to be 1% of the application rate (US-EPA 1997, 1998b). Therefore, where isoxaflutole is used, care is required to prevent injury to neighboring crops and non-target plants (Bayer 2013, 2017d). At current application rates for corn (Bayer 2017d), this equates to about 0.002 lbs a.i./acre, which is quite low.

While spray drift is a potential issue for all pesticides, adherence to herbicide label directions would minimize potential issues with spray drift (Bayer 2017d). Subsequent to any approval of Bayer’s petition, the EPA will establish isoxaflutole label requirements for use with GHB811 cotton. In addition, developers commonly require product stewardship agreements with growers who use their products. For example, Bayer provides pesticide stewardship guidance that promotes integrated pest and weed management (Bayer 2017a). As part of this program growers are encouraged to ensure proper herbicide application, including correct timing, full use rates, and appropriate spray volumes and nozzle types to minimize the potential for spray drift.

4.8.2 International Trade Economic Environment

No Action Alternative: Trade Economic Environment

Denial of the petition would have no effect on trade. U.S. cotton production will continue to have a central role in global supply. The United States is the world’s third-largest cotton producer and the leading cotton exporter, accounting for one-third of global trade in raw cotton. Most (about 91%) of the cotton varieties currently cultivated in the United States are GE HR varieties. This trend is unlikely to substantially change for the foreseeable future.

Preferred Alternative: Trade Economic Environment

Approval of the petition is unlikely to have any effects on the global trade of cotton products. To the extent that adoption of GHB811 cotton facilitates growers minimizing or reducing weed populations (which can reduce product quality) and helps control costs, its introduction may enhance the competitiveness of U.S. producers in global markets.

5 CUMULATIVE IMPACTS

CEQ regulations (40 CFR 1508.7) define a cumulative effect as "... the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time." Emissions of air pollutants from a multitude of individual sources, and impairment of air quality, is an example of a cumulative environmental impact.

In Chapter 4, APHIS analyzed individually the environmental consequences that may derive from denial and approval of the petition. As part of that analysis, APHIS considered the potential direct and indirect impacts on those aspects of the human environment considered germane to the petition, and any subsequent commercial production of GHB811 cotton. In this chapter, APHIS considers the potential cumulative impacts that could derive from APHIS' decision on the petition.

5.1 Assumptions and Uncertainties

If there are no direct or indirect impacts associated with those aspects of the human environment discussed in Chapter 4, APHIS assumes there can be no cumulative impacts. Further assumptions and uncertainties that are part of evaluation of potential cumulative impacts are summarized as follows.

While certain decisions, such as pesticide application rates are specified by the EPA label use requirements, most decisions about what cultural practices to use, when to apply pesticides, and in what sequence, are largely determined by individual growers. Individual growers vary in their decisions on which of the various cultural practices in crop rotations, planting and harvest dates, the sequence and timing of crop management practices, which varieties and traits are grown, and what tillage and other practices are used. Insect, plant pathogen, and weed control practices also vary among growers. While all pesticides must be applied in strict accordance with their EPA-approved label instructions, growers can determine certain patterns of use. For example, they can determine what products are used, formulation types, dosages, timing, and application methods, as long as they are used within the ranges allowed by the labels. Growers can also deploy mechanical and cultural control methods. These management practices attempt to achieve optimal crop yield and quality. They may also impact soil, water, air, and biological resources.

Bayer intends to cross GHB811 cotton and offer as commercial products stacked-trait cotton varieties that will be resistant to isoxaflutole, glyphosate, and glufosinate (Bayer 2017b). In addition, GHB811 cotton may be stacked with traits for insect (lepidopteran) resistance (Cry1Ab, Cry2Ae, and Vip3Aa19). It is anticipated that isoxaflutole will be labeled for pre-emergence and early post-emergence use with GHB811 cotton (Bayer 2017b). Bayer states that it is seeking a registration label from the EPA that will support tank mixes of isoxaflutole with glufosinate, glyphosate, and other herbicides labeled for use on cotton (Bayer 2017b). Stacking GHB811 cotton with traits that confer resistance to herbicides with different MOAs would offer growers more choices for herbicide use as part of integrated weed management program.

APHIS would not regulate cotton varieties derived from nonregulated GHB811 cotton. It is reasonably foreseeable that other new GE cotton varieties will be determined not subject to 7 CFR part 340 regulations in the future, such as those resistant to herbicides, insect pests, or that have enhanced traits. If APHIS makes a determination of nonregulated status for GHB811 cotton, this variety would be available for crossbreeding with current and future GE cotton varieties no longer regulated under 7 CFR part 340, as well as non-GE varieties.

5.2 Land Use and Acreage

Cumulative impacts resulting from an APHIS decision to no longer regulate GHB811 cotton on land use patterns and acreages used to produce cotton are unlikely. Market factors such as demand for cotton fiber, cottonseed meal, and oil, domestic and international supplies of cotton, subsidies provided to cotton farmers, and the suitability of land for cotton production are primary factors that influence land use. Because the site requirements for GHB811 cotton production do not differ from that of other cotton varieties, the availability of GHB811 cotton is not likely to alter current cotton land use patterns. It is expected that, if growers adopt GHB811 cotton, they would substitute GHB811 cotton for other available HR- and non-HR cotton varieties. Most of the cotton grown in the United States is GE cotton. GE varieties of cotton, containing either herbicide resistance, insect resistance, or both traits, comprised 96% of all cotton planted in 2017 (USDA-ERS 2017a).

Based on the information summarized above, APHIS concludes that if APHIS no longer regulates GHB811 cotton, there are no past, present, or reasonably foreseeable actions that would combine with effects of the proposed action to significantly impact current total U.S. cotton acreage, or the areas where cotton is currently grown in the United States.

5.3 Agronomic Inputs and Practices in Cotton Production

5.3.1 Herbicide Use

GHB811 cotton, if commercially produced, would contribute in a cumulative manner to shifts in patterns of herbicide use. To the extent GHB811 cotton is adopted, use of isoxaflutole would increase, glufosinate use may increase, albeit marginally, glyphosate use will likely remain around current rates (it is already widely used in cotton), and use of some other herbicides may decline (in terms of lbs a.i./acre/year). It is possible that there will be future varieties of GE cotton resistant to herbicide MOAs that are not currently utilized in GE varieties. Consequently, GHB811 cotton, in combination with future stacked-trait cotton varieties, would contribute to shifts in the types of herbicides used in cotton. Any such shifts would be subject to EPA use requirements. Region-specific patterns of herbicide use will vary relative to the prevalence and variety of weeds and HR weeds present in the area, grower choice in the variety of cotton grown, as well as the tillage and other practices employed for weed management. Shifts toward utilization of multiple herbicide MOAs in a cropping systems, in rotation, and as part of an IWM program, would be considered largely beneficial. This is further discussed in *Section 5.3.5 – Weed and Weed Resistance Management*.

5.3.2 Tillage

Under the No Action Alternative, increased or more extensive tillage may continue to occur in certain regions where HR weed populations have evolved where they will evolve in the future. As discussed in Chapters 3 and 4, HR weeds in cotton are at least partially responsible for increases in conventional tillage and declines in conservation tillage (CAST 2012), particularly in the Mid-south states. Under the Preferred Alternative, use of GHB811 cotton, a stacked-trait variety resistant to multiple herbicide MOAs (isoxaflutole, glyphosate, and likely glufosinate), would be expected to help in the management of weeds, to include the development of HR weeds, which could reduce the need for tillage. If IWM strategies that use GHB811 cotton are effective in reducing and preventing HR weeds (discussed further below), fewer growers would be expected to use tillage for weed control, which can reduce tillage-induced soil erosion and associated impacts on water quality. For example, an increase in the use of tillage for weed management has occurred particularly for the management of glyphosate resistant Palmer amaranth in cotton. It is expected the GHB811 cotton, as part of IWM program, may prove effective in managing this and other HR weeds.

5.3.3 Fertilizer Use

Adoption of GHB811 cotton is not expected to change the general agronomic inputs associated with cotton production, except to increase isoxaflutole use. There are no cumulative impacts associated with fertilizer requirements.

5.3.4 Insect and Pest Management

Bayer plans to stack GHB811 cotton with insect (lepidopteran) resistant traits (Cry1Ab, Cry2Ae, and Vip3Aa19). Future stacked varieties may also contain insect (lepidopteran) resistant traits (Cry1Ab, Cry2Ae, and Vip3Aa19). Insect-resistant varieties of cotton and corn have largely been found to facilitate reductions in insecticide use. In areas where cultivation of IR cotton is high a decrease in overall insecticide used has been shown (NAS 2016). The use of IR varieties has also been associated with reduced insecticide use in adjacent cropping systems cultivating non-IR varieties, a result of the area-wide suppression of insect pest populations (NAS 2016). For example, several studies have found that the use of IR corn and IR cotton are positively associated with the area-wide suppression of European corn borer and pink bollworm, respectively (e.g., see review by (Fernandez-Cornejo et al. 2014b). These trends in decreased insecticide use in the United States are likely to continue under both the No Action and Preferred Alternatives (NAS 2016).

While future stacked-trait varieties of GHB811 cotton may be insect-resistant, these would only support continued limited use of insecticides, as such stacked-trait varieties would be expected to replace current IR cotton varieties. Because additional acreage allotted to cultivation of stacked-trait IR GHB811 cotton is not expected, further reductions in insecticide use, a cumulative contribution to reduction on overall insecticide use, are unlikely.

5.3.5 Weed Management and Herbicide Resistant Weed Management

With repeated sublethal exposures, certain weeds can, over time, evolve resistance to herbicides that contain a particular active ingredient and there can also be shifts in the weed populations present in a field (Owen and Zelaya 2005b). Evolved resistance to an active ingredient or group of active ingredient compounds with a similar MOA is less likely when herbicides with differing MOAs (i.e., herbicide diversity) are available and used by growers. While herbicide diversity may allay the development of evolved resistance, this alone may not prevent it. Palmer amaranth that is resistant to several different types of herbicide MOAs (Salas et al. 2016) has become widespread throughout cotton-growing states and elsewhere (Heap 2017).

The practice of using multiple herbicide MOAs can potentially help diminish the populations of certain HR weeds and reduce the likelihood for the development of new HR weed populations (Owen 2011; Vencill et al. 2012). The availability of isoxaflutole-based herbicides in cotton would increase the diversity of herbicide MOAs available to growers and by that may reduce the likelihood of evolved resistance. Bayer intends to cross GHB811 cotton with other lines of cotton to produce seeds of stacked-trait cotton varieties resistant to multiple herbicide MOAs, namely isoxaflutole, glyphosate, and glufosinate based herbicides. As a stacked trait cotton with resistance to 3 herbicide MOAs, GHB811 cotton varieties may provide for effective weed and weed resistance management. Such varieties would allow growers to use multiple herbicide MOAs in tank mixtures, reducing the likelihood that HR weed populations will evolve.

