Texas AgriLife Research Petition 17-292-01p for Determination of Nonregulated Status for Ultra-Low Gossypol TAM66274 Cotton

OECD Unique Identifier:
TAM-66274-5

Draft Environmental Assessment

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Acronyms and Abbreviations

ACCase	Acetyl CoA Carboxylase
a.i.	active ingredient
ALS	Acetolactate Synthase
A&M	Agricultural and Mechanical
APHIS	Animal and Plant Health Inspection Service (USDA)
BMP	best management practices
BRS	Biotechnology Regulatory Services (USDA)
Bt	*Bacillus thuringiensis*
C	Carbon
CAA	Clean Air Act
CFR	Code of Federal Regulations
CWA	Clean Water Act
dCS	δ-Cadinene synthase genes
dCS	δ-Cadinene synthase enzyme
DW	Dray Weight
EA	environmental assessment
EFSA	European Food Safety Agency
EIS	environmental impact statement
E. coli	*Escherichia coli*
EPA	U.S. Environmental Protection Agency
EPSP	5-enolpyruvylshikimate-3-phosphate
ERS	Economic Research Service (USDA)
ESA	Endangered Species Act
EO	Executive Order
FAO	Food and Agriculture Organization of the United Nations
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FR	Federal Register
G	Gossypol
GE	genetically engineered
GR	glyphosate-resistant
HR	herbicide-resistant
IP	identity-preserved
IPPC	International Plant Protection Convention
IPM	integrated pest management
IWM	integrated weed management
K	Potassium
L	Liter
lb	pound (mass, U.S.)
lbs	pounds
LC	lethal concentration
LD_{50}	lethal dose for 50 % of a population
LP	limited partnership
m	meter

MARB	Mississippi/Atchafalaya River Basin
µg	Microgram
µl	Microliter
MOA	mode of action
mRNA	Messenger ribonucleic acid
NAAQS	national ambient air quality standards
NASS	National Agricultural Statistics Service (USDA)
NEPA	National Environmental Policy Act
ng	nanogram
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOI	Notice of Intent
NPDES	National Pollution Discharge Elimination System
NPS	nonpoint source pollution
nptII	Neomycin phosphotransferase II gene from *Escherichia coli* Tn5
NPTII	Neomycin phosphotransferase II protein
NRCS	Natural Resources Conservation Service (USDA)
NWQI	National Water Quality Initiative
OECD	Organization for Economic Co-operation and Development
PDP	Pesticide Data Program
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
PPI	pre-plant incorporated, herbicides applied prior to planting
PPRA	Plant Pest Risk Assessment
RNA	Ribonucleic acid
RNAi	Ribonucleic acid interference
SDWA	Safe Drinking Water Act
siRNA	Small interfering RNA
spp	Species
TAM66274	A genetically modified cotton variety that expresses low levels of gossypol in the seed
TAMU	Texas A&M University
U.S.	United States
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
USDA-AMS	U.S. Department of Agriculture Agricultural Marketing Service
USDA-APHIS	U.S. Department of Agriculture Animal and Plant Health Inspection Service
USDA-ERS	U.S. Department of Agriculture Economic Research Service
USDA-FS	U.S. Department of Agriculture Forest Service
USDA-NASS	U.S. Department of Agriculture National Agricultural Statistics Service
WHO	World Health Organization
WPS	Agricultural Worker Protection Standard (by the EPA)
WSSA	Weed Science Society of America

1 PURPOSE AND NEED

1.1 Background

In October 2017, Texas A&M AgriLife Research University, TX (henceforth referred to as TAMU) submitted petition 17-292-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) requesting that genetically engineered (GE) TAM66274 cotton, and any progeny derived from it, no longer be regulated under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). TAM66274 cotton is a GE cotton variety that expresses low levels of gossypol in the seed. Gossypol is naturally-occurring plant pigment produced in glands of the cotton plant that is toxic to certain insects and most vertebrates. Gossypol can be toxic when consumed by humans or monogastric animals at high enough doses. TAM66274 cotton is currently regulated by APHIS because it was developed using the plant pest *Agrobacterium tumefaciens*; this renders it a regulated article under 7 CFR part 340.2.[1] TAMU's petition asserts that APHIS should not regulate TAM66274 cotton because this variety is unlikely to pose a plant pest risk. As part of evaluation of TAMU's petition for nonregulated status APHIS has developed this draft Environmental Assessment (EA) to help to inform APHIS' decision regarding the regulation of TAM66274 cotton.

1.2 Purpose of TAM66274 Cotton

Cottonseed is rich in plant protein and used as feed for ruminant livestock animals. However, it is not typically consumed by humans directly or fed to monogastric animals due to the presence of gossypol. Gossypol is plant pigment produced in glands of the cotton plant that is toxic to insects and most vertebrates. In cotton plants, gossypol serves as a natural defense against insect pests. At sufficient doses (e.g., more than about 450 ppm) it can have toxic effects in humans and monogastric animals. There are on-going efforts to produce cotton varieties through traditional breeding that express low levels of gossypol. "Glandless" varieties, which do not produce gossypol, have been developed, but they have not been widely adopted because they are more vulnerable to plant pests than cotton varieties with glands. Cottonseed products modified either by mechanical or solvent extraction, or derived from glandless cotton varieties, which are low in gossypol, are approved by the U.S. Food and Drug Administration (FDA) for use in human food, provided the free gossypol content does not exceed 450 parts per million (ppm). Similarly, the Association of American Feed Control Officials established standards for low gossypol cottonseed meal for use in monogastric animal feed provided the free gossypol content does not exceed 400 ppm.

While maintaining normal levels of gossypol in the rest of the plant, TAM66274 cottonseed contained approximately 97% less gossypol (equivalent to approximately 3% of that observed in Coker 312), (TAMU 2017). Gossypol is a natural plant defense against pests and some diseases.

[1] Disarmed Agrobacterium is commonly used in the genetic modification of plants. Disarmed means the Agrobacterium is non-virulent.

The normal production of gossypol in the vegetative parts of the plant maintains TAM66274 cotton's inherent pest and pathogen defense. The reduced gossypol in TAM66274 cottonseed lowers cottonseed oil refining costs, and potentially expands the use of cottonseed in livestock and aquaculture feed industries, as well as for human food uses.

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 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 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.[2]

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.

[2] 2017 Update to the Coordinated Framework for the Regulation of Biotechnology: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

Any 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.

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. An example of such pesticides that are regulated by the EPA are plant incorporated protectants[3] (PIPs). They are regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). The EPA also regulates certain GE microorganisms (agricultural uses other than pesticides) under the Toxic Substances Control Act (15 U.S.C. 53 *et seq*.) (US-EPA 2016b).

Before a pesticide may be marketed and legally used in the United States, the EPA evaluates the proposed pesticide to ensure that it will not harm human health or the environment. Pesticides that complete this evaluation are issued a license or "registration" that permits their sale and use according to requirements set by the EPA to protect human health and the environment. The EPA must approve the pesticide use label in accordance with 40 CFR part 158. It is a violation of federal law to use a pesticide in a manner inconsistent with its labeling. The courts consider a label to be a legal document. The purpose of the label is to provide clear directions for the appropriate use of the product while minimizing risks to human health and the environment. The EPA reviews each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration and safety (US-EPA 2017b).

The EPA also sets tolerances (maximum limits) for pesticide residues that may remain on or in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq*.). In establishing a pesticide tolerance, the EPA conducts dietary risk assessments to ensure that all tolerances established for each pesticide and food product reach a safety determination based on a finding of reasonable certainty of no harm. The USDA and FDA have programs that monitor pesticide residues in foods, and provide this information to the EPA for use in their risk assessments. The FDA enforces the pesticide tolerances set by the EPA.

[3] Plant-incorporated protectants are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance.

1.3.3 Food and Drug Administration

The FDA oversight of GE organisms falls under the authority of the FFDCA (21 U.S.C. 301 et seq.). The FDA published its policy statement concerning its authoring over 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 summarized above in 1.3.1, GE organisms that were developed using a plant pest, such as *Agrobacterium spp.*, are regulated articles under 7 CFR part 340. The regulations provide that any person may submit a petition to APHIS requesting that a GE organism should not be regulated, because it is unlikely to present a pest risk. As required by 7 CFR § 340.6, APHIS must respond to petitioners with a regulatory status decision. A GE organism is no longer subject to the requirements of 7 CFR part 340 or the plant pest provisions of the PPA if APHIS determines through conduct of a Plant Pest Risk Assessment (PPRA) that it is unlikely to pose a plant pest risk.

As part of the evaluation of petitions for nonregulated status, APHIS also conducts environmental analyses, such as this EA, pursuant the requirements of the National Environmental Policy Act (NEPA, 42 U.S.C. § 4321 et seq.); the Council of Environmental Quality’s (CEQ) NEPA-implementing regulations (40 CFR parts 1500-1508); and USDA and APHIS NEPA-implementing regulations and procedures (7 CFR part 1b, and 7 CFR part 372). APHIS has prepared this draft EA to consider the potential effects of a determination of nonregulated status for TAM66274 cotton on the human environment.[4]

[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).

1.5 Public Involvement

APHIS seeks public comment on EAs and other documents through notices published in the *Federal Register* and also by other means. On March 6, 2012, APHIS published a notice in the *Federal Register* on the procedures for 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.[5] A summary of current practices follows.

1.5.1 First Opportunity for Public Involvement

Once APHIS deems a petition for nonregulated status complete, APHIS will publish a notice in the *Federal Register* to inform the public that APHIS will accept written comments on the petition for a 60-day period that begins on the date of the published notice. APHIS invites the public to provide input on the petition itself and topics of concern that APHIS should consider in development of the draft EA and draft PPRA.

1.5.2 Second Opportunity for Public Involvement

Once APHIS completes the draft EA and draft PPRA, it publishes a notice of their availability in a second *Federal Register* notice. This second notice follows one of two approaches for further public participation based on whether or not APHIS decides the petition is for a GE organism that raises substantive new issues:

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

APHIS follows this approach for public participation when the agency decides, based on review of the petition and evaluation of public comments received during the first 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 GE organism. Under this approach, APHIS will publish a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the draft EA, draft PPRA and preliminary Finding of No significant Impact (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 final and effective upon public notification through an announcement on its website. APHIS will not publish any further notice in the *Federal Register* announcing the final regulatory determination.

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

APHIS follows the second approach for public participation when the agency finds 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 APHIS has not

[5] This notice can be accessed at: http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf

previously determined to have nonregulated status or when APHIS has not previously analyzed gene modifications that raise substantive biological, cultural, or ecological issues. APHIS identifies substantive issues based on its review of the petition and its evaluation of comments received from the public during the 60-day comment period on the petition.

APHIS will solicit comments on its draft EA and draft PPRA for 30 days, as announced in a *Federal Register* notice. APHIS will review and evaluate all written comments and other relevant information, after which it will revise the draft PPRA, as necessary, and prepare a final EA, PPRA, and NEPA decision document. 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, National Environmental Policy (NEPA) decision document, and regulatory determination.

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

1.5.3 Public Involvement for Petition 17-292-01p

On December 5, 2017, APHIS announced in the *Federal Register* (82 FR No. 232, pp. 57426-7) that it was making TAMU'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.[7] APHIS accepted written comments on the petition for a period of 60 days, until midnight on February 5, 2018. At the end of the comment period, APHIS had received 47 comments on the petition; 44 were supportive, two opposed, and one not related to the TAMU petition.

APHIS evaluated all comments received during the 60-day comment period on the petition. No new issues were presented to APHIS regarding potential environmental, human and animal health, cultural, or socioeconomic impacts beyond those that APHIS identified. Because the plant-trait combination for TAM66274 cotton is new, in that it utilizes ribonucleic acid interference (RNAi) for reduction of gossypol levels in the seed, public involvement for petition 17-292-01p will follow the procedure described above for Approach 2.

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 TAMU'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

[6] This notice can be accessed at: https://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf

[7] Public comments can be reviewed at: https://www.regulations.gov/document?D=APHIS-2017-0097-0001

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 and Plant Communities
- Soil Biota
- Gene Flow and Weediness
- Biological Diversity

Human Health

- Consumer Health and Worker Safety

Animal Health

- Animal Feed/Livestock Health

Socioeconomic

- Domestic Economic Environment
- International Trade

2 ALTERNATIVES

NEPA implementing regulations (40 C.F.R. § 1502.14) require agencies to evaluate all alternatives that appear reasonable and appropriate to the purpose and need for the Agency's action (in this case, a regulatory decision). Two alternatives are evaluated in this EA: (1) No Action, that is, APHIS would deny the petition and TAM66274 cotton would remain a regulated article; and (2) a Preferred Alternative, a determination of nonregulated status for TAM66274 cotton, approval of the petition.

2.1 No Action Alternative: Continuation as a Regulated Article

APHIS must consider a "No Action Alternative" pursuant to CEQ regulations at 40 CFR part 1502.14. Under the No Action Alternative there would be no change in the regulatory status of TAM66274 cotton. TAM66274 cotton and any progeny derived from TAM66274 cotton would continue to be regulated articles under 7 CFR part 340. APHIS would continue to require permits or notifications for introductions of TAM66274 cotton. This alternative is not the Preferred Alternative because APHIS has concluded through a draft PPRA that TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018b). Choosing this alternative would not be an appropriate response to the petition for nonregulated status, nor satisfactorily meet the purpose and need for making a science based regulatory status decision pursuant to the requirements of 7 CFR part 340.

2.2 Preferred Alternative: Determination of Nonregulated Status for TAM66274 Cotton

Under this alternative TAM66274 cotton and progeny derived from it would no longer be subject to APHIS regulation under 7 CFR part 340 because it was determined that, based on the scientific evidence before the Agency, TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018b). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of TAM66274 cotton. This alternative best satisfies the purpose and need to respond appropriately to the petition for nonregulated status pursuant to the requirements of 7 CFR part 340.6 and the Agency's statutory authority under the PPA.

2.3 Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS assembled a list of alternatives that it might consider for TAM66274 cotton, but dismissed these alternatives from further analysis in the EA. 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 TAM66274 cotton. The alternatives considered are summarized below along with the reasons for dismissal from detailed analysis.

2.3.1 Prohibit the Release of TAM66274 Cotton

APHIS could consider prohibiting the environmental release of TAM66274 cotton, including denying permits for field testing. However, this alternative would be inappropriate and legally challenging because APHIS determined that TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018b). 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 PPRA and the scientific data evaluated therein, APHIS has concluded that TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018b). Accordingly, there is no basis in science for prohibiting the release of TAM66274 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 TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018b). 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 TAM66274 Cotton and Non-GE Cotton Production and Geographical Restrictions

In response to public concerns regarding gene movement between GE and non-GE plants, APHIS could consider requiring isolation distances for separation of TAM66274 cotton from non-GE cotton production systems. APHIS could also considered geographically restricting the production of TAM66274 cotton based on the location of production of non-GE cotton, or organic production systems, or production systems for GE-sensitive markets. Because APHIS concluded that TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018b), , the Agency has no jurisdiction to continue regulating TAM66274 cotton. Consequently, prescribing isolation distances or geographic restrictions on production would be inconsistent with APHIS' statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340. Therefore, it would be unreasonable to evaluate an alternative for approval of the petition absent any jurisdiction to implement the alternative. For these reasons, this alternative was dismissed from detailed analysis.

While a determination that TAM66274 cotton is unlikely to present a plant pest risk means that APHIS has no further regulatory control over the planting, distribution, or other actions related to TAM66274 cotton, growers continue to be subject to any contract restrictions imposed by TAMU, or the requirements of other federal or state agencies. Individual cotton producers may also voluntarily choose to isolate or geographically restrict their GE and/or non-GE cotton production systems, or use other management practices to minimize gene movement between cotton fields.

2.3.4 Requirement of Testing for TAM66274 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 TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018b), the imposition of a testing requirement would be inconsistent with the plant pest provisions of the PPA and the regulations at 7 CFR part 340. Therefore, imposing such a requirement for TAM66274 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 Sections 4 and 5 of this EA.

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

Attribute/Measure	Alternative 1: No Action – Continuation as a Regulated Article	Alternative 2: Preferred Alternative - Determination of Nonregulated Status for TAM66274 Cotton
Meets Purpose and Need	No	Yes
Unlikely to pose a plant pest risk	Addressed by the use of regulated field trials.	Satisfied through the plant pest risk assessment (USDA-APHIS 2018b).
Agricultural Production		

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Continuation as a Regulated Article**	**Alternative 2: Preferred Alternative - Determination of Nonregulated Status for TAM66274 Cotton**
Acreage and Areas of Cotton Production	Continuation as a regulated article would have no effect on the areas or acreage utilized for cotton crop production. In general, cotton acreage is projected to remain steady through 2026, at around 10 million acres.	Approval of the petition would not significantly influence the geographic areas in which cotton is grown. Total acreage planted to cotton is expected to remain about the same as that under the No Action Alternative. Because this would be considered a specialty crop, there could be a minor increase in acreage allotted to production of this variety. TAM66274 cotton would likely replace other cotton varieties currently grown in the United States.
Agronomic Practices and Inputs	Agronomic practices and inputs used in cotton crop production would remain unchanged.	Studies evaluating the phenotypic and agronomic properties of TAM66274 cotton indicate agronomic practices and inputs would be the same as for other varieties of cotton (TAMU 2017).
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 cotton.	Approval of the petition would reduce total seed gossypol levels compared to other cotton varieties. This would be a novel ultra-low level of gossypol below established safety standards for cottonseed products used in human food (450 ppm) and for monogastric animal feed (400 ppm). TAM66274 cotton would likely increase the adoption of GE cotton.
Physical Environment		
Soils	Agronomic practices, inputs, and other factors potentially impacting soils would be unchanged under the No Action Alternative. Growers will continue management practices, such as crop rotation, conservation tillage, and pest and weed management strategies that maximize crop yield, preserve soil quality, and avoid soil erosion.	The agronomic practices and inputs are the same for both TAM66274 and existing cotton varieties – potential impacts on soils would be unchanged.
Water Quality	The impacts of cotton production on water resources are expected to	Because TAM66274 cotton is agronomically similar to currently

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Continuation as a Regulated Article**	**Alternative 2: Preferred Alternative - Determination of Nonregulated Status for TAM66274 Cotton**
	remain largely unchanged from current practices.	cultivated cotton, and the transgenes and gene products occur naturally in the environment, approval of the petition and subsequent commercial production of TAM66274 cotton would present the same potential risks to water resources as currently cultivated cotton varieties.
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.	Sources of potential impacts on air quality are the same as those under the No Action Alternative.
Biological Resources		
Animal Communities	Commercial cotton fields provide limited food and habitat for wildlife. Consumption of regular cottonseed by rodents and other pests is limited due to gossypol toxicity.	Potential impacts of TAM66274 cotton crop production on animal communities are expected to be the same as No Action Alternative. The *dCS* RNAi and *npt*II transgenes and their gene products present negligible risk to wildlife.
Plant Communities	Potential impacts on plant communities 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, and are managed as such. Plant communities surrounding cotton fields are generally encouraged as they provide habitat for pollinators and other beneficial insects.	Because the agronomic practices and inputs that will be used for TAM66274 cotton production will be similar to those for the No Action Alternative, the potential impacts on vegetation close to cotton fields are virtually the same under both the Preferred and No Action Alternatives. The *dCS* RNAi and *npt*II transgenes and their gene products present in TAM66274 cotton are not expected to increase the potential for gene flow, hybridization and/or introgression of genes from TAM66274 cotton to other sexually compatible relatives, including wild, feral or cultivated species in the