As part of IWM, weed resistance management is recommended by academia, weed and pest specialists, and required by the EPA (e.g., (US-EPA 2017f) to mitigate the development of future resistant populations. APHIS assumes that growers will likely employ these management practices to help deter the development of HR weeds, and development of insect resistance, as there are both economic and practical incentives for doing so (Fernandez-Cornejo and Osteen 2015; Livingston et al. 2015). APHIS further assumes that growers would adopt GHB811 cotton, and any potential stacked-trait progeny, based on the efficiencies provided by this variety in maximizing crop yields, and managing insect pests, pathogens, and weeds, to include weed resistance. The EPA is currently evaluating the proposed new uses of isoxaflutole containing herbicides for GHB811 cotton. Isoxaflutole registration would be issued for restricted use and only certified pesticide applicators could apply the product legally.

If GHB811 cotton were no longer regulated and isoxaflutole were registered for use with this variety, herbicide use patterns and application rates could change beyond those discussed above in *Section 5.3.1– Herbicide Use*. In addition to isoxaflutole based herbicides, growers who plant

GHB811 cotton could apply any of the other herbicides registered for use on this variety. They could apply these products alone or in combination, if such applications are allowed by their legally-binding label instructions. Although HPPD inhibitor herbicides other than isoxaflutole exist, the developer has not demonstrated that GHB811 cotton has resistance to commercial application rates of other registered HPPD inhibitor herbicides. APHIS is not aware of any requests to register other HPPD inhibitor herbicides other than isoxaflutole. Furthermore, it would not be legal to use any other HPPD inhibiting herbicides on GHB811 cotton.

Relative to potential cumulative impacts on herbicide use; as shown in Figure 5-1 the rate of application of herbicides (lbs a.i./acre) in cotton increased from 2010 to 2015 (USDA-NASS 2016a; Kniss 2017), yet the number of cotton acres has declined over the same period. This increased use of herbicides may be due in part to the need to apply additional herbicides to control HR weeds, primarily GR weeds (Benbrook 2012; Kniss 2012).

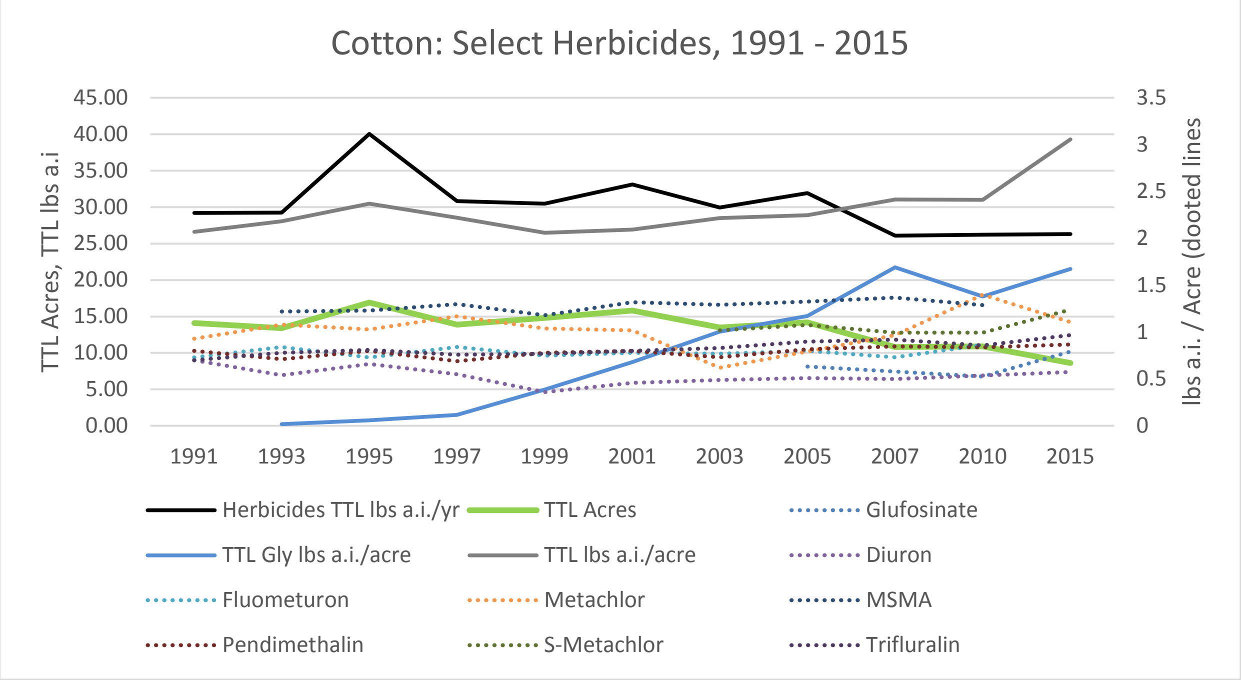

Figure 5-1. Cotton, Herbicide Use, 1991 - 2015
TTL = Total, Gly = glyphosate
Source: (USDA-NASS 2016b)

There are ten different mode of actions (MOAs) currently available for pre-plant (i.e., burndown) and pre-emergence (i.e., at planting) application use in cotton (Table 5-1). There are six different MOAs recommended for early post-emergence applications in cotton, including glyphosate and glufosinate. GHB811 cotton, resistant to isoxaflutole (WSSA Group 27), would add another MOA for pre-emergence and early post-emergence application in cotton, expanding grower options in the management of weeds including HR weeds.

Table 5-1. Herbicides Used in U.S. Cotton Production

Timing	WSSA Group Number*	Mode of action (MOA)	Example active ingredients
Pre-Plant Burndown	2	ALS Inhibitor	trifloxysulfuron, thifensulfuron-methyl, tribenuron, rimsulfuron
	4	Synthetic Auxins	2,4-D
	9	EPSP synthase inhibitor	glyphosate
	10	Glutamine synthetase inhibitor	glufosinate
	14	PPG oxidase	oxyfluorfen, saflufenacil, flumioxazin
	15	Long chain fatty acid inhibitor	s-metolachlor
	22	Photosynthesis I diverter	paraquat
Pre-Plant Incorporated	3	Microtubule assembly inhibitor	pendimethalin, trifluralin,
Pre-emergence (at planting)	2	ALS inhibitor	pyrithiobac
	3	Microtubule assembly disruptor	pendimthalin
	5	Photosystem II inhibitor	prometryn
	7	Photosystem II inhibitor	fluometuron, diuron
	9	EPSP synthase inhibitor	glyphosate
	13	Carotenoid biosynthesis Inhibitor	clomazone
	15	Long chain fatty acid inhibitor	s-metolachlor, acetochlor,
Early Post-emergence	1	ACCase (Acetyl CoA Carboxylase)	fluazifop-p-buytl, fenoxaprop-p-ethyl, clethodim, quizalofop, sethoxydim
	2	ALS inhibitor	pyrithiobac
	7	Photosystem II inhibitor	flumeturon
	9**	EPSP synthase inhibitor	glyphosate
	10***	Glutamine synthetase inhibitor	glufosinate
	15	Long chain fatty acid inhibitor	s-metolachlor, acetocholor

*The Weed Science Society of America herbicide classification system[24] was first published by Retzinger and Mallory-Smith in 1997. A revised system was published in Weed Technology. 2003. Volume 17:605-619
**Only when planting a GE-cotton variety with glyphosate tolerance
***Only when planting a GE-cotton variety with glufosinate tolerance, or using a hooded sprayer to shield non-glufosinate tolerant cotton.

Regardless of whether APHIS approves or denies the petition, HR weeds will remain an issue in most regions where cotton is grown. Considering current trends (discussed in *Section 3.2.5 – Weed Management and Herbicide Resistance in Weeds*), it is possible that the number of acres infested with HR weeds may continue to increase. Growers are expected to become less reliant on glyphosate-containing herbicides because of the prevalence of glyphosate resistant weeds and use additional herbicide MOAs and non-chemical methods to control HR weeds. Changes in management practices will likely include diversifying herbicide MOAs applied to cotton and

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[24] http://www.weedscience.org/Documents/ShowDocuments.aspx?DocumentID=1192

making adjustments to crop rotation, tillage, and hand weeding practices (Wilson et al. 2011). Additional herbicides may be used by certain growers to control HR weeds (Vencill et al. 2012).

It is foreseeable that isoxaflutole could be labeled for pre-emergence and early post-emergence use with GHB811 cotton (Bayer 2017b). Applications of isoxaflutole made pre-emergence or early post-emergence are expected to control a variety of annual weeds. The proposed new label uses would allow tank mixes of isoxaflutole with glufosinate, glyphosate, and other herbicides labeled for use in cotton. There is also a potential for the residual control of weeds for up to six weeks after cotton emergence if isoxaflutole residues are reactivated in soil, which can occur with ≥ 0.5 inches of precipitation or irrigation.

As a stacked-trait variety that would utilize herbicides with 3 different MOAs, GHB811 cotton could contribute, along with future stacked-trait varieties resistant to 3 MOAs, to a reduction in the rate of development of HR weed populations, and in the long term, may help ameliorate the trend of increasing herbicide use for management of resistant weeds in cotton, relative to cropping systems using only 1 or 2 MOAs. For example, isoxaflutole is effective in controlling glyphosate, triazine, PPO, ALS, and auxin resistant weed populations. In regard to HPPD inhibitors, there are 2 resistant weed species in the United States that occur on corn, soybean, and sorghum crops; Palmer amaranth and tall waterhemp have developed evolved resistance to the HPPD inhibitors mesotrione, tembotrione, topramezone, and isoxaflutole (Heap 2017). While, to what extent growers will use GHB811 cotton and the mixtures and rotations of herbicides they may employ is relatively uncertain, a summary of projected uses follows.

Changes in Isoxaflutole Use

If APHIS no longer regulates GHB811 cotton, the EPA registers isoxaflutole based herbicides for use with GHB811 cotton, growers adopt this variety and choose to use isoxaflutole-based herbicides, and other uses of isoxaflutole herbicides remain constant or increase, the total annual use of isoxaflutole in the United States is likely to increase. HPPD inhibitors are currently used on crops rotated with cotton such as corn, sorghum, and small grains. Isoxaflutole, specifically, is currently only registered for use with corn, although it is anticipated that registration for use with GE soybean will occur. APHIS issued determinations of nonregulated status for two GE soybeans, glyphosate and isoxaflutole resistant FG7 (8/21/2013), and HPPD- and glufosinate-resistant SYHT0H2 (7/18/2014). A proposed label for glyphosate and isoxaflutole-resistant soybean is currently under review by EPA (Balance GT soybean) with potential approval in 2018. Soybean is a common rotational crop with cotton. Therefore, GHB811 cotton, and glyphosate- and isoxaflutole-resistant soybean would contribute cumulatively to increased use of isoxaflutole on U.S. crops. Because isoxaflutole controls more than 30 broadleaf weeds, more than 15 grasses, and several important glyphosate-resistant weeds in cotton, including Palmer amaranth, GHB811 cotton may be planted more frequently in states where glyphosate-resistant weed pressure is highest.

It is not possible to provide an accurate estimate of a potential increase in isoxaflutole use with GHB811 cotton. Growers have various GE cotton varieties available to them, and herbicides with different MOAs, from which they can choose and use in rotation. In addition, weed problems are unique and vary among different cropping systems. There are also restrictions on where and how growers can use isoxaflutole. For example, isoxaflutole cannot be used in areas where the surface soil texture is sandy loam, loamy sand or sand; the subsoil texture is loamy sand or sand; the average organic matter (in the upper 12 inches) is less than 2% by weight (Bayer 2013, 2017d). Growers may also not use isoxaflutole in areas receiving less than 15 inches of average annual precipitation that are not supplemented with irrigation (Bayer 2013). States may also impose additional restrictions on isoxaflutole, such as banning its use in certain counties within their jurisdiction. If the EPA approves isoxaflutole for use on cotton, it is likely that some states will impose additional limits on isoxaflutole use. Consequently, any estimate of the extent of potential production of GHB811 cotton would be laced with a high degree of uncertainty. Although reductions in the use of other herbicides or their replacement are likely, quantifying such reduction cannot be reasonably predicted.

It is reasonably foreseeable that other GE HPPD-resistant crops, including cotton varieties, may not be regulated in the future. Development of GE isoxaflutole-resistant crops and/or ones resistant to other HPPD inhibitors would allow growers to apply these herbicides to crops that were previously sensitive to HPPD inhibitor herbicides. This could lead to increased use of HPPD inhibitors on agricultural lands. Such an increase could reduce or eliminate choices available to growers when selecting rotational crops because crops sensitive to HPPD inhibitors could not follow those engineered for resistance to HPPD inhibitors.

Changes in Glufosinate Use

APHIS issued determinations of nonregulated status for 2,4-D and glufosinate-resistant DAS-8191Ø-7 cotton and for dicamba- and glufosinate-resistant MON-887Ø1-3 cotton in 2015, and for glufosinate-resistant T303-3 cotton and GHB119 cotton in 2012. There are also several varieties of GE glufosinate-resistant corn and soybean. Bayer states their proposed label for GHB811 cotton will be for tank mixes of isoxaflutole with glufosinate, glyphosate, and other herbicide active ingredients (Bayer 2017b). GHB811 cotton, if adopted, could potentially contribute in a cumulative manner to increased glufosinate use in the United States. However, because there are currently four different varieties of GE cotton resistant to glufosinate that growers have rapidly adopted (Barnes 2016), any cumulative increased use of glufosinate with GHB811 cotton would be expected to be marginal, if it occurred at all. Currently, about 60% of the cotton varieties available to growers are resistant to glufosinate. Of the 20 cotton varieties most frequently planted in the United States in 2016, nine were glufosinate-resistant (Barnes 2016). In 2015, more than 85% of cotton acreage in Arkansas was planted to varieties resistant to glufosinate (Bourland and Robertson 2015). Glufosinate-resistant varieties have been increasingly planted because they offer an effective control strategy for several difficult to control weeds including GR Palmer amaranth (Barnes 2016). Considering that about 60% of current cotton varieties are resistant to glufosinate, any a cumulative increase in glufosinate use with GHB811 cotton is likely to be limited due to current level of adoption of other glufosinate-resistant cotton varieties.

Changes in Glyphosate Use

Glyphosate has been the most widely used herbicide in U.S. cotton production since the launch of GR cotton varieties in 1998. Because of the current market saturation of GR cotton varieties in the United States (~ 90% of cotton acres), and problems with the management of GR weeds, glyphosate use on cotton is not expected to increase under either the No Action or Preferred Alternatives. Since 2007, the rates that glyphosate-containing herbicides are applied to cotton has remained constant within the range of 1.4 to 1.7 lbs a.i./acre (USDA-NASS 2017a). This is attributed to: 1) a decrease in the efficacy of glyphosate due to the development of GR weeds and, 2) increasing awareness among cotton farmers (and farmers in general) of the importance of weed resistance management, the pitfalls of overreliance on a single MOA, and the recognition of the need for incorporation of multiple MOAs in weed management programs. If GHB811 cotton is no longer regulated, glyphosate use would likely continue at current levels as an active ingredient in herbicide mixtures. There are no reasonably foreseeable cumulative impacts on glyphosate use that would result from approval or denial of the petition.

Likelihood That Use of Isoxaflutole and Glufosinate Will Select for Resistant Weeds

Use of GHB811 cotton could potentially promote development of weed populations resistant to HPPD inhibitors, glyphosate, and glufosinate. As with glyphosate resistance, the increased use of isoxaflutole and glufosinate will increase selection pressure for weeds resistant to their modes of action. At present, glufosinate resistance has emerged in one species, Italian ryegrass (Oregon, California), and HPPD inhibitor resistance in two species, Palmer amaranth (Kansas, Nebraska, Wisconsin) and tall waterhemp (Illinois, Iowa, Nebraska) (Heap 2017). HPPD inhibitors are comprised of three classes of chemicals:

1. Pyrazolones: pyrazolate; pyrazoxyfen; benzofenap; pyrasulfotole; and topramezone
2. Triketones: sulcotrione; mesotrione; benzobicyclon; tembotrione
3. Diketonitriles: isoxaflutole

Five HPPD inhibitors have been available on the market for weed control: isoxaflutole (Balance) in 1998, mesotrione (Callisto) in 2001, tembotrione (Laudis) in 2006, pyrasulfutole (Huskie for small grains) and topramezone (Impact) in 2008. Despite relatively recent market availability, resistance to this class of chemicals has been detected in five U.S. states. To date, among the 2 weeds, Palmer Amaranth (*Amaranthus palmeri*) and Tall Waterhemp (*Amaranthus tuberculatus* (=*A. rudis*)) resistant to HPPD inhibitors, there have been 9 reported unique cases of resistant biotypes (Table 5-2). Several of these have also developed resistance to other herbicides – resistance to multiple MOAs. For instance, Palmer amaranth in Kansas has resistance to three herbicide MOAs including three HPPD inhibitors, mesotrione, tembotrione and topramezone. Only one weed species is reported to be resistant to isoxaflutole, waterhemp (*A. tuberculatus*). While the frequency of use on corn has been limited to about 30% of corn acreage for all herbicides of the class, resistance has developed rapidly, indicating frequent, repeated, and ineffective use of isoxaflutole can readily result in development of resistant weed biotypes. Mesotrione resistant waterhemp developed in Nebraska by 2011 on seed corn production acres, and that occurred after five seasons of repetitive use of mesotrione (Oliveira et al. 2018). Similarly, another population in Illinois after six sequential seasonal applications of multiple HPPD inhibitors, once or twice per season, also became resistant to mesotrione (Hausman et al. 2011).

Table 5-2. HPPD Inhibitor Resistant Weeds

2009	*Amaranthus tuberculatus* (=*A. rudis*)	Iowa	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	atrazine, mesotrione, rimsulfuron, tembotrione, thifensulfuron-methyl, topramezone
2009	*Amaranthus tuberculatus* (=*A. rudis*)	Illinois	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	atrazine, chlorimuron-ethyl, imazethapyr, mesotrione, tembotrione, topramezone
2009	*Amaranthus palmeri*	Kansas	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	atrazine, mesotrione, pyrasulfotole, tembotrione, thifensulfuron-methyl, topramezone
2011	*Amaranthus tuberculatus* (=*A. rudis*)	Nebraska	HPPD inhibitors (F2/27)	mesotrione, tembotrione, topramezone
2011	*Amaranthus palmeri*	Nebraska	HPPD inhibitors (F2/27)	mesotrione, tembotrione, topramezone
2011	*Amaranthus tuberculatus* (=*A. rudis*)	Iowa	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	atrazine, chlorimuron-ethyl, glyphosate, imazamethabenz-methyl, isoxaflutole, mesotrione, thifensulfuron-methyl
2014	*Amaranthus palmeri*	Wisconsin	ALS inhibitors (B/2), HPPD inhibitors (F2/27)	imazethapyr, tembotrione, thifensulfuron-methyl
2014	*Amaranthus palmeri*	Nebraska	HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	atrazine, mesotrione, tembotrione, topramezone
2016	*Amaranthus tuberculatus* (=*A. rudis*)	Illinois	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5), PPO inhibitors (E/14), Synthetic Auxins (O/4)	2,4-D, acifluorfen-sodium, atrazine, chlorimuron-ethyl, fomesafen, imazethapyr, lactofen, mesotrione, tembotrione, topramezone

Source: (Heap 2017)

Selection pressure is strongly related to the repeated use of one or a limited number of herbicide MOAs (Durgan and Gunsolus 2003; Duke 2005). Modeling studies suggest that exclusive use of an herbicide active ingredient can select for HR weeds in as little as five years (Neve et al. 2011). The relative risk that a particular resistant biotype will be selected for is also correlated to the herbicide MOA (Sammons et al. 2007). Herbicide MOAs have been classified according to their risk of promoting weed resistance development. Beckie (2006) lists ALS- and ACCase-inhibiting herbicides as high risk for selection of resistant biotypes, while EPSPS inhibitors (e.g., glyphosate), glutamine synthetase inhibitors (e.g., glufosinate), and synthetic auxins (e.g., 2,4-D) are considered low risk. Pigment inhibitors (isoxaflutole) are considered medium risk. While the risk of development of resistance to glyphosate (EPSPS inhibitors) was considered low, the failure to use best management practices and diversify weed control among mechanical, cultural, chemical, and biological tactics has promoted a rapid increase in emergence of resistant weed biotypes. The potential for resistant weeds development from use of isoxaflutole and glufosinate on cotton would be similar.

Because growers who adopt GHB811 cotton are likely to be those who have had the most difficulty with GR weeds, the selection pressure toward the evolution of biotypes exhibiting multiple resistance to glyphosate, isoxaflutole, and glufosinate is possible; it would be related to the probability of selecting resistance to just isoxaflutole and glufosinate. Therefore, weeds resistant to all three herbicide active ingredients could appear within five years if glyphosate, isoxaflutole, and glufosinate are used repeatedly and exclusively. The Southeast is expected to be a region of concern because GR weeds are present on greater than 90% of cropland (Farm-Industry-News 2013). In this region, GR Palmer amaranth would be at potential risk for selection of biotypes with resistance to different herbicide MOAs.

From a weed management standpoint, selection for resistant biotypes is a function of how mechanical, cultural, chemical, and biological tactics are integrated (Vencill et al. 2012). The greater the diversity of management practices, the less pressure for selection of HR weeds. 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 option for weed management. Reliance on the chemical management of weeds alone will result in the continued emergence of HR weed populations over the long-term.

Herbicide Resistant Corn and Soybean in Rotation with GHB811 Cotton

Crop rotation is fairly common in cotton. The overwhelming majority (77.7%) of southeastern cotton growers use crop rotation (Cotton-Incorporated 2018). Cotton is rotated with corn, soybean, and non-GE crops such as wheat, alfalfa, and peanuts. Farmers indicate that cotton, soybean, and corn are the main crops impacted by weed-resistance problems (Zhou et al. 2015).

In 2015, APHIS issued determinations of nonregulated status for 2,4-D and glufosinate resistant DAS-8191Ø-7 cotton and for dicamba and glufosinate resistant MON-887Ø1-3 cotton. In 2012, determinations of nonregulated status were made for glufosinate resistant T303-3 cotton and glufosinate resistant GHB119 cotton. APHIS has made determinations of nonregulated status for glyphosate and isoxaflutole resistant FG7soybean in 2013, for HPPD inhibitor and glufosinate resistant SYHT0H2 soybean, and for 2,4-D, glufosinate and glyphosate resistant DAS-444Ø6-6 soybean in 2014. While the use of HPPD inhibitors has not yet been registered for use with soybean, a proposed label for glyphosate and isoxaflutole resistant soybean is currently under review by EPA (Balance GT soybean). Isoxaflutole has been used with isoxaflutole tolerant corn varieties since 1998. These isoxaflutole tolerant corn varieties were not genetically engineered; rather, they were produced via crossbreeding.