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Continuation as a Regulated Article**	**Alternative 2: Preferred Alternative - Determination of Nonregulated Status for TAM66274 Cotton**
		United States and its territories is not likely to occur.
Soil Biota	Potential impacts on soil biota would be unaffected by denial of the petition.	TAM66274 cotton is agronomically similar to those currently used by growers of non-GE varieties. Consequently, commercial production of TAM66274 cotton and hybrid crops are not expected to present any risk to soil biota.
Biological Diversity	Under the No Action Alternative, cropping systems generally are not expected to change, so biodiversity in regions where cotton is produced will not change.	Commercial production of TAM66274 cotton would present similar potential impacts on biodiversity as current cotton production.
Gene Flow and Weediness	Denial of the petition would have no impact on potential matters concerning gene flow and weediness associated with commercial cotton production.	The introduction of the transgenes and the associated gene products in TAM66274 cotton does not alter its weediness characteristics (USDA-APHIS 2018b), nor increase the rate of successful transgene introgression from TAM66274 cotton into native or naturalized cotton populations relative to the rate of gene introgression from conventional cultivars. The low gossypol trait in TAM66274 cotton would not be expected to confer a selective advantage or result in increased plant pest potential if crossing with feral populations were to occur. In the unlikely event that this should occur, progeny resulting from such a cross could easily be controlled via herbicides and hand weeding.
Human and Animal Health		
Human Health and Safety	Denial of the petition would have no impact on human health or worker safety. Consumer use of cotton and cottonseed products will continue	Approval of the petition would not be expected to present any risks to human health. RNAi-mediated gene suppression has been used in a number of biotechnology-derived

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Continuation as a Regulated Article**	**Alternative 2: Preferred Alternative - Determination of Nonregulated Status for TAM66274 Cotton**
	similarly to current uses. The use of cottonseed products other than oil in human food will continue to be limited due to the presence of gossypol. EPA regulation of pesticides and worker protection standards would remain unchanged.	food crops including papaya, potato, plum, corn, canola, and soybean. These plant varieties have been previously evaluated by the FDA. The FDA did not identify any safety or regulatory issues regarding food and feed derived from these varieties (US-FDA 2018). The FDA has approved NPTII as an indirect food additive in GE cotton, canola, and tomatoes for human consumption (21 CFR §173.170) and in animal feed (21 CFR §573.130). The EPA has granted an exemption from the requirement of a tolerance for residues of NPTII in all food commodities when used as an inert ingredient in a plant-incorporated protectant (40 CFR § 174.521). As part of the consultation process, TAMU submitted its food and feed safety and nutritional assessment finding of TAM66274 to FDA on September 22, 2017.
Animal Health and Welfare	Denial of the petition would have no effect on animal health and welfare.	TAM66274 cotton, which has low levels of gossypol in the seed, is intended to provide for expanded uses of cottonseed products in the food and feed industries. This would be considered a benefit to livestock and aquaculture, as well as processors and end users in the livestock and aquaculture industries.
Socioeconomics		
Socioeconomics	Denial of the petition would have no impact on 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.	Approval of the petition would not be expected to present any risks to domestic or international markets. TAM66274 cotton, low in gossypol (e.g., 3% of that in conventional cottonseed varieties (TAMU 2017), facilitates cottonseed oil refining, use of cottonseed oil in the food industry,

Table 2-1. Summary of Issues and Potential Impacts of the Alternatives		
Attribute/Measure	**Alternative 1: No Action – Continuation as a Regulated Article**	**Alternative 2: Preferred Alternative - Determination of Nonregulated Status for TAM66274 Cotton**
		and use of whole seed, oil, and crushed meal in the livestock and aquaculture feed industries. Consequently, its introduction would be considered of potential benefit to domestic and foreign food and feed markets. In general, TAM66274 cotton expands opportunities for cottonseed use in the food and feed sectors, without adversely affecting the quality or value of the fiber or other byproducts such as hulls and linters. It is assumed that growers would adopt and produce TAM66274 cotton commensurate with market demand for cottonseed products low in gossypol.
Coordinated Framework		
FDA Consultations and EPA Registrations	Consultations with the FDA and changes to the EPA registrations would be unnecessary.	TAMU initiated food safety consultations with FDA in 2012 in accordance with FDA's policy statement and industry guidance. TAMU submitted its food and feed safety and nutritional assessment of TAM66274 to FDA on September 22, 2017. TAMU has no obligations under EPA's authorities related to this product.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Compliant	Compliant

3 AFFECTED ENVIRONMENT

This chapter provides an overview of those aspects of the human environment potentially affected by APHIS' decision to either approve or deny the petition. Broadly, those aspects considered are U.S. cotton production, the physical environment, biological resources, public health, animal feed, and socioeconomics. Because the introduced genes are involved in limiting the biosynthesis of gossypol, and the intended use of TAM66274 cotton is in the food and feed industries, the primary focus of this EA is on: (1) potential human and animal (livestock/aquaculture) health impacts, (2) effects on wildlife that may consume TAM66274 cotton or TAM66274 cotton hybrids (wild or commercial cotton hybrids), and (3) gene flow and potential weediness – ecosystem level impacts.

3.1 Areas and Acreage of Cotton Production

3.1.1 Conventional Cotton Production Areas and Acreage

Cotton (*Gossypium* spp.) is a fiber crop[8] that is grown in many countries. The major producers are China (31%), India (18%), the United States (17%), Pakistan (8%), Brazil (6%), Uzbekistan (5%), and Turkey (5%) (Evett et al. 2012). Global cotton production is projected at 120 million bales and global trade is projected at 38.5 million bales (1 bale = 480 pounds) in 2017/18 (USDA-ERS 2017b). The United States is the world's third-largest producer of cotton fiber, after China and India, and the leading cotton exporter (NCCA 2017a, b). The major cotton by-products include edible oil refined from seeds, hulls and high-protein meal used for livestock feed, and linters, which are used for a variety of industrial products (OECD 2008).

Commercial production of cotton requires, full sun, relatively warm temperatures, and moderate rainfall or irrigation, usually from 24 to 47 inches of water (60 to 120 centimeters) per growing season (Evett et al. 2011). It is geographically more limited in the United States than other major crops, such as corn and soybeans, because its growth requires a relatively long growing period of a minimum of 180 frost-free days per year (Rude 1984; Smith and Cothren 1999; OECD 2008).

In 2017, cotton was planted on approximately 12.6 million acres (USDA-ERS 2018), across 17 states in the southern United States, commonly referred to as "The Cotton Belt." These are: 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 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 2017b; USDA-NASS 2018). Market conditions play a larger role in determining how much cotton is planted than agronomic factors.

[8] There are textile fibers (used in production of cloth), cordage fibers (used in production of rope), and filling fibers (used to stuff upholstery and mattresses).

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	5,800	6,200	4,800	5,650	6,900	3,100	4,600	4,500	4,500	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 2017b; USDA-NASS 2018)

Of the four cultivated forms of cotton, the dominant species in production is *Gossypium hirsutum*, also known as upland cotton, which while capable of perennating is managed as an annual (Evett et al. 2012). In the United States, upland cotton (*G. hirsutum*), comprises about

98% of planted cotton (USDA-NASS 2015). 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 2018) Figure 3-1 illustrates the primary areas of upland cotton crop production, and Figure 3-2 the areas for Pima cotton.

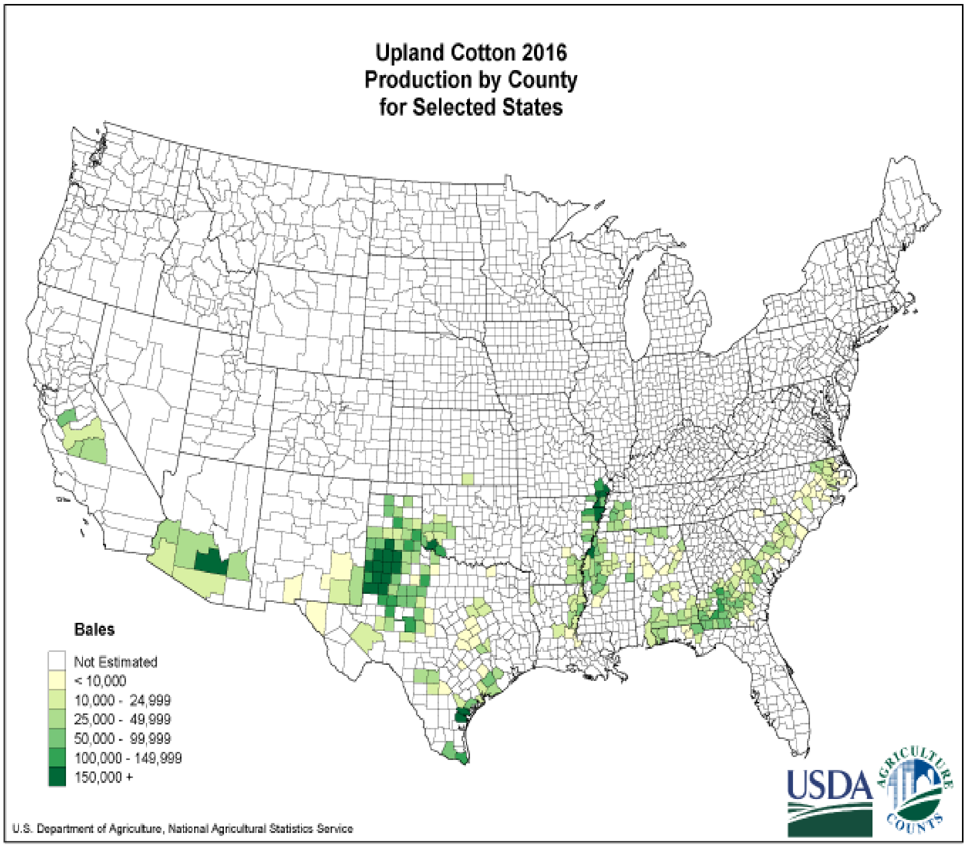

Figure 3-1. Upland Cotton Planted Acres in the United States in 2016
Source: (USDA-NASS 2016b)