Growers will need to be mindful when considering rotating any crop resistant to HPPD inhibitors, glyphosate, and/or glufosinate. While some crops commonly rotated with cotton are sensitive to isoxaflutole, certain varieties of corn are not, and soybean requires only a 6-month plant back restriction (NDSU). From the farmer’s perspective, it may be convenient to adopt a new herbicide trait technology in cotton, especially if they are also growing soybean or corn varieties with the same technology, as there could be some advantages in utilizing machinery and ease of crop management (Steadman 2017). However, one of the primary purposes of rotation is to use herbicides with different MOAs. One concern is that cotton farmers will need to ensure that as part of crop rotation they are likewise rotating chemistries. Where crops resistant to HPPD inhibitors, glyphosate, and glufosinate were rotated back-to-back, there would be an increased risk for selection of resistant weeds. Growers utilizing GHB811 cotton will need to develop a crop rotation system that prevents back-to-back growing seasons of the same or similar crops, or crops grown back-to-back that utilize the same herbicide MOAs for weed control. They will need to ensure that herbicides are rotated so that the repeated use of herbicide MOAs during consecutive growing seasons is avoided.

Summary of Potential Cumulative Impacts on Weed and Weed Resistance Management

Selection pressure toward the evolution of weed populations resistant to glufosinate and isoxaflutole, and selection pressure toward the evolution of weeds resistant to both in combination with glyphosate resistance, is possible. GHB811 cotton, if commercially produced, would contribute in a cumulative manner to changes in patterns of herbicide use. Use of isoxaflutole may increase, glufosinate use may increase, albeit marginally, glyphosate use is expected to remain at current levels (in lbs a.i./acre/year), and use of some other herbicides may decline. Region-specific patterns of herbicide use will vary in relation to the prevalence and variety of weeds and HR weeds present in the area, as will the tillage and other practices employed for weed management.

IWM strategies that at best prevent or at least delay development of HR weed populations must be in place to sustain herbicides as effective tools in weed management. Current EPA policy for herbicide registrations associated with a GE herbicide resistance trait includes a registration condition requiring the registrant to develop and implement an herbicide resistance management plan. EPA’s Pesticide Registration Notice 2017-2, *Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship*, provides guidance on labeling, education, training, and stewardship for herbicides (US-EPA 2017f). Prior to commercialization, Bayer will develop a resistance management plan for isoxaflutole herbicide use in GHB811 cotton varieties (Bayer 2017a). Bayer, provides resistance management strategies for crop protection products under their Respect the Rotation™ program.

APHIS assumes that GHB811 cotton will be grown using IWM practices such as those recommended by the Weed Science Society of America (WSSA) and extension services (WSSA 2018a), in accordance with the EPA label requirements, the EPA guidance for herbicide resistance management (US-EPA 2017f), and Bayer stewardship requirements (Bayer 2017a). It is in the best interest of growers to effectively control weeds in their crops. Growers understand that the incidence of HR weeds can increase when IWM recommendations are not followed. Consequently, while potential cumulative impacts on compounding of HR weed problems are possible, they are not considered probable. Instead, the potential for adverse cumulative impacts is expected to be limited by the EPA, Bayer, and grower efforts to utilize herbicides, including glufosinate and isoxaflutole, in a sustainable manner.

If production practices include an IWM program, GHB811 cotton would offer cotton growers additional herbicide diversity and possibly facilitate the control of GR weed populations. EPSPS-, HPPD-, and glutamine-synthetase inhibitor-resistant GHB811 cotton may also prevent, or at least delay, the further development of HR weed populations. Any additional option for managing weeds and weed resistance in the context of multiple crops with various resistance traits can be useful in an IWM framework. However, the eventual selection for weeds resistant to isoxaflutole, glufosinate, and/or glyphosate would, over time, limit the use of this stacked-trait cotton variety and any benefits to weed management it may provide. The benefit of GHB811 cotton to managing weeds is uncertain because individual growers make IWM decisions.

Volunteer Cotton

Volunteer cotton plants are unwanted in cotton and rotated crops and considered weeds. Stacked-trait HR cotton can complicate management of volunteer cotton. There are two primary methods for removing volunteer cotton, tillage and/or herbicide options. In conventional tillage systems, tillage a very viable option. In reduced tillage systems or where herbicides may be more economical, herbicide control of volunteer cotton is common. The herbicides, 2,4-D, dicamba, dicamba + diflufenzopyr, pyraflufen-ethyl, paraquat, fomesafen, saflufenacil, and flumioxazin, are available to control volunteer GHB811 cotton. GHB811 cotton could present as a volunteer, but it would not be expected to contribute in any cumulative manner to an increase in the occurrence of volunteer cotton, or problems in the management of volunteer cotton.

5.4 Physical Environment

5.4.1 Soil Quality

A determination of nonregulated status of GHB811 cotton, and subsequent commercial production, is unlikely to contribute to any cumulative impacts on soil quality. The phenotypic and agronomic characteristics of GHB811 cotton are not substantially different from other cotton varieties (Bayer 2017b). Consequently, commercial production of this variety would not substantially modify the impacts of cotton production on soils.

The cultivation of a cotton variety stacked with resistance to herbicides with multiple modes of action may benefit soil quality. This benefit would likely result from growers' ability to manage difficult to control weeds, facilitating the continued use of, and in some instances a return to, conservation tillage, an agricultural practice with strong direct and positive effects on soil quality, erosional capacity, and compaction. Avoiding conventional tillage for management of weeds, particularly HR weeds, would provide benefits to soils via reducing erosion and compaction. Such an approach is consistent with the IWM strategies currently advocated by weed scientists and industry.

5.4.2 Water Quality

All agricultural chemicals can potentially contaminate surface and groundwater. While the presence of a pesticide in surface and groundwater poses a hazard, it is the inherent toxicity of the pesticide, and dose, duration, and frequency of exposure of humans and wildlife to the pesticide (and/or its degradation products) that characterize the risk. It is expected that glyphosate, glufosinate, and isoxaflutole-based herbicides will be used with GHB811 cotton. Glyphosate and glufosinate are currently registered for use, and have been used, in cultivation of cotton; use of isoxaflutole, if approved by the EPA, would be new. Isoxaflutole is currently an active ingredient in restricted-use pre-emergent herbicides used on corn in several states that are part of the Cotton Belt. Isoxaflutole is a restricted use herbicide because of its potential to persist and accumulate in surface and groundwater. However, used as required by the EPA label restrictions, isoxaflutole is not considered to present significant hazards to humans or wildlife (characterized a Class III - Class IV pesticide).[25] An EPA human health hazard assessment determined the LD50 for acute oral exposure is > 5,000 mg/kg, and dermal exposure > 2,000 mg/kg. It is non-irritating to the eye and skin, nor is it a dermal sensitizer (US-EPA 1998a).

Isoxaflutole has a photolytic half-life in water of 6.7 days. The two degradation products of isoxaflutole, RPA 202248 and RPA 203328, do not, however, readily undergo hydrolysis or photolysis, and are stable in water (US-EPA 1997). Isoxaflutole is mobile in sand and sandy loam soils indicating the potential to leach into ground water. RPA 202248 has a half-life of about 60 days in aerobic soils, and RPA 203328 a half-life of 977 days (US-EPA 1998a).

To the extent GHB811 cotton is adopted, the total amount of isoxaflutole used each year would increase, glufosinate use may increase, while the use of other herbicides in cotton production could decline. Glyphosate-based herbicides are currently used widely in cotton; the amount of these herbicides used would likely remain about the same. Consequently, cumulative increases in glyphosate use and associated increases in potential surface and groundwater contamination are considered unlikely. In general, the EPA determines the use requirements for pesticides, which are intended to be protective of water quality and aquatic biota (US-EPA 2018d, e). The EPA considers the potential impacts to water resources from the agricultural application of

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[25] Class III and IV indicates low toxicity, and that the word "Caution" must be used on the pesticide label. These categories of pesticides may have oral lethal doses (for 150-lb person) of 1 ounce to more than a pint, or may only cause nausea.

glufosinate-ammonium, glyphosate, and isoxaflutole, and provides label use restrictions and guidance for product handling intended to prevent impacts to water. Label restrictions specific to water resources include, for example, prohibiting applications directly to water or to areas where surface water is present, managing proper disposal of equipment wash water, and adopting cultivation methods (e.g., no till) to limit runoff to surface water.

EPA label use restrictions for application rates and methods, state restrictions, as well as surface and groundwater monitoring, would likely serve to mitigate potential cumulative impacts on water quality that may derive from the increased use of glufosinate and isoxaflutole. APHIS assumes that applicators will adhere to the EPA label use requirements for glyphosate, glufosinate, and isoxaflutole. Federal and state agencies routinely monitor water sources for residues in areas where growers use pesticides. For example, the USDA surveys for isoxaflutole and degradates in groundwater as part of the PDP (USDA-AMS 2017a). While isoxaflutole has, in the past, been detected in surface and groundwater (in the late 1990s and early 2000s) (US-EPA 2001c, b), APHIS is not aware of reports describing detection of isoxaflutole in surface or groundwater in recent years. Since its detection in surface and groundwater, the use of isoxflutole has been restricted. Current EPA label requirements restrict isoxaflutole use in certain soil types and in certain areas to prevent leaching into groundwater and run-off to surface waters (Bayer 2013, 2017c).

In the long term, further development of herbicide-resistant weed populations in cotton cropping systems may continue to result in growers abandoning conservation and no-till and adopting more similar aggressive tillage practices, which, via run-off, can adversely affect surface water quality. This is a possibility under both alternatives, although it could be more likely under the No Action Alternative if there are no new tools to help improve the management of weeds and HR weed development. In terms of cumulative impacts, this could present a problem in those areas where HR weeds are currently difficult to manage.

5.4.3 Air Quality

Air pollution is fundamentally the result of cumulative emissions from multiple sources. The emission sources associated with cotton production would be unaffected by a decision to approve or deny the petition. The trend of increasing tillage in some areas of the South would likely continue under the No Action Alternative, contributing to cumulative emissions of NAAQS pollutants in these areas. These potential emissions would contribute to transient and local impacts on air quality. To the extent of GHB811 cotton, as a weed management tool, helps sustain, or in some cases facilitate a return to, conservation and no-till practices in cotton, benefits to air quality through limited contribution to cumulative emissions would be expected, relative to tillage trends under the No Action Alternatives.

As discussed in Chapter 4, glyphosate, isoxaflutole, and glufosinate, proposed for use with GHB811 cotton, are characterized as having low-volatility. Consequently, use of these with GHB811 cotton, even if the cumulative uses of glufosinate and isoxaflutole are increased, is not expected to present any significant risk to air quality, no more than already occurring under the No Action Alternative, as glufosinate and isoxaflutole are expected to replace the use of other herbicides.

5.5 Biological Resources

5.5.1 Animal, Plant, and Microbial Communities

Approval of the petition and subsequent commercial cultivation of GHB811 cotton would not be expected to contribute in a cumulative manner to impacts on biological resources any differently than that of cultivation of current cotton varieties. Neither GHB811 cotton nor stacked-trait progeny would necessitate a significant increase in the overall use of pesticides in commercial cotton production. As discussed in Chapter 4, it is unlikely that the *2mepsps* and *hppdPfW336* genes and their products that occur in GHB811 cottonseed present any risk to animals. Because the agronomic practices and inputs that will be used for GHB811 cotton production will be similar to those for the No Action Alternative, except for applications of isoxaflutole, the potential impacts on vegetation close to cotton fields are virtually the same under both the Preferred and No Action Alternatives. The potential impacts on soil microbiota under the Preferred Alternative are no different than those under the No Action Alternative. Cultivation of GHB811 cotton would present the same potential impacts on biodiversity in and around a GHB811 cotton cropping systems as do currently cultivated cotton varieties, both GE and non-GE.

Because potential direct and indirect impacts on biological resources do not significantly differ between the No Action and Preferred Alternatives, there are no reasonably foreseeable cumulative impacts that would derive from the commercial cultivation of GHB811 cotton or its progeny.

5.5.2 Gene Flow and Weediness

As discussed in Chapter 4, there are no differences between the No Action and Preferred Action Alternatives in regard to matters concerning gene flow and weediness. The risk of gene flow and weediness with GHB811 cotton is no more or less than that of conventional cotton varieties. Consequently, there are no reasonably foreseeable cumulative impacts that would derive from approval of the petition and subsequent commercial cultivation of GHB811 cotton.

5.6 Human Health and Worker Safety

The only potential impacts identified concerning human health are those associated with increased isoxaflutole use and the potential for surface and groundwater contamination by isoxaflutole and its degradates (US-EPA 2011f). The potential for isoxaflutole to contaminate surface and groundwater is well known to the EPA and state agencies (US-EPA 2001c, 2011d). The EPA imposes various restrictions on isoxaflutole use that are intended to protect surface and groundwater (Bayer 2013, 2017c). States may likewise impose restrictions on isoxaflutole use. When used consistent with the EPA label requirements, as well as with any additional state requirements, it is unlikely that isoxaflutole will affect surface or groundwater (US-EPA 2011f). It is noted that, currently, isoxaflutole is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the CWA.

In terms of mitigation measures, in areas where isoxaflutole is used, surface and groundwater will likely be monitored. For example, Bayer is working to register isoxaflutole in Minnesota. As part of the registration process, Bayer will install and sample up to eight monitoring wells in 2016 – 2017 in areas where isoxaflutole will be used. The Minnesota Department of Agriculture (MDA) will coordinate with Bayer on the location and installation of these monitoring sites. Bayer will sample for isoxaflutole and its degradates, and provide sampling data to the MDA for review and comment.[26]

Based on EPA and state requirements, as well as likely monitoring and mitigation programs that will be implemented where isoxaflutole is used, adverse cumulative impacts on surface and groundwater from the additive uses of isoxaflutole are unlikely to occur.

5.7 Animal Health and Welfare

As discussed above, the only potential impacts identified that are related to animal health and welfare are those associated with surface and groundwater contamination by isoxaflutole and its degradates. There are no foreseeable adverse cumulative impacts on animal health and welfare that would result from an APHIS determination to no longer regulate GHB811 cotton.

5.8 Socioeconomics

Weed and Herbicide Resistant Weed Management Costs

If GHB811 cotton were no longer regulated, its eventual commercialization would have no effect on cotton commodities markets. The primary potential cumulative impacts would be on weed and weed resistance management costs to the grower. For example, a 2012 study found the average costs of managing weeds increased by $98/ha ($40/acre) following the establishment of HR weeds (Lambert et al. 2017). Post-resistance changes in weed management costs ranged between $85/ha ($34/acre) and $138/ha ($56/acre), depending on the combination of adopted practices. Weed management costs increased by $88/ha ($36/acre) when cost-neutral practices were adopted (Lambert et al. 2017). Similarly, another study found the percentage of farmers who indicated they had total weed-control costs ≥$50 per acre nearly doubled with the emergence of HR weeds on their farms (Zhou et al. 2015).

As of 2012, more than two-thirds of surveyed farmers reported HR weeds on their farms. Pigweed was the dominant weed problem, followed by horseweed, ragweed, and other non-specific weeds. Farmers indicated they used various combinations of labor, mechanical/chemical, and cultural practices to manage weed resistance on their farms: 90% indicated they hand hoed or pulled weeds in the field, 54% increased field scouting, 69%

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[26] http://www.mda.state.mn.us/~/media/Files/chemicals/maace/2016workplangw.pdf

changed in-season herbicide program/chemistry, 21% used fall tillage after harvest to kill growing weeds, 12% used fall residual herbicide programs, 47% controlled weeds in field boarders/ditches, 36% used winter cover crop to suppress weeds, and 35% used more crop rotations (Zhou et al. 2015). Cotton producers extensively relied on mechanical/chemical methods to control weed resistance, which made up 42% of those surveyed. The chemical practices used by 69% of farmers were changes in in-season herbicide program/chemistry programs (Zhou et al. 2015).

Depending on several factors discussed below, GHB811 cotton could, over time, facilitate reductions in the rate of development of new HR weed populations, as well as the overall number of HR weed populations, relative to cropping systems using only 1 or perhaps 2 MOAs, and the efficacy of the IWM program employed with GHB811 cotton varieties. Such reductions in the rate of development of HR weed populations and prevention of emergence of new populations could result in cumulative reductions in weed management costs to U.S. cotton farmers (Livingston et al. 2015).

GHB811 cotton could potentially provide growers options in reducing weed resistance management costs over the long-term. Farmers could potentially realize savings in weed management costs through reduced expenditure on herbicides, lowered application (labor and fuel) costs, and decreased tillage, hoeing, hand-pulling, and scouting costs. To the extent that adoption of GHB811 cotton helps growers minimize or reduce weed control costs and overall production costs, it may also improve the competitiveness of U.S. producers in global markets. Whether and to what degree this outcome would be realized is uncertain.

If new isoxaflutole and glufosinate resistant weeds should arise in association with use of GHB811 cotton, there are registered and effective herbicide alternatives (MOAs) for control. Any economic impacts in control of isoxaflutole and glufosinate resistant weeds are likely to be marginal, or avoidable, compared to the costs growers currently incur. With respect to commercial production of GHB811 cotton, a significant increase in weed management costs, in the event that HR weeds develop, is unlikely. These costs would be a continuation of current conditions, although from a chemicals management and environmental perspective, this outcome would be undesirable. In consideration of this outcome, development of weeds resistant to isoxaflutole and glufosinate would most likely be limited in incidence and prevalence. APHIS assumes growers will follow EPA and industry stewardship requirements regarding the use of herbicides with the same MOA. Cotton growers recognize that certain management practices, such as no diversification of herbicide MOAs, will lead to unsustainable herbicide use and crop production, reducing economic value over the longer term. In the long term, the cumulative economic impacts of GHB811 cotton will depend on the prevention of further development of HR weeds and elimination of existing ones.

6 THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1973, as amended, is a far-reaching wildlife conservation law. The purpose of the ESA is to prevent extinctions of fish, wildlife, and plant species by conserving endangered and threatened species and the ecosystems upon which they depend. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), together "the Services," as well as other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens.

Before a plant or animal species can receive the protection provided by the ESA, it must be added to the Federal list of threatened and endangered wildlife and plants. Threatened and endangered (T&E) species are those plants and animals recognized for being at risk of becoming extinct throughout all or part of their geographic range (endangered species) or species likely to become endangered in the foreseeable future throughout all or a significant portion of their ranges (threatened species).

The Services add a species to the list when they determine the species to be endangered or threatened because of any of the following factors:

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

Once a species is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of federal activities.

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

APHIS met with USFWS officials on June 15, 2011, to help determine whether APHIS has specific direct obligations under the ESA for analyzing the effects on T&E species that may occur from use of pesticides associated with the GE crops that APHIS may consider no longer regulating, including changes in use patterns that may be expected with production of a particular crop plant. USFWS and APHIS agreed that it is not necessary for APHIS to perform an ESA effects analysis on pesticide use associated with GE crops because EPA has both regulatory authority over the labeling of pesticides under FIFRA as well as the necessary technical expertise to assess pesticide effects on the environment, including T&E species. APHIS has no statutory authority to authorize or regulate the use of glyphosate, isoxaflutole, or any other herbicide, by cotton growers. Such uses by cotton growers under federal law must be done in strict compliance with their EPA-approved label instructions. Under APHIS' current Part 340 regulations, APHIS has the authority to regulate GHB811 cotton if it has determined that GHB811 cotton is likely to pose a plant pest risk (7 CFR § 340.1). APHIS does not have regulatory jurisdiction over any other aspects of GE organisms including risks associated with changes in use patterns of herbicides or other pesticides.

After completing a PPRA and presenting relevant information for public comment, APHIS may determine that GHB811 "regulated articles" e.g., cotton seeds, plants, or parts thereof, are unlikely to pose a plant pest risk. If so, then these articles would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340. In that case, APHIS would not have jurisdiction over these articles and can no longer regulate them. As part of its analysis in this Environmental Assessment, APHIS is analyzing the potential effects of GHB811 cotton on the environment including, as required by the ESA, any potential effects to T&E species and species proposed for designation, as well as designated critical habitat and habitat proposed for designation. As part of this process, APHIS thoroughly reviews the GE product information and supporting data related to the organism. For each GE plant that APHIS receives a petition to no longer regulate, APHIS considers the following:

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

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of GHB811 cotton may have, if any, on federally-listed T&E species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Prior to this review, APHIS considered the potential for GHB811 cotton to extend the range of cotton production and also the potential to extend agricultural production into new natural areas. APHIS has determined that agronomic characteristics and cultivation practices required for GHB811 cotton are essentially indistinguishable from practices used to grow other cotton varieties, including other herbicide-tolerant varieties (Bayer 2017b). Although GHB811 cotton may replace certain other varieties of cotton that are cultivated currently, APHIS does not expect the introduction of GHB811 cotton to result in new cotton acres or to be planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences that a determination of nonregulated status for GHB811 cotton would have on T&E species in the areas where cotton is currently grown. Based upon the scope of the EA and production areas identified in *Chapter 3 – Affected Environment*, APHIS reviewed the USFWS list of T&E species (both listed and proposed for listing) for each state where cotton is commercially produced (USFWS 2018). Because this list can change, APHIS continually monitors changes in status of T&E species, critical habitats, and other relevant actions by USFWS and NMFS (USFWS 2018).

For its analysis on T&E plants and critical habitat, APHIS focused on the agronomic differences between the regulated article and cotton varieties currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing.

For its analysis of effects on T&E animals, APHIS focused on the implications of exposure to the novel proteins expressed in the plants as a result of the transformation, as well as the ability of the GHB811 cotton plants to serve as a host for a T&E species. The proteins produced by GHB811 cotton that are novel in cotton are listed in Table 6-1.