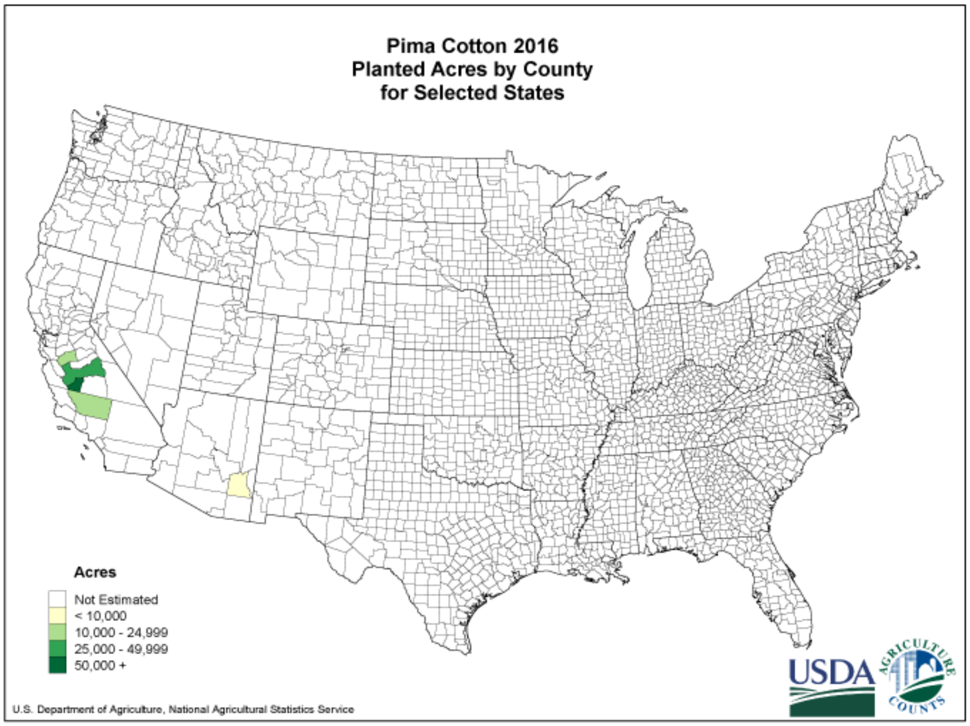

Figure 3-2. Pima Cotton Planted Acres in the contiguous United States in 2016
Source:(USDA-NASS 2016c)

Market prices for cotton vary over time and so do the total acres planted to cotton. Factors such as global demand, supplies, and global cotton stocks/reserve (Figure 3-3) levels can have an effect on cotton markets. Cotton yields (lbs/acre) also differ from year to year, but they have increased over the last several decades. Since 1965, average upland cotton yields, increased from 530 to 790 lbs/acre; this is an increase of about 67% (USDA-NASS 2017e).

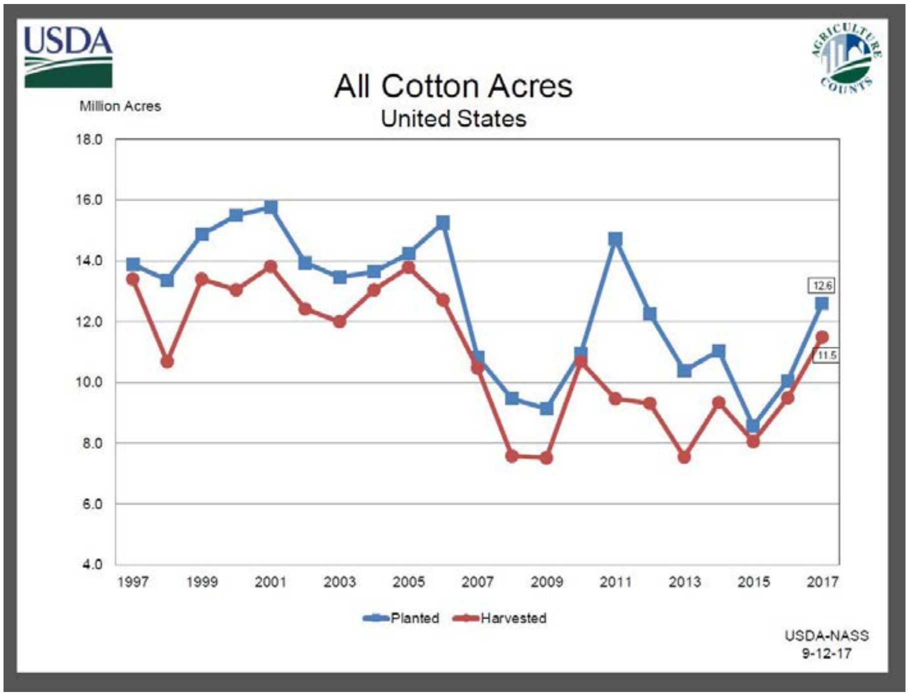

Figure 3-3. Acres of Cotton Planted and Harvested from 1997 to 2017
Source: (USDA-NASS 2017a, d)

3.1.2 GE Varieties of Cotton

Many varieties of cotton have been genetically engineered to be either herbicide resistance (HR), insect resistance (IR), or both (Green and Owen 2010). GE cotton comprises about 96% of cotton acres (USDA-ERS 2017a) (USDA-NASS 2017b; USDA-AOF 2018) (Figure 3-4). In 2017, single trait GE HR cotton comprised 11% of upland cotton acreage, GE IR cotton (also referred to as *Bacillus thuringiensis* (Bt) cotton)[9] comprised about 5%, and GE cotton varieties stacked with both HR and IR traits about 80% (USDA-ERS 2017b)

[9] Certain genetically engineered insect resistant crops (Bt crops) contain a gene from a soil bacterium, *Bacillus thuringiensis* (Bt); this gene when expressed in plants produces a protein that is toxic to specific types of insects.

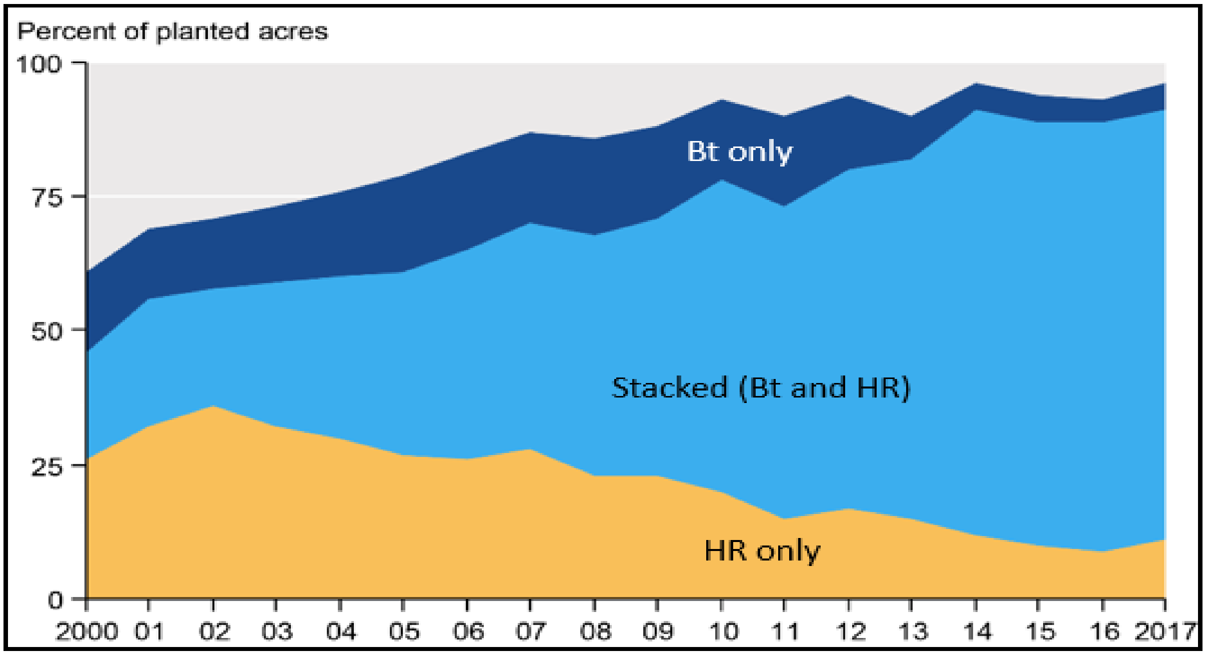

Figure 3-4. Adoption of Genetically Engineered Cotton in the United States with Herbicide Resistance (HR), Bt-Conferred Insect-Resistance (Bt), or Both Traits (Stacked), 2000-2017
Adapted from: (USDA-ERS 2017c).

Table 3-2 lists GE cotton varieties that APHIS previously regulated. APHIS determined upon petition review, and assessment of the plant pest risk each of these varieties may pose, that none were subject to regulation under 7 CFR part 340.

Table 3-2. 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-8191Ø-7	7/23/2015
12-185-01p	Monsanto	Dicamba and Glufosinate Tolerant	MON-887Ø1-3	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)
Source: (USDA-APHIS 2018a).

Note: The terms resistance and tolerance are used frequently in a range of documents. They can have different meanings. “Resistance” to herbicides is defined by the Weed Science Society of America (WSSA) as the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type. In a plant, resistance may be naturally occurring, induced by such techniques as genetic engineering, or by tissue culture or mutagenesis. “Tolerance” is distinguished from resistance and defined by WSSA as the inherent ability of a plant to survive and reproduce following exposure to an herbicide. This implies that there was no selection or genetic manipulation to make the plant tolerant. Because of the variation in usage of the terms, in this document, these terms are considered to be equivalent.

3.2 Agronomic Practices in Cotton Production

Producing food and fiber involves agronomic practices and inputs that can potentially present environmental and human health risks. For cotton production, these practices and inputs may involve crop rotation, crop monitoring, tillage, fertilizers, pesticides, seeding, hand weeding and harvesting, and in some cases, irrigation. Those practices and inputs that can present environmental and human health risks are summarized below.

3.2.1 Tillage

Growers primarily use tillage to control weeds and soil-borne pests and disease. Certain tillage practices may also 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.

The tillage system and frequency of tillage impacts soil susceptibility to erosion, and water and air quality. In addition, tillage operations can be costly, labor intensive, 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.

Conventional tillage is associated with intensive plowing and leaving less than 15% crop residue in the field (Stichler et al. 2006; US-EPA 2010). In contrast, reduced tillage is associated with 15 % to 30 % crop residue. No-till farming only disturbs the soil between crops. This is minimal compared to other tillage systems and is mostly associated with planting. Conservation tillage relies on methods that result in less soil disruption and leaves at least 30% of crop residue on the surface. 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; conserving soil moisture by reducing evaporation, and reducing soil and wind erosion and run-off (Tyler et al. 1994; Papendick and Moldenhauer 1995; USDA-NRCS 2006; Mathew et al. 2012).

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 (USDA-NASS 2016a). In 2010-2011, no-till and strip-till (a type of conservation tillage) accounted for 33% of cotton acres. No-till/strip-till adoption in 2010-2011 was 11.9% higher than 2007 cotton (Wade et al. 2015). 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 growers in some areas to include or intensify 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 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.

3.2.2 Fertilizer Use

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). Fertilizers are necessary for good yield and product quality in some areas, but can present a problem when run-off carries these nutrients into surface waters such as rivers and lakes. For cotton, these are primarily nitrogen, phosphate, and potash. For the 2015 crop year, farmers in the Southeast, Texas, New Mexico, and California, applied nitrogen to 78% of planted acres, at an average rate of 79 lbs/acre, for a total of 503.7 million pounds (Table 3-3). They applied phosphate to 56% of cotton planted acres and potash to 42% of planted acres.

Table 3-3. Fertilizer Applied to Cotton, 2015 Crop Year in southeast Texas, New Mexico, and California

	Planted Acres Receiving Fertilizer (%)	Avg. Rate per Year (lbs/acre)	Total Applied (millions lbs)
Nitrogen	78	79	503.7
Phosphate	56	41	187.7
Potash	42	74	250.3

Source: (USDA-APHIS 2018a).

3.2.3 Pest Management

Insect pests decrease yield and reduced product quality. In all cotton production regions in the United States insect pests are common. In 2016, the total costs and losses in cotton production due to insects amounted to nearly six million dollars, with overall yields reduced by 2.6%. The top ranked pests in terms of yield loss in 2016 are shown in Table 3-4. The highest yield losses (0.73%) were associated with lygaeid bugs, followed by stink bugs (0.64%) and thrips (0.42%). Bollworm/budworm complex ranked fourth at 0.41%, and spider mites and cotton fleahoppers caused reduced yields by 0.12% and 0.76%, respectively. All other pests caused less than 0.1% 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. Planting IR cotton seed is associated with higher net returns when pest pressure is high (Fernandez-Cornejo et al. 2014b).

The potential development of evolved resistance in pest populations to various classes (differing Modes of Action (MOAs)) of insecticides, to include those genetically engineered into the plant, requires growers to make and implement management decisions to achieve effective control of pests while preventing emergence of insect and pathogen populations resistant to the pesticide (US-EPA 2018b). This is commonly called integrated pest management (IPM), a strategy that focuses on sustainable control of pests using a combination of techniques such as biological controls, chemical controls, habitat manipulation, cultural practices, and use of resistant crop varieties. Pesticides are generally used only after monitoring indicates they are needed, and treatments made with the goal of removing only the target insect pest or pathogen.

Most developers of GE IR crops require growers to enter into an agreement to implement an IPM program in production of the crop, so as to support the sustainable use that particular IR variety. In 2017, the EPA issued pesticide Registration Notice (PRN) 2017-1, *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling* (US-EPA 2017a). PRN 2017-1 revises and updates PRN 2001-5, and applies to all conventional pesticides (i.e., fungicides, bactericides, insecticides, and acaricides). The guidance is intended to provide:

- additional guidance for resistance management on pesticide labels;
- references to external technical resources for guidance on resistance management; and

- updated instructions on how to submit changes to existing labels in order to enhance resistance-management language.

In the EPA's *Guidance on FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants*, any incidents of pest resistance for registered pesticide products must be reported to the EPA.[10] This reporting requirement is in accordance with FIFRA Adverse Effects Reporting Section 6(a)(2), which requires pesticide product registrants to submit adverse-effects information about their products to the EPA.

3.2.4 Weed and Herbicide Resistance Weed Management[11]

Weed Management in Cotton

Weed control in cotton is essential for efficient crop production. Weeds can have direct and/or indirect impacts, such as (a) reduce fiber quality, (b) reduce crop yield, (c) increase production costs, (d) reduce irrigation efficiency, and (e) serve as hosts and habitats for insect pests, disease-causing pathogens, nematodes, and rodents (Ashigh et al. 2012b). Weeds can directly impair cotton growth by competing for resources and, in some cases, by releasing allelopathic, or growth-suppressing, chemicals (Ashigh et al. 2012b). The degree of damage caused by weeds is related to the weed species composition (type of weeds), weed densities, and the duration of weed-cotton competition relative to the lifecycle of the cotton plant (Ashigh et al. 2012b). In general, as the weed density in cotton fields increases the damage on fiber yield and quality also increases.

Herbicides provide a convenient, economical, and effective way to help manage weeds. They allow crops to be planted with less tillage, allow earlier planting dates, and provide additional time to perform the other tasks on the farm (Lingenfelter 2018). Due to reduced tillage, soil erosion is reduced, thus limiting soil and agricultural run-off from entering waterways and decreasing the quality of the nation's surface water (see Section 3.3.1 – Water Resources). Without herbicide use, no-till agriculture becomes impossible. However, herbicide use also presents some well recognized risks that include environmental, ecological, and human health effects. In terms of ecological effects, various weeds can be inherently (naturally) resistant to an herbicide, discussed below.

Herbicide Resistant Weeds in U.S. Cotton Crops

Herbicides impart selection pressures on these types of plants, resulting in survival of those plants resistant an herbicide active ingredients (a.i.) (Owen 2011; Vencill et al. 2012). HR weed populations naturally develop when the resistant individuals survive and reproduce after repeated

[10] See https://www.epa.gov/pesticide-registration/prn-98-3-guidance-final-fifra-6a2-regulations-pesticide-product-registrants

[11] The terms "weed control" and "weed management" are both used in the published literature. APHIS considerers "weed management" to be a more comprehensive term than "weed control." Management suggests greater consideration of thresholds, critical periods, the environmental context, and possibly even social outcomes, before specific weed control methods are imposed (see Harker KN and O' Donovan JT. 2012. *Recent Weed Control, Weed Management, and Integrated Weed Management*. Weed Technology 27, pp. 1-11. Retrieved from http://www.bioone.org/doi/full/10.1614/WT-D-12-00109.1).

exposure to an herbicide a.i., passing the inherent (non-GE) herbicide resistant trait on to their progeny.

The development of HR weed populations is not a recent phenomenon nor is it unique to GE crops. HR weed populations have been developing 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 cotton crop producers. It should be noted that weeds could also become resistant to cultural control practices, such as tillage, if they are over used.

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 or more MOAs are increasingly common. Table 3-5 lists weeds with resistance to one or more herbicides that occur in U.S. cotton crops.

Table 3-5. Herbicide-Resistant Weeds in Cotton with Resistance to One or More Herbicides

Mode of Action (MOA)	Weed-Common Name	States Present
Acetyl CoA Carboxylase (ACCase) inhibitors	Johnsongrass	Louisiana, Mississippi, Tennessee
ALS inhibitors	Palmer Amaranth	South Carolina, Tennessee
	Spiny Amaranth	Mississippi
	Tall Waterhemp	Missouri
	Horseweed	Kansas
5-enolpyruvylshikimate-3-phosphate (EPSP) 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
	Palmer Amaranth	Arizona, Georgia, Mississippi, South Carolina, Tennessee

Table 3-5. Herbicide-Resistant Weeds in Cotton with Resistance to One or More Herbicides		
Multiple Resistance: 2 MOAs - ALS inhibitors & EPSP synthase inhibitors	Tall Waterhemp	Missouri

Source: (Heap 2017)

ACCase refers to acetyl CoA carboxylase and 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 most instances, crop producers are advised to, and are using, integrated weed management (IWM) practices to address HR weed concerns (e.g., (Wilson et al. 2009; Shaw et al. 2011; Vencill et al. 2012). As with IPM, IWM consists of utilizing multiple practices, including mechanical, cultural, chemical, and biological weed control tactics, to optimize control of weeds. IWM can include specifically timed applications of herbicides, the use of herbicides with multiple MOAs, crop rotation, cover crops, various tillage practices, weed surveillance, and hand-pulling or hoeing (Owen 2011; Garrison et al. 2014; CLI 2015).

In 2017, the EPA issued PR Notice 2017-2, *Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship* (US-EPA 2017h). Through PRN 2017-2, the EPA provides HR weed management guidance for herbicides undergoing registration review and for label registration (i.e., new herbicide active ingredients, new uses proposed for HR 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 the USDA (IPM 2015).

Volunteer Cotton

In some crop rotation systems, cotton can volunteer in a subsequent crop cycle., This 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 can result in yield loss. The primary methods for removing volunteer cotton in fields is tillage and/or herbicides. Management of volunteers is also important for any region that has an active Boll Weevil Eradication Program. 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).

3.3 Physical Environment

3.3.1 Water Resources

Crop Irrigation

Over the period of 2009 to 2012, approximately 39% of cotton acres were irrigated (USDA-NASS 2009; Schaible and Aillery 2012). In 2012 (latest data available), among 18,155 farms totaling 9.38 million acres total acres, 9,130 of these farms used irrigation on about 3.81 million acres., (USDA-NASS 2014). The remaining majority of U.S. cotton (about 60%) is currently not irrigated. Nationally, cotton accounts for only 7% of irrigated agricultural acres in the United States. In the South and the Southeast, non-irrigated cotton systems dominate, while in the more arid West nearly all of the crop's water requirements are met by irrigation water. Cotton is heavily irrigated in California, Arizona, western Texas, but also in Georgia, and the Mississippi River Valley (Figure 3-5). The lack of affordable water has been noted as one factor in the reduction of acres of cotton grown in California, Arizona, and New Mexico in the past decade (Cotton Incorporated 2018). In these areas, cotton has been displaced by higher value crops and land uses (Cotton Incorporated 2018).