Table 6-1. Proteins Produced by GHB811 Cotton that are Novel in Cotton

Regulated Article	Protein	Desired Phenotypic Effects
GHB811 cotton	Double mutant 5-enol pyruvylshikimate-3-phosphate synthase (2mEPSPS)	Resistance to the herbicide active ingredient glyphosate
	4-hydroxyphenylpyruvate dioxgenase (HPPD W336)	Resistance to the herbicide active ingredient isoxaflutole

(Bayer 2017b)

6.1 Potential Effects of GHB811 Cotton on T&E Species and Critical Habitat

6.1.1 Threatened and Endangered Plant Species and Critical Habitat

Upland cotton (*G. hirsutum*) possesses few of the characteristics that are often found in plants that hinder crop yields and production or successfully naturalize and become problematic in the environment (i.e., are weeds) (Baker 1965; Keeler 1989), or successfully naturalize in the environment and is not considered to be a serious problem or frequently a common weed in the United States. It is not listed as a Federal Noxious weed or as invasive by any state other than Hawaii (weed in the major weed references (Crockett 1977; Holm LG et al. 1979; Muenscher 1980; USDA-NRCS 2018). Modern upland cotton is a domesticated perennial typically grown as an annual crop that is not generally persistent in unmanaged or undisturbed environments without human intervention. Modern cultivars are not frost tolerant and do not survive freezing conditions. They do not produce abundant or long-lived seeds that can persist or lie dormant in soil, do not exhibit vegetative propagation, over-wintering structures, or rapid vegetative growth, and do not compete effectively with other cultivated plants (OECD 2008). In areas where temperatures are mild and freezing does not occur, cotton plants can occur as volunteers in the following growing season. These volunteers can be controlled by herbicides or mechanical means. With the exception of glyphosate and isoxaflutole, GHB811 cotton is expected to be controlled by the same herbicides as other cotton varieties should they occur where they are not wanted (USDA-APHIS 2018). Feral cotton plants can become naturalized in suitable areas, such as southern Florida, Hawaii, and Puerto Rico (Coile and Garland 2003; Fryxell 1984; Wunderlin 2008; USDA-NRCS 2012b).

The agronomic and morphologic characteristics data provided by Bayer were used in the APHIS analysis of the weediness potential for GHB811 cotton and evaluated for the potential to impact T&E species and critical habitat. Agronomic studies conducted by Bayer tested the hypothesis that the weediness potential of GHB811 cotton is unchanged with respect to conventional cotton (Bayer 2017b). Bayer conducted field trials in fifteen locations representative of the major cotton-growing areas of the United States to evaluate phenotypic, agronomic and ecological characteristics (Bayer 2017b). GHB811 cotton, control Coker 312 cotton, seven near isogenic nontransgenic lines, and reference variety plants were grown under conditions of conventional herbicide use and GHB811 cotton was also treated with one application of glyphosate and one application of isoxaflutole (Bayer 2017b). In its petition, Bayer provided evaluations of 31 agronomic characteristics, comparing GHB811 cotton (both treated with glyphosate and isoxaflutole and untreated), the control, and the seven non-GE lines. Statistically significant differences were detected for the continuous parameters final stand count, seed cotton yield, lint yield, and height to node ratio between the non-GE counterpart (Coker 312) and GHB811 cotton not treated with trait-specific herbicides. Statistically significant differences were also detected for boll weight between the non-GE counterpart and both GHB811 cotton entries (treated and not treated) (Bayer 2017b). All mean values of the continuous agronomic parameters of GHB811 cotton (treated or not treated) were within the range of means of the reference varieties with the exception of boll weight. Boll weight for both GHB811 cotton entries were within the overall range of values for reference varieties and tolerance intervals, but fell below the range of means for the reference varieties (Bayer 2017b). However, literature values for boll weight show a wide variability of boll weight within the *G. hirsutum* species. Thus, statistically significant differences were considered not biologically relevant. This leads to the conclusion that the agronomic characteristics of GHB811 cotton sprayed with glyphosate and isoxaflutole are equivalent to non-sprayed GHB811 cotton. The combined site summary of statistical results for the categorical parameters of plant growth, four insect stressor ratings, four disease stressor ratings, and four abiotic stressor ratings were also presented in the petition. No statistically significant differences were detected for thirteen of the fourteen categorical parameters. Statistically significant differences were observed for the third disease stressor rating between the non-GE counterpart and treated and not treated GHB811 cotton. All mean values for GHB811 cotton in this disease stressor rating fell within the range of the reference varieties and thus statistically significant differences were considered not biologically relevant (Bayer 2017b). Based on the agronomic assessment, GHB811 cotton demonstrated no biologically relevant differences from the non-GE counterpart and showed equivalent agronomic performance to non-GE reference varieties (Bayer 2017b).

Seed dormancy is a characteristic that is often associated with plants that are considered weeds. Lab studies found no significant differences in germination (as an indicator of dormancy) of GHB811 cottonseed compared with non-GE control cottonseed (Coker 312) under warm and cool conditions (Bayer 2017b). In summary, no differences were detected between GHB811 cotton and non-GE cotton in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tolerance to the two herbicides.

Based on the agronomic field and laboratory data and a survey of scientific literature focused on the weediness potential of cotton, GHB811 cotton is unlikely to persist as a difficult-to-control weed or to have a significant impact on current weed management practices (USDA-APHIS 2018). GHB811 cotton volunteer plants and feral populations can be managed using a variety of currently available methods and herbicides other than glyphosate and isoxaflutole. Furthermore, extensive post-harvest monitoring of field trial plots planted with GHB811 cotton under USDA-APHIS notifications, and field data reports did not reveal any differences in survivability or persistence relative to other varieties of the same crop currently being grown (Bayer 2017b). From these data, APHIS determined that that GHB811 cotton is no more likely to become a weed than those varieties of cotton that are in current use (USDA-APHIS 2018).

As part of its analysis of effects on species and habitat, APHIS evaluated the potential of GHB811 cotton to cross with wild relatives. Cultivated *G. barbadense* (Pima or Egyptian cotton) is grown in Arizona, California, New Mexico, and Texas (Pleasants and Wendell 2005; USDA-NASS 2012).

Naturalized populations of *G. barbadense* grow in Puerto Rico, the Virgin Islands and several Hawaiian Islands (Fryxell 1984; Bates 1990; Pleasants and Wendell 2005; USDA-NRCS 2012d).

Two wild species of cotton are native to the United States, *G. thurberi* and *G. tomentosum*, and grow in Arizona and Hawaii, respectively (Fryxell 1984; Pleasants and Wendell 2005; USDA-NRCS 2012d). *G. hirsutum* is tetraploid and thus effectively sexually incompatible with diploid species such as *G. thurberi*. Plants from these two species do not normally spontaneously hybridize with each other to produce fertile offspring, and experimental crosses are difficult (OECD 2008). In contrast, *G. hirsutum* is sexually compatible with the tetraploids *G. barbadense* (cultivated Pima or Egyptian cotton) and *G. tomentosum* and can form viable and fertile progeny with both species (Brubaker et al. 1993; SAHA et al. 2006; OECD 2008). Thus, unassisted outcrossing and gene introgression could potentially occur in areas where these species are co-located (USDA-APHIS 2018).

For transgene introgression from GHB811 cotton to occur, the recipient variety or species would have to be both near GHB811 cotton and have temporal overlap in their flowering periods. In addition, because cotton is insect pollinated, the two potential parent plants must share similar pollinators (Pleasants and Wendell 2005). Published studies report that there has been relatively little gene introgression from *G. hirsutum* into native or naturalized *G. barbadense* in Mesoamerica and the Caribbean, despite the fact that *G. barbadense* has been grown in the presence of the predominant *G. hirsutum* since prehistoric times (Wendel et al. 1992; Brubaker et al. 1993). In contrast, introgression from *G. barbadense* to native or naturalized *G. hirsutum* in these areas has been relatively common (Wendel et al. 1992; Brubaker et al. 1993). While various mechanisms have been suggested to account for this difference (Percy and Wendel 1990; Brubaker et al. 1993; Jiang and PW Chee 2000; OGTR 2008), none of these mechanisms leads to complete isolation between the two species reported asymmetry in gene flow suggests that gene introgression from cultivated *G. hirsutum* varieties such as GHB811 cotton to native or naturalized *G. barbadense* should be rare (USDA-APHIS 2018).

Natural populations of *G. tomentosum* are found on all Hawaiian Islands except Kauai and Hawaii. Populations are located on the drier, leeward coastal plains of the islands at low elevations, which are also the areas that are primarily used for agriculture (Pleasants and Wendell 2005). As discussed in the Preliminary PPRA, there is overlap in the timing of flowering (both in time of year and time of day), and potential pollinators with *G. hirsutum* (USDA-APHIS 2018). However, *G. hirsutum* has not been grown as an agricultural commodity in Hawaii for decades, and to the best of APHIS’ knowledge, seed companies no longer use the Hawaiian Islands as a winter nursery for cotton (Grace, J.K. personal communication with A. Pearson. November 20, 2012; USDA-APHIS 2017). Even if gene introgression into wild relatives were to occur, expression of the 2mEPSPS and HPPD W336 proteins does not cause any major changes in the phenotype of cotton plants other than to confer resistance to the herbicides glyphosate and isoxaflutole. In the absence of treatment with these herbicides, the transgenic material in GHB811 cotton is unlikely to confer a selective advantage on any hybrid progeny that may result from outcrossing (USDA-APHIS 2018).

None of the relatives of cotton are Federally listed (or proposed) as endangered or threatened species (USFWS 2018). In the State of Florida, wild populations of upland cotton, *G. hirsutum*, have been listed as endangered by the state (Coile and Garland 2003). However, wild *G. hirsutum* is not present in the northwestern panhandle where cotton cultivation occurs and cultivation of cotton is prohibited by the EPA in those areas of southern Florida where it is found (Coile and Garland 2003; Wunderlin 2008). Thus, outcrossing from GHB811 cotton to naturalized *G. hirsutum* in Florida is highly unlikely. Accordingly, a decision to no longer regulate GHB811 cotton is not expected to impact state endangered feral cotton populations.

Based on agronomic field data, literature surveyed on cotton weediness potential, the biology of cotton, and the lack of sexual compatibility of T&E species with cotton in areas where cotton is commercially grown, APHIS has concluded that GHB811 cotton will have no effect on T&E plant species or on critical habitat.

6.1.2 Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products in GHB811 cotton would comprise those T&E species that inhabit cotton fields and potentially feed on GHB811 cotton. To identify potential effects on threatened and endangered animal species, APHIS evaluated the risks to threatened and endangered animals from consuming GHB811 cotton.