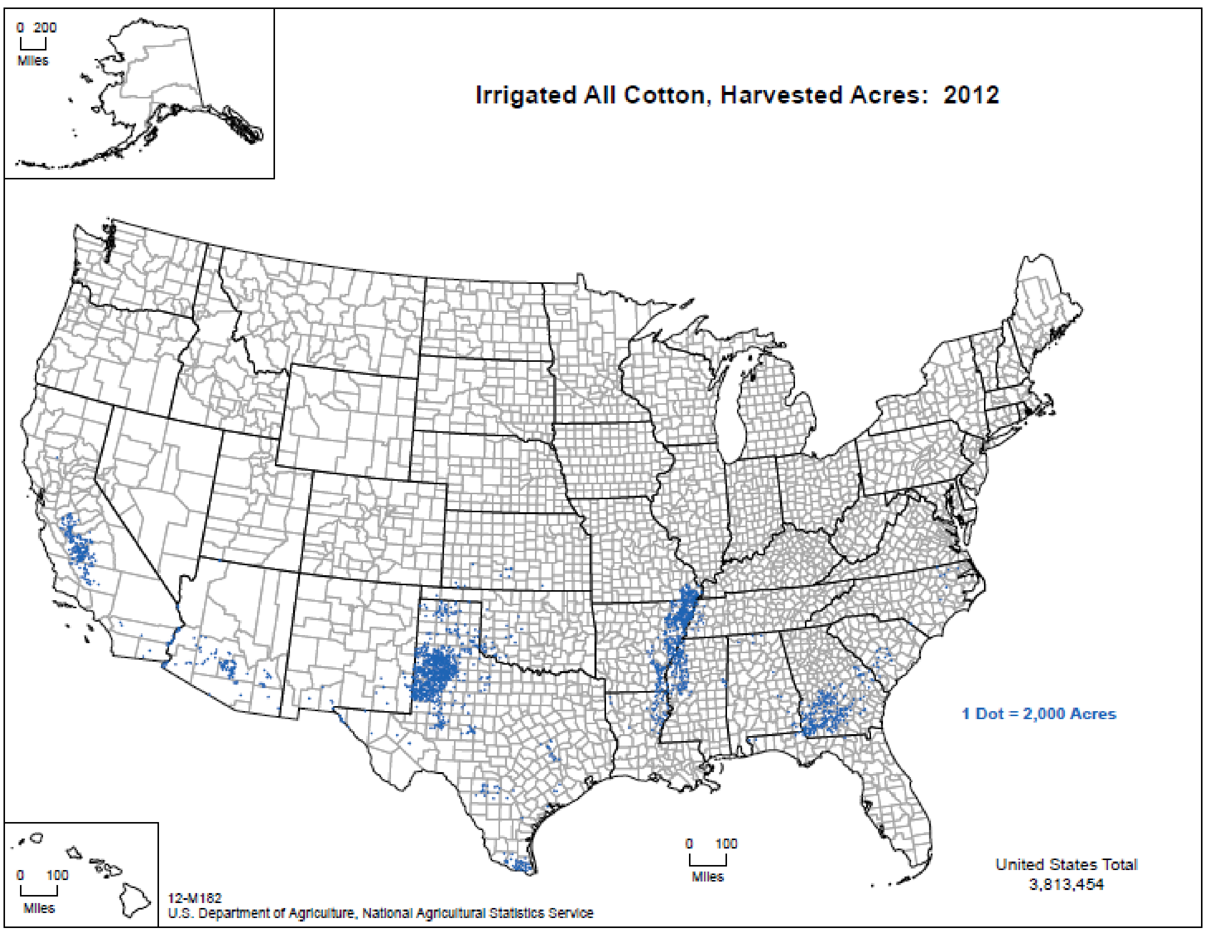

Figure 3-5. Irrigated Cotton Acreage in the United States in 2012

Source: USDA National Agricultural Statistics Service Map # 12-M182 (USDA-NASS 2012a)

Water Quality

Tillage and agronomic inputs used in cotton crop production 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 non-point source (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 2015b, 2017e). The most common NPS contaminants in agricultural run-off are sediment, fertilizer based 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 2017j). For lakes, reservoirs, and ponds, nutrients are second, sediments twelfth, and pesticides thirteenth (US-EPA 2017j). Pesticides may enter water through spray drift, runoff, improper disposal of pesticides, and other pathways especially when there is a 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. In some cases, such as when pesticide label requirements are not followed, pesticides can enter into water from point sources as well as NPS. Not strictly following all pesticide label instructions is a violation of federal law. The United States Geological Survey (USGS) monitors and maintains information on pesticide concentrations in surface and groundwater in its Pesticide National Synthesis Project (USGGS 2012).

Excess fertilizer in run-off can adversely affect aquatic ecosystems by causing hypoxic (low dissolved oxygen) or anoxic (no dissolved oxygen) conditions. This is commonly seen on an annual basis in the northern Gulf of Mexico hypoxic zone (US-EPA 2017f), which receives run-off from the Mississippi/Atchafalaya River Basin (MARB). The MARB drains parts or all of 31 states in the central United States, most with extensive areas of cropland. Cotton producing states in the MARB include Oklahoma, Texas, Arkansas, Missouri, Louisiana, Tennessee, Alabama, and Kansas.

While fertilizer run-off from cotton fields continues to impact surface waters in the MARB, and Gulf of Mexico, refinements in the timing and precision of fertilizer application, in tandem with improved irrigation efficiencies, such as the Pipe Hole and Universal Crown Evaluation Tool irrigation program, have decreased fertilizer loads in run-off over the years (Gilley and MArk 2000; USDA-NRCS 2011). For example, recent studies in Arkansas cotton crops have found that about 1% of nitrogen applied ends up in runoff, with 99% utilization by the crop (Farmpress 2014). Similarly, about 3% to 5% of phosphorus was found in run-off, with 95% to 97% crop utilization.

The Clean Water Act (CWA; 33 U.S.C. §1251 et seq.) establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulation of water quality. Under the CWA, the EPA implements pollution control programs, such as wastewater standards for industry, and water quality standards for contaminants in surface waters. The CWA provides for two types of discharge permits: (1) Section 402 permits (National Pollutant Discharge Elimination System, or National Pollution Discharge Elimination System (NPDES), permits) address the discharge of most point source pollutants,[12] 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, which are NPS, do not fall within the definition of point source, and thus are outside of the jurisdiction of the NPDES permitting program. In general, 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 (US-EPA 2018a).

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 2017d) and USDA Natural Resources Conservation Service's (NRCS) National Water Quality Initiative (NWQI)(USDA-NRCS 2017a). 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

Agronomic practices, such as tillage, the timing of practices, fertilizer and crop protection application rates, and other actions have the potential to impact soil erosion, off-site transport of sediments, pesticides, and fertilizers, and soil biodiversity. Tillage, cover crops, crop rotation, and pesticide and fertilizer inputs can influence the biological, physical, and chemical properties of soil, which in turn can affect fertility, crop yield potential, and soil erosional capacity (Baumhardt et al. 2015). While soil erosion occurs through natural processes, the rates of which

[12] 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 storm water discharges and return flows from irrigated agriculture.

are determined by factors such as soil type, topography, local ecology, and weather; tillage is the primary practice that can facilitate topsoil loss via wind and water erosion; a process that can take centuries to reverse. Soil erosion occurs in many areas but is more concentrated in those regions where there is a larger proportion of the land considered highly erodible (Magleby et al. 1995; USDA-NRCS 2010b; Baumhardt et al. 2015). Excessively eroding cropland soils is concentrated in the Midwest, Southern High Plains of Texas, and the Northern Plain States (Figure 3-6).

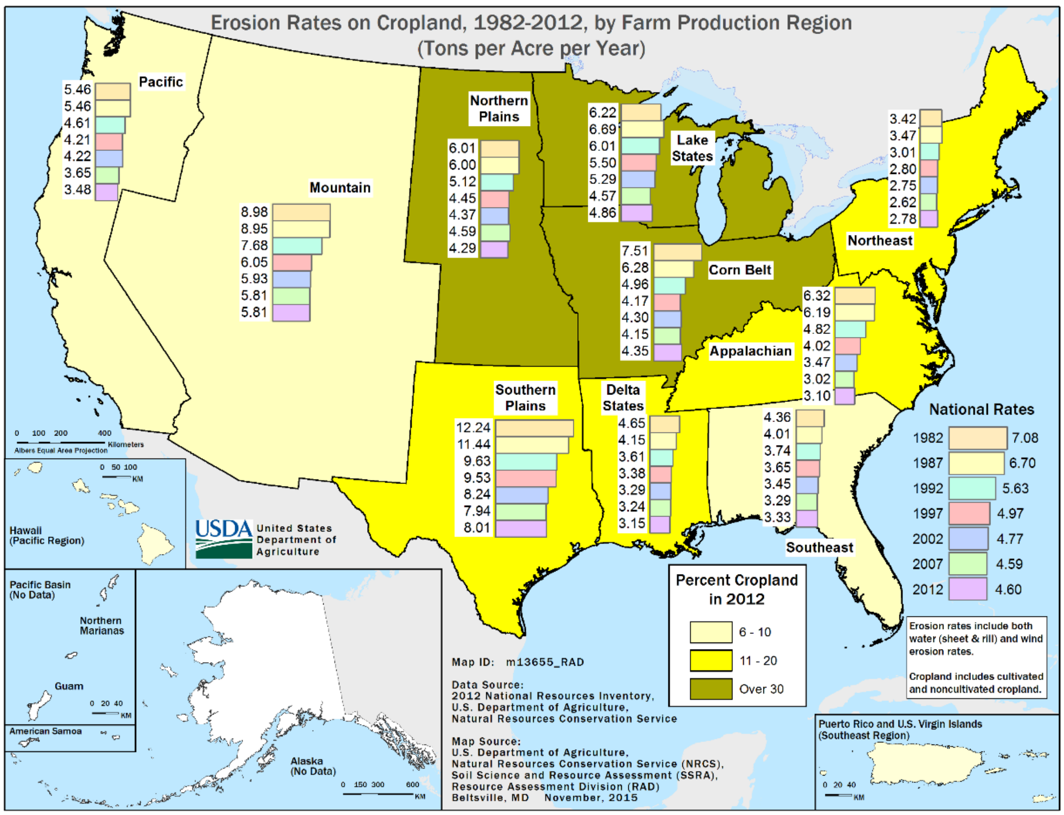

Figure 3-6. Locations and Status of U.S. Croplands Subject to Erosion
Source: (USDA-NRCS 2018c)

Since 1985, conservation programs have specifically targeted highly erodible lands in the United States. As part of these efforts use of conservation tillage on U.S. cropland increased from around 16% in 1979 to about 36% in 1996. As of 2011 (latest data), around 40% of cropland, on average, was under conservation tillage (USDA-NASS 2014; Wade et al. 2015). No-till/strip-till was used on 39% of total acreage in major crops, including 33% of cotton (Wade et al. 2015).

As conservation tillage and no-till practices increased, total soil loss on erodible croplands in the United States decreased. Soil erosion on cropland decreased 44% between 1982 and 2012. Water (sheet and rill) erosion declined from 1.59 billion tons per year to 0.96 billion tons per year, and erosion due to wind decreased from 1.38 billion tons per year to 0.71 billion tons per year, over the same time period (USDA-NRCS 2015).

As discussed in Section 3.2 – Agronomic Practices, cotton farmers largely use minimum or no-till systems, which limits impacts on erosion and run-off from cotton croplands. Due to technological advances in production and best management practices in the United States, there has been a 31% reduction in land required to produce one kilogram of cotton lint since 1980 (NIR 2016). The main factor of this improvement is two-thirds of U.S. cotton growers employ conservation tillage. Between 2008 and 2015, the number of growers using no-till practices increased from 36% to 45%. (Reed et al. 2009). The widespread adoption of these practices has resulted in a 44% reduction in soil loss per pound of cotton produced on U.S. cotton acreage over the past 30 years (NIR 2016).

3.3.3 Air Quality

The EPA establishes National Ambient Air Quality Standards (NAAQSs) pursuant to the Clean Air Act (CAA) that are intended to protect public health and the environment. NAAQS are established for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and particulate matter (PM). The EPA determines if the air sheds within each state are either in attainment or in nonattainment for each criteria pollutant under the NAAQS. For air sheds that are in nonattainment, the EPA requires states 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.

Some cotton production practices can generate NAAQS pollutants and may contribute to challenges in maintaining regional NAAQS. Agricultural emission sources associated with cotton production include fossil fuels used with farm equipment (e.g., pesticide application, harvest, tillage); soil PM; and pesticide volatilization or drift (Aneja et al. 2009; US-EPA 2013).

While the EPA establishes NAAQS, the standards do not set emission control requirements for any particular industry, including agriculture. The USDA and the EPA provide guidance for regional, state, and local regulatory agencies, and farmers, on how to best manage agricultural emissions sources (USDA-EPA 2012). These measures allow stakeholders the flexibility in choosing which measures are best suited for their specific situations/conditions and desired purposes. The EPA and USDA provide guidance to the agriculture sector for limiting NAAQS emissions. The USDA Environmental Quality Incentives Program Air Quality Initiative provides financial and technical assistance to help farmers and ranchers limit air pollution. The EPA has developed USDA-approved measures to help manage air emissions from cropping systems to help satisfy state implementation plan requirements. The EPA recommends that in areas where agricultural activities have been identified as a contributor to a violation of NAAQS, USDA-approved conservation systems and activities may be implemented to limit emissions. 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.

The EPA's Office of Pesticide Programs, which regulates the use of pesticides, introduced initiatives to help pesticide applicators minimize off-target pesticide drift. The EPA's voluntary Drift Reduction Technology Program was developed to encourage the manufacture, marketing, and use of spray technologies that reduce pesticide drift. The EPA is also working with pesticide manufacturers through the registration and registration review programs on improvements to pesticide label instructions to reduce drift and volatilization (e.g., see (US-EPA 2015a).

3.4 Biological Resources

The biological resources described in this section include animals, plants, and 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. Insect pests of cotton are discussed in Section *3.2.3 – Pest Management*.

3.4.1 Animal Communities

Wildlife refers to native and introduced species of mammals, birds, reptiles, amphibians, fish, and invertebrates. The environment surrounding cotton fields, such as woods, pasture/grassland, or aquatic environments, may serve as important food sources, shelter, nesting, or other needs for these species. Wildlife may feed on cotton plants and/or use habitat surrounding cultivated fields for nesting and refuge.

3.4.1.1 Vertebrates

Species of wildlife across cotton growing regions of the United States are diverse, ranging from more common field mice, deer, squirrel, and rabbit, to more localized species such as armadillo and coyote. In general, cotton fields provide little habitat for wildlife, although post-harvest residues left on the field such as stalks, branches, leaves, bolls, and seeds may be browsed by wildlife (Huang et al. 2012). Cottonseed consumption is likely selective; laboratory feeding trials and field surveillance indicate that neither feral pigs nor raccoons found cottonseed to be palatable, while tailed deer readily consumed cottonseed (Taylor et al. 2013b). Birds generally avoid cotton fields, although some generalist species (geese, egret, blackbirds) may periodically be observed in or around cotton fields (Butcher et al. 2007). Cattle egrets (*Bubulcus ibis*) use cotton fields in the summer, which could be in response to increased invertebrate densities (Abdullah et al. 2017).

Reptiles tend to be localized, including box turtles, garter snakes and rattlesnakes 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, such as frogs, toads, and salamanders, would be limited by access to aquatic habitats.

3.4.1.2 Invertebrates

Various invertebrate species are associated with cotton fields. As with other taxa, the community composition of invertebrates present in the vicinity of cotton production fields will vary by location. Numerous species of arthropods among 69 families have been reported in commercial cotton fields in the United States (Sisterson et al. 2004). As discussed for pest management (Section 3.2.3), some insects are pests of cotton, while many insects and other invertebrates are beneficial to cotton production – providing services such as nutrient cycling and predation on plant pests. Table 3-6 lists the major beneficial arthropods in cotton fields, such as pollinators, and Table 3-7 lists those beneficial insects that prey on plant pests (USDA-NRCS 2014). Major pollinators of upland cotton are bumble bees (*Bombus* spp.), black bees (*Melissodes* spp.), and honey bees (*Apis mellifera*) (Catchot et al. 2008; USDA-NRCS 2014). Other beneficial invertebrates include earthworms, termites, ants, beetles, and millipedes, which contribute to the decay of organic matter and the cycling of soil nutrients (Catchot et al. 2008; Ruiz et al. 2008).

Table 3-6. 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
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 3-7. 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), 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),

Table 3-7. Beneficial Insects that Prey on Pest Species of Cotton Plants	
Pest Species	**Natural Enemies (Beneficial Predator Insects)**
	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 ; 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 of cotton fields. These include ponds, lakes, streams, and rivers, and marine environments such as the Gulf of Mexico. Aquatic species may be exposed to sediments, 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.

3.4.2 Plant Communities

Cotton fields may be bordered by other cotton fields (or another crop) or surrounded by woodlands, rangelands, and pasture or grassland areas. The plant communities in these surrounding areas may be natural, managed (such as to control soil and wind erosion), or a combination. 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. Herbicides can potentially drift if sprayed and damage flora in the vicinity of the crop.

Plant diversity is an important component of a sustainable agricultural system (Scherr and McNeely 2008; CBD 2015b), and hedgerows, woodlands, fields, and other surrounding habitat serve as important reservoirs for beneficial insects and other animals. By providing habitats, pollen and nectar resources, and serving as hosts, plants adjacent to cotton fields help support a suite of beneficial arthropod species, including pollinators and biological control agents that prey on agricultural plant pests (Scherr and McNeely 2008; Nichols and Altieri 2012). Surrounding plant communities can also help regulate runoff, reduce soil erosion, and improve water quality

(Egan et al. 2014a). In general, surrounding habitat and plant communities provide invaluable ecosystem services such as pollination, pest control, and control of run-off.

Declining plant diversity in agroecosystems has often been attributed to use of herbicides; they are among those most often implicated in drift complaints – situations where herbicides float off-site and cause unintended harm to sensitive plant species in areas adjacent to crops. All herbicides have some degree of environmental mobility, and vegetation outside of the treated crop can be exposed through a variety of mechanisms, including spray drift, volatilization, surface and subsurface water flow, and deposition in rainfall (Egan et al. 2014a). Given these diverse routes of exposure, it is likely that plants growing in habitats adjacent to crops routinely experience contact with a variety of herbicides at a range of phytotoxically active doses (Egan et al. 2014a). The structure and function of plant and associated arthropod communities are nuanced and will depend on species composition, successional patterns, and to some degree the timing of herbicide exposure.

These factors considered, recent studies have found that herbicides alone are not the causative factor in shaping plant communities proximate to crops. Rather, for the purposes of conserving plant species diversity in agricultural landscape, other strategies like preserving habitats such as woodlots, pastures, and riparian buffers may be more effective than reducing herbicide use (Egan et al. 2014a). While herbicides will continue to play a fundamental role in weed management programs and can affect surrounding vegetation, how surrounding habitats are managed (Egan et al. 2014b) likewise determines the diversity of plants, pollinators, and natural predators of plant pests (Nichols and Altieri 2012; Egan et al. 2014b).

3.4.3 Soil Biota

The inorganic and organic matter comprising soil is home to a great variety of fungi, bacteria, and arthropods (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 (Garbeva et al. 2004). These microorganisms also suppress soil-borne plant diseases and promote plant growth (Doran et al. 1996).

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 (Donegan and Seidler 1999; Buckley and Schmidt 2001; Buckley and Schmidt 2003). Consequently, 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 Gene Flow and Weediness

Upland cotton is a domesticated plant, it does not generally persist in areas outside of cultivation and is not considered a problem plant in terms of weediness (Keeler et al. 1996). Upland cotton (*G. hirsutum*) is not listed as a weed in major weed references (USDA-NRCS 2018a, b), 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. However, in suitable areas, such as southern Florida, Hawaii, and Puerto Rico, upland cotton can become locally feral or naturalize (e.g.,(Andersson and de Vicente 2010)).

3.4.5 Biodiversity

As previously discussed for animal communities, cotton fields provide little habitat for wildlife. Consequently, biodiversity in and around cotton fields will be limited. The homogeneity of cotton crops (monoculture), and frequent disturbance of the fields through planting, harvesting, cover cropping, tillage, pesticide application, scouting, and related production activities limit the diversity of plants and animals in and around cotton fields. While biodiversity will be inherently limited, 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 (SARE 2012).

Biodiversity in an agroecosystem depends on four primary factors: 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. Strategies that promote biodiversity include intercropping (planting of two or more crops together in the same field at the same time), agroforestry, crop rotations, cover crops, no-till, 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).

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 (Ward et al. 2002). Conservation tillage practices that leave greater amounts of crop residue serve to increase the diversity and density of local bird and mammal populations (USDA-NRCS 1999; Sharpe 2010a). Increased residue also provides habitat for insects and other arthropods, increasing prey species for insect predators. The increased use of conservation tillage practices can benefit birds, mammals, and other wildlife through sustaining water quality, the availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Sharpe 2010b; Towery and Werblow 2010a; Towery and Werblow 2010b).

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 considered.

The safety assessment of GE crop plants, summarized following, 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 refined cottonseed oil is used for food purposes. The refining process almost completely eliminates, or substantially reduces the levels of gossypol and CPFAs in cottonseed oil, as well as other undesired compounds (AOCS 1990).

The FDA is responsible for ensuring the safety of plant-derived foods.[13] The FDA created a voluntary plant biotechnology consultation process in the 1990’s to work cooperatively with GE

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

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). TAMU states they will consult with the FDA as to the safety of food products derived from TAM66274 cotton (TAMU, 2017).

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 food tolerances, for pesticide residues in or on food, or to establish an exemption for a tolerance (21 U.S. Code § 346a). Pesticide tolerance limits are to ensure the safety of food for human consumption (US-EPA 2017i). 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 safely maintained 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 residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities 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.

The EPA also sets limits for potential drinking water contaminants 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. Other applicable EPA regulations include 40 CFR part 152 - Pesticide Registration and Classification Procedures, part 174 - Procedures and Requirements for Plant Incorporated Protectants (PIPs) and part 172 - Experimental Use Permits.

3.5.2 Worker Safety

Agriculture is one of the most hazardous industries in the United States. Workers are exposed to risks from operating farm machinery and from applying chemical pesticides and fertilizers. Agricultural operations are covered by several Occupational Safety and Health Administration standards including Agriculture (29 CFR part 1928), General Industry (29 CFR part 1910), and the General Duty Clause (29 USC 654). 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 crushed seeds. Cottonseed and cottonseed meal provide a good source of protein, fiber, and energy for ruminants (cattle, sheep, goats), and is used as such in cotton-producing areas such as India, China, and the United States. Whole cottonseed, cottonseed oil, and cotton meal can also serve 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 (e.g. < 100 ppm).

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. TAMU initiated food safety consultations with FDA in 2012 in accordance with FDA's policy statement and industry guidance. TAMU will consult with the FDA as to the safety of food and feed derived from TAM66274 cotton (TAMU 2017).

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. 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 (NCCA 2017a, b).

The United States is the world's third-largest cotton fiber producer, after China and India, and the leading cotton exporter (NCCA 2017a, b). 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 2017a, b). Consequently, the cotton industry is a vital part of rural economies in the 17 major cotton-producing states, generating more than 125,000 jobs from the farms to textile mills (NCCA 2017a, b).

Upland cotton, is the most widely planted species of cotton in the United States, constituting some 95% of all cotton production. Pima cotton accounts for the remaining acreage and is grown only in California, Texas, Arizona and New Mexico.

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 (NCCA 2017a, b). 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 2017a, b).

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. In the Unites States, 11.5 million acres of cotton were harvested in 2017, a 30 % increase from 2016 (USDA-ERS 2017b; USDA-AOF 2018). Upland cotton acreage harvested in 2017 increased 30% from a year earlier to 11.3 million acres; American Pima acreage also increased to 243,000 acres or about 28% from 2016 (USDA-NASS 2017c).

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 2015b) from an estimated harvested 9,262 acres (15,685 acres were planted) (OTA 2015b). 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 2015a). 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 cottonsuch as Pima is also grown in New Mexico and minor amounts in California and North Carolina (OTA 2015b). 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 Organic Trade Association 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 (Gibson et al. 2015). This compares to an average price for conventional upland cotton of 61.20 cents per pound in the 2014-2015 market year, and 69.70 cents in the 2016-2017 market year (Heuzé et al. 2016). In 2016, U.S. organic cottonseed prices ranged from $500 to $600 per ton. This compares to $225 to $300 per ton for conventional cottonseed (USDA-AMS 2017b)

Increases in U.S. organic cotton production during the next several years is expected to be limited (Morris and Maggiani 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 large contribution to the U.S. economy. Annual values of U.S. cotton sold overseas have averaged more than $2 billion. Currently, the United States accounts for about 37% of the total world export market. The largest customers for U.S. cotton are Asia and Mexico (NCCA 2017a). Exports to the Indian subcontinent also rose sharply during 2016/17, with India, Pakistan, and Bangladesh combined representing the second-largest U.S. trading partner.

The United States ended 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 exports 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). For 2017/18, global production and stocks are forecast to be substantially higher, only slightly offset by higher consumption and lower beginning stocks. The global trade estimate is slightly higher. The U.S. production estimate has increased by 1.2 million bales, leading to higher exports and ending stocks.

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% (Morris and Maggiani 2016). For 2014 to 2015, 193,840 farmers on 350,033 hectares (864,950 acres) in 19 countries grew approximately 112,488 metric tons (2.47 million pounds) of organic cotton. 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 (Morris and Maggiani 2016).

4 ENVIRONMENTAL CONSEQUENCES

This chapter identifies and evaluates the possible environmental consequences that could derive from the alternatives considered in this EA; continue to regulate TAM66274 cotton (no action alternative), or issue a determination of nonregulated status for TAM66274 cotton (preferred alternative). In evaluating potential impacts, APHIS considers the likelihood that they will occur, and their potential to cause significant impacts if they do occur. Potential direct and indirect impacts are discussed in this chapter, and potential cumulative impacts in Chapter 5.

4.1 Land Use and Acreage

No Action Alternative: Land Use and Acreage

Denial of the petition would not affect the acreage required or areas where cotton is grown in the United States. The domestic and international demand for cotton products determines acreage, these market factors are independent of APHIS' regulatory status decision for TAM66274 cotton. In general, cotton acreage is projected to remain steady through 2026, at around 10 million acres (USDA-OCE 2017).

Preferred Alternative: Land Use and Acreage

Approval of the petition is also unlikely to have an effect on cotton acreage or areas where cotton is grown. Because the site requirements for TAM66274 cotton production do not differ from those of other cotton varieties, the availability of TAM66274 cotton is unlikely to alter the current areas used for cotton production (TAMU 2017). If grown, TAM66274 cotton would be considered a "specialty cotton," i.e., low in gossypol, with the potential to expand uses in the food and feed industries. However, these new uses or expanded markets, would not be expected to result in a significant expansion of cropland used for cotton cultivation. It is expected that TAM66274 cotton, if adopted, would likely supplant other varieties of cotton currently in production.

4.2 Agronomic Practices in Cotton Production

No Action Alternative: Agronomic Practices

The potential environmental impacts associated with the agronomic practices and inputs used for the production of either GE or non-GE cotton varieties, such as tillage, volunteer management, pest and weed management, and pest and weed resistance management, would be unaffected by denial of the petition.

Preferred Alternative: Agronomic Practices

Approval of the petition, which would provide growers the option to produce TAM66274 cotton, subject to TAMU consultation with the FDA, and any approval of pesticides that may be used with this variety by the EPA, would have no effect on agronomic practices and inputs. Tillage, crop rotation, fertilizers, and pesticide use is expected to be the same/similar under both alternatives. Low gossypol levels can render certain cotton plants more susceptible to plant pests.

However, this is not the case for TAM66274 cotton, where gossypol production was only reduced in seed, leaving gossypol levels unchanged in other plant tissues, e.g., roots, stems, leaves where it retains its plant protection activities (TAMU 2017). In field studies no statistically significant differences were recorded in seed germination and stand count, vegetative growth, or plant susceptibility to disease and insect pests or rodents for TAM66274 cotton relative to the non-GE parental line (Coker 312) (TAMU 2017). It is expected that growers will mostly plant the progeny of TAM66274 cotton with other hybrids, e.g., HR/IR + low gossypol. This is discussed further under potential cumulative impacts in chapter 5.

4.3 Physical Environment

4.3.1 Water Resources

No Action Alternative: Water Resources

As discussed in Chapter 3, the agronomic practices and inputs (i.e., tillage, fertilizer and pesticide inputs) used for cotton production can potentially impair water quality. These potential impacts would be unaffected by denial of the petition. The conservation tillage and no-till practices commonly used in cotton crop production can help to reduce agricultural runoff, and are largely considered favorable to water resources, relative to cropping systems using conventional tillage. 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 in cotton cropping systems, conservation and no-till practices are being used less in many of areas of the Southeast, and more aggressive tillage