Gossypol is a yellow polyphenolic pigment found in the cotton plant and in the small pigment glands in the seed (Ely and Guthrie 2012). Gossypol can be an antinutrient and play a role in defense of cotton against insect pests (Chan et al. 1978; Kong et al. 2010). High dosages of gossypol can be fatal to cotton bollworm (*Helicoverpa armigera*), yet lower levels were found to be beneficial to their growth (Paz Celorio-Mancera et al. 2011). Gossypol is harmful to monogastric animals such as chickens, swine, and also to young ruminants (Ely and Guthrie 2012). However, it seems to have little effect in reducing herbivory by adult ruminants. In North Carolina, 92% of cotton growers surveyed reported crop damage from white-tailed deer feeding (NCDA&CS 2010), suggesting that deer will also eat cotton. In fact, whole cottonseed is often used by deer managers as a supplemental feed because it is cheaper than protein pellets and feral hogs and raccoons will not consume it (DeYoung 2005; Taylor et al. 2013). When using cottonseed as deer feed, managers generally stop feeding in June to allow time for a reduction in plasma gossypol levels prior to breeding season. Although feeding studies of whole cottonseed to whitetailed deer is lacking, there is a general belief that feeding high concentrations of cottonseed, especially during breeding season, may reduce breeding success (Bullock et al. 2010). Studies on European red deer indicate that bucks fed whole cottonseed had negative response in regard to body weight and antler growth (Brown et al. 2002). In studies of fallow deer, feeding whole cottonseed to bucks resulted in decreased body weight, body condition score, antler growth, and plasma testosterone concentration (Mapel 2004). Gossypol may act as a contraceptive in male deer (Gizejewski et al. 2008). While deer will consume supplemental cottonseed and do cause crop damage to cotton, deer are not expected to consume GHB811 cotton in the field more than they consume other varieties currently in production.

Whole cottonseed is commonly used as a supplemental protein feed for cattle (Ely and Guthrie 2012). However, care must be taken to not overfeed because of the possibility of gossypol toxicity. If fed too much whole cottonseed, even mature dairy cows have been known to become ill and fatalities have occurred when it was the sole diet (Ely and Guthrie 2012). Other domestic ruminants such as goats have also shown negative effects from consumption of whole cottonseed feed, but some of the effects were attributed to the increased dietary intake of ether extract and neutral detergent fiber rather than gossypol (Luginbuhl et al. 2000). One study indicated that whole cottonseed introduced as 15% of the diet to Nubian buck kids had positive results in growth, but at 30% had increased red blood cell fragility and reduced reproductive performance (Solaiman 2007).

There is little reported information about wildlife damage to cotton, other than some information about whitetail deer damage. Many wildlife species, especially non-ruminants, may avoid eating cotton because of the toxic effects of gossypol. However, wildlife may find food in cotton fields and consume insects that live on and among the plants. Quail and some other birds are known to nest in grassy strips on the edge of cotton fields and will enter the fields to obtain food or grit (Palmer and Bromley NoDate). However, T&E species generally are found outside of agricultural fields in more natural habitats. It is unlikely that T&E species would use cotton fields because they do not provide suitable habitat.

Bayer carried out a compositional assessment of GHB811 cotton by comparing GHB811 cottonseed to seed from conventional control varieties. The samples for compositional assessment were collected from field trials at eight locations in 2014 and 2015, chosen to represent typical cotton growing regions in the United States (Bayer 2017b). To provide a range of values of the normal variability of commercial cotton lines, the ranges in natural variation of the analytes was obtained from planting seven commercial non-GE cotton reference lines as reference varieties, along with values provided from published literature ranges (Bayer 2017b). Compositional analyses of cotton seed samples included: five proximates (moisture, ash, carbohydrates, crude fat, and crude protein), fiber, nine minerals, eighteen amino acids, thirteen fatty acids, five anti-nutrients, and alpha tocopherol (Bayer 2017b).

Of the 69 composition analytes tested, 15 were excluded from the combined site analysis because more than 30% of the results were below the limit of quantification; 54 had sufficient levels above the limit of quantification for statistical analysis (Bayer 2017b). Of the 54 analytes that were analyzed, statistically significant differences ($p < 0.05$) were observed for 11 analytes, six of which were statistically different between both the non-GE counterpart and GHB811 cotton not treated or treated with trait-specific herbicides, and five of which were statistically different between the non-GE counterpart and GHB811 cotton treated with trait-specific herbicides (Bayer 2017b). However the means of all analytes were within the overall range of values of the reference varieties and the tolerance intervals. In most cases, values for the non-GE counterpart, and both GHB811 cotton entries fell within the range of means for reference varieties (Bayer 2017b). In any case where they did not meet these criteria, they fell within the range of values provided in the ILSI crop composition database (ILSI 2016). Therefore, the statistically significant differences are not considered biologically relevant. Based on these results, it can be concluded that cottonseed from GHB811 cotton can be considered compositionally and nutritionally equivalent to those derived from convention cotton with the exception of the expression of 2mEPSPS and HPPD W336 proteins (USDA-APHIS 2018).

APHIS considered the potential for the expression of 2mEPSPS and HPPD W336 proteins in GHB811 cotton to impact other organisms. Levels of the proteins were analyzed for both plants grown in plots treated with glyphosate or isoxaflutole and in untreated (no herbicides) plots. The level of 2mEPSPS protein in untreated and treated GHB811 cotton leaf, root, square, boll, whole plant and fuzzy seed matrices ranged from 76.36 to 1762.54 µg/g dry weight in treated, and 86.67 to 1685.85 µg/g dry weight in untreated (Bayer 2017b). The 2mEPSPS protein concentrations in untreated and treated GHB811 cotton pollen ranged from 12.86 to 33.47 µg/g fresh weight and 21.42 to 33.15 µg/g fresh weight, respectively (Bayer 2017b).

The level of HPPD W336 expression in untreated and treated GHB811 cotton leaf, root, square, boll, whole plant and fuzzy seed matrices ranged from 10.91 to 1673.89 µg/g dry weight and 11.01 to 1402.82 µg/g dry weight, respectively (Bayer 2017b). The HPPD W336 protein concentrations in untreated and treated GHB811 cotton pollen ranged from below the lower limit of quantitation (<LLOQ) to 0.69 µg/g fresh weight and <LLOQ to 0.68 µg/g fresh weight, respectively, with the majority being below LLOQ (Bayer 2017b).

Searches of 2mEPSPS and HPPD W336 amino acid sequence similarities with known toxins and allergens were evaluated using several approaches. None of the searches found biologically relevant similarities with any known allergens or toxins (Bayer 2017b). In addition, acute oral toxicity studies on mice have indicated that the 2mEPSPS and HPPD W336 proteins have no adverse effects in mice at 2000 mg/kg body weight (Bayer 2017b). The lack of known toxicity of 2mEPSPS and HPPD W336 proteins suggests that there is not a potential for deleterious effects on organisms that may contact or consume GHB811 cotton due to the expression of these two proteins.

Since 1994, the APHIS has issued determinations of nonregulated status to 24 GE plants containing the *2mepsps* gene. Each of these GE plants have gone through EPA reviews and FDA Food Safety Consultations (180.364 ; US-FDA 2017a). Of those 24 GE plants, three were for cotton, including Bayer GHB614 (Bayer 2006).

The *hppd* gene in the Bayer petition was isolated from the bacterium *Pseudomonas fluorescens*, strain A32. *P. fluorescens* is a Gram-negative, rod-shaped, motile, asporogenous, aerobic bacterium. *P. fluorescens,* is ubiquitous in the environment, including soil, water and food, and is unlikley to pose a plant pest (USDA-APHIS 2018). USDA has issued determinations of nonregulated status for two GE soybean plants containing an HPPD inhibitor gene, Syngenta SYHT0H2 soybean (petition 12-215-01p) and Bayer FG72 soybean (petition 09-328-01p).

On April 17, 2017, Bayer submitted a Premarket Biotechnology Notification to FDA. To date, an administrative number has not been assigned to this Premarket Biotechnology Notification (USDA-APHIS 2018).

In summary, APHIS has determined that contact and ingestion of GHB811 cotton plants or plant parts is unlikely to affect T&E species. There is no evidence of allergenicity with GHB811 cotton, and no evidence of an increased toxicity. Therefore, APHIS concludes there is no increased risk of toxicity or allergenicity impacts directly to animal species or indirectly through their biological food chains, associated with contacting or feeding on GHB811 cotton. Based on this analysis, APHIS concludes that contact with or consumption of GHB811 cotton plants or plant parts by T&E species is unlikely, and if it occurred it would have no effect on any listed T&E animal species or animal species proposed for listing.

APHIS did consider the possibility that GHB811 cotton could serve as a host plant for a T&E species (i.e., a listed insect or other organism that may use the cotton plant to complete its lifecycle). A review of the T&E species list did not reveal any species that would be likely to use cotton as a host plant (USFWS 2018).

6.1.3 Conclusion

After reviewing the possible effects of a determination of nonregulated status of GHB811 cotton, APHIS has not identified any stressor that would or could affect the reproduction, numbers, or distribution of a listed T&E species or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. APHIS also considered the potential effect of a determination of nonregulated status of GHB811 cotton on designated critical habitat or habitat proposed for designation. Compared to other cotton varieties that are currently in use, APHIS determined that GHB811 cotton production would not differentially affect critical habitat. Like many crops, cotton has been selected for yield rather than its ability to compete and persist in the environment. GHB811 cotton is not expected to outcompete other plants and persist outside of direct cultivation. Cotton is not sexually compatible with, and does not serve as a host species for, any T&E listed species or species proposed for listing. Consumption of GHB811 cotton by any T&E listed species or species proposed for listing will not result in an allergic reaction or increase the risk of a toxic reaction. Based on this evidence, APHIS has concluded that a determination of nonregulated status of GHB811 cotton, and the corresponding environmental release of this cotton variety will have no effect on T&E listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this “no-effect” determination, consultation under Section 7(a)(2) of the ESA, or the concurrence of the USFWS or NMFS is not required.

7 CONSIDERATIONS OF FEDERAL AND STATE LAWS AND REGULATIONS, EXECUTIVE ORDERS, STANDARDS, AND TREATIES

7.1 Federal Laws and Regulations

The statutes most relevant to APHIS determinations of regulatory status are the National Environmental Policy Act of 1969 (NEPA), the Clean Water Act of 1972 (CWA), the Safe Drinking Water Act of 1974 (SDWA), the Clean Air Act of 1970 (CAA), the Endangered Species Act of 1973 (ESA), and the National Historic Preservation Act of 1966 (NHPA). Compliance with the requirements of the ESA has been addressed in Chapter 6. Compliance with the requirements of the other relevant laws, NEPA, CWA, SDWA, CAA, and NHPA, is specifically addressed in the following subsections.

7.1.1 National Environmental Policy Act (NEPA)

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

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

The CWA, SDWA, and Clean Air Act authorize the EPA to regulate air and water quality in the United States. This EA evaluates the potential changes in cotton crop production and byproducts associated with approving the petition for a determination of nonregulated status to GHB811 cotton. APHIS determined that the cultivation of GHB811 cotton would not lead to the increase in or expansion of the area in cotton production. Because GHB811 cotton is compositionally, agronomically, and phenotypically equivalent to other non-GE and GE commercially cultivated cotton (Bayer 2017b), the potential impacts to water and air quality from the commercial cultivation of GHB811 cotton would be no different than that of currently cultivated cotton varieties. The herbicide resistance conferred by the genetic modification of GHB811 cotton is not expected to result in any changes in water usage for cultivation or post-harvest processing of seed and lint. APHIS assumes any use of isoxaflutole will be compliant with any potential future EPA registration and label requirements. Based on these analyses, APHIS concludes that a determination of nonregulated status for GHB811 cotton would not lead to circumstances that resulted in non-compliance with the requirements of the CWA, CAA, and SDWA.

7.1.3 National Historic Preservation Act (NHPA) of 1966 as Amended

The National Historic Preservation Act of 1966 (NHPA; Public Law 89-665; 16 U.S.C. 470 et seq.) designates federal agencies that are proposing federally funded or permitted projects on historic properties (buildings, archaeological sites, etc.) to consider the impacts using the required Section 106 Review process.

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

A determination of nonregulated status of GHB811 cotton would not directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. It would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of important scientific, cultural, or 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 the EPA label use restrictions for pesticides will mitigate impacts to the human environment, including historic and cultural resources.

In general, common agricultural activities that would be used in cultivation of GHB811 cotton do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in impacts on the character or use of historic properties. These cultivation practices are already being conducted throughout the cotton production regions. The cultivation of GHB811 cotton is not expected to change any agronomic practices that could result in an adverse impact under the NHPA.

7.2 Executive Orders with Domestic Implications

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

- **EO 12898 – Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations**

  The EO requires federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities and Tribes from being subjected to disproportionately high and adverse human health or environmental impacts.

- **EO 13045 – Protection of Children from Environmental Health Risks and Safety Risks**

  The EO addresses the fact that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and differing behavior patterns, in comparison to adults. To the extent permitted by law and consistent with the Agency's mission, the EO requires each federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

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

  Executive departments and agencies are charged with engaging in consultation and collaboration with tribal governments; strengthening the government-to-government relationship between the United States and Indian Tribes; and reducing the imposition of unfunded mandates upon Indian Tribes. The EO emphasizes and pledges that federal agencies will communicate and collaborate with tribal officials when proposed federal actions have potential tribal implications.

The No Action and Preferred Alternatives were evaluated with respect to EO 12898, EO 13045, and EO 13175. Neither of the alternatives is expected to have a disproportionately adverse impact on minorities, low-income populations, children, or tribal entities. APHIS determined that the cultivation of GHB811 cotton would not lead to the increase in or expansion of the area in cotton production. A determination of nonregulated status of GHB811 cotton is not expected to adversely impact cultural resources on tribal properties. Prior to the publication of this EA, APHIS sent a letter to tribal leaders in the continental United States on October 26, 2017. This letter contained information regarding GHB811 cotton and asked tribal leaders to contact APHIS if they believed that there were potentially significant impacts to tribal lands or resources that should be considered. No responses were received by APHIS from tribal leaders regarding GHB811 cotton. Any farming activities by farmers on tribal lands are only conducted at a Tribe's request. Thus, the Tribes would have control over any potential conflict with cultural resources on tribal properties. The Proposed action, a determination of nonregulated status of GHB811 cotton is not expected to adversely impact cultural resources on tribal properties.

Based on the information submitted by the applicant and reviewed by APHIS, GHB811 cotton is agronomically, phenotypically, and compositionally comparable to conventional cotton except for the introduced 2mEPSPS and HPPD W336 proteins. As reviewed in *Chapter 4 – Environmental Consequences*, these two proteins present no risk to human health. Bayer initiated the consultation process with the FDA for evaluation of the safety of GHB811 cotton on April 17, 2017. GHB811 cotton and its products present no risk to humans, including minorities, low-income populations, children, and Tribal entities who might be exposed to them through agricultural production and/or processing.

The EPA has evaluated potential human health impacts associated with glyphosate (US-EPA 2016b, 2017e) and isoxaflutole (US-EPA 2011c, 2017d). Pesticide labels, which are in part developed based on human and ecological risk assessments, include use precautions and restrictions intended to protect consumers, and workers and their families from exposures. As discussed in *Section 4.5 – Human Health*, the potential use of glyphosate and isoxaflutole on GHB811 cotton would not have adverse impacts on human health when used in accordance with the EPA label use requirements.

The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

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

  Invasive species are defined as those species that are both not native to the ecosystem under consideration and that also harm the environment, economy or human health. Collectively, they constitute a major concern in the United States and elsewhere. This EO directs actions to continue coordinated federal prevention and control efforts related to invasive species. This order maintains the National Invasive Species Council (Council) and the Invasive Species Advisory Committee; adds additional members to the Council; clarifies the operations of the Council; incorporates increased considerations of human and environmental health, climate change, technological innovation, and other emerging priorities into federal efforts to address invasive species; and strengthens coordinated, cost-efficient federal action.

Outcrossing and weediness potential of GHB811 cotton are addressed in the PPRA (USDA-APHIS 2018) and summarized here. Upland cotton (*G. hirsutum*) is a domesticated perennial grown as an annual crop that is not generally persistent in unmanaged or undisturbed environments without human intervention. It possesses few of the characteristics common to plants that are successful weeds and is not considered to be a serious or common weed in the United States. It is not listed as a weed in the major weed references, nor is it present on Federal or State lists of noxious weed species. Cotton can become locally feral or naturalized in suitable areas, such as Hawaii, and Puerto Rico. Modern cultivars are not frost tolerant and do not survive freezing winter conditions, do not produce abundant or long-lived seeds that can persist or lie dormant in soil, do not exhibit vegetative propagation or rapid vegetative growth, and do not compete effectively with other cultivated plants. In areas where winter temperatures are mild and freezing does not occur, cotton plants can occur as volunteers in the following growing season. However, these volunteers can be easily controlled by herbicides or mechanical means.

While pollen-mediated gene transfer can occur, there are no differences in the potential for gene flow and weediness as compared to conventional or other GE varieties. The risk of gene flow and weediness of GHB811 cotton is no greater than that of other nonregulated GE or conventional cotton varieties.

- **EO 13186 – Responsibilities of Federal Agencies to Protect Migratory Birds**

  The EO directs states where federal actions have, or are likely to have, a measurable negative impacts on migratory bird populations to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

As discussed in Chapter 6, migratory birds may visit cotton production fields during migration periods, although would not be present during normal farming operations. If migratory birds did visit GHB811 cotton fields, they would be exposed to a crop that does not differ from existing cotton crops in terms of agronomics, nutrition, or pesticide use. Bayer data shows no substantial difference in composition or nutritional quality of GHB811 cotton compared with other GE or non-GE cotton, apart from the presence of the 2mEPSPS and HPPD W336 proteins. As discussed in Chapter 4, it is highly unlikely that the *2mepsps* and *hppdPfW336* genes and their products, which occur naturally in the environment, present any risk to birds. Isoxaflutole is practically non-toxic to the mallard duck and the bobwhite quail on an acute basis (LD_{50} > 2,150 milligrams/kilogram (mg/kg) and slightly toxic to the mallard duck and the bobwhite quail on a sub-acute basis (5-day LD_{50} > 4,255 parts per million (ppm) (US-EPA 1998b). It is practically non-toxic to rats (LD_{50} > 5,000 mg/kg) and honey bees (LD_{50} > 100 µg/bee). Glyphosate is considered no more than slightly to nontoxic for birds (US-EPA 2016b, 2017e). Glyphosate is only slightly toxic on an acute/sub-acute basis, with acute oral LD_{50} values of >3196 mg a.i./kg-body weight (bw) for bobwhite quail and >2000 mg a.i./kg-bw for canary (US-EPA 2017e). Acute dietary LC_{50} values are > 4971 mg a.i./kg-bw for mallard ducks and bobwhite quail. Chronic exposure studies find glyphosate to be of low risk to bobwhite quail and mallard duck (US-EPA 2017e).

Based on these factors, it is unlikely that the determination of nonregulated status of GHB811 cotton, and subsequent commercial production of this variety, would have a negative effect on migratory bird populations.

7.3 Executive Orders on International Issues

- **EO 12114 – Environmental Effects Abroad of Major Federal Actions**

  This EO requires federal officials to take into consideration any potential environmental impacts outside the United States, its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect any major environmental impacts outside the United States in the event of a determination of nonregulated status for

GHB811 cotton. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new cotton and cotton cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of GHB811 cotton subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC 2018). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC 2018). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (183 parties as of March 2017). In April 2004, a standard for pest risk analysis of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measures No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the pest risk analysis for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for GE organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* is a treaty under the United Nations Convention on Biological Diversity that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 171 countries are Parties to it as of 2015 (CBD 2018). Although the United States is not a party to the Convention on Biological Diversity, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation.

LMOs imported for food, feed, or processing are exempt from the AIA procedure and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for food, feed, or processing that may be subject to transboundary movement. These data will be available to the CropLife website's Biotrade Status database.[27]

7.4 State and Local Requirements

The PPA contains a preemption clause (7 U.S.C. § 7756) that prohibits state regulation of any, "plant, biological control organism, plant pest, noxious weed, or plant product" to protect against plant pests or noxious weeds if the Secretary (USDA) has issued regulations to prevent the dissemination of biological control organisms, plant pests, or noxious weeds within the United States. The PPA preemption clause does however allow states to impose additional prohibitions or restrictions based on special needs supported by sound scientific data or risk assessment. Consequently, while the PPA limits states' issuance of laws and regulations governing GE organisms and bars conflicting state regulation, it does allow state oversight when there is a special need for additional prohibitions or restrictions.

States use a variety of requirements to regulate the movement or release of GE organisms within their jurisdiction. For example, South Dakota simply authorizes holders of a federal permit issued under 7 CFR part 340 to use it within the state (SD Stat § 38-12A-31 (2015)). Minnesota issues state permits for release of genetically engineered agriculturally related organisms only after federal applications or permits are on file (MN Stat § 18F.07 (2015)). Nebraska may rely on APHIS or other experts before they issue their permit (NE Code § 2-10,113 (2015)). These illustrative examples show the range of state approaches to regulating the movement and release of GE organisms within state boundaries.

States with an organic program generally adopt 7 CFR part 205 by reference and may codify provisions. For example, Iowa (Iowa Code 190C.1-190C.26), Puerto Rico (5 L.P.R.A. §§ 131 to 141 (2013)), Oklahoma (Okla. Admin. Code §§ 35:37-15-1 to 35:37-15-11), Texas (Texas Agric. Code Ann. § 18 (2015)), and Utah (Utah Admin. Code r. R68-20 (2016)). When a state adopts the prohibitions on methods excluded by the USDA National Organic Program[28], then organic producers cannot use GE seed unless an exception in 7 CFR § 205.204 applies.

Neither of the alternatives considered would affect APHIS partnerships with states in the oversight of GE organisms, specifically in regulation of interstate movement and environmental releases. Under both alternatives, APHIS would continue working with states. The range of state legislation addressing agricultural biotechnology, namely in the way of permitting, crop protection, seed regulation, and economic development, would be unaffected by denial or approval of the petition.

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[27] http://www.biotradestatus.com

[28] https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program

7.5 Impacts on Unique Characteristics of Geographic Areas

Approving the petition for a determination of nonregulated status to GHB811 cotton is not expected to impact unique characteristics of geographic areas such as parklands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

The Preferred Alternative for GHB811 cotton does not propose major ground disturbances or new physical destruction or damage to property, or any alterations of property, wildlife habitat, or landscapes. Likewise, no prescribed sale, lease, or transfer of ownership of any property is expected as a direct result of a determination of nonregulated status for GHB811 cotton. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to GHB811cotton, including the use of EPA-registered pesticides. APHIS assumes that EPA's pesticide label use requirements will be adhered to by growers. Based on these factors, approving the petition for a determination of nonregulated status for GHB811 cotton is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas any differently than cotton varieties already in commercial agriculture.

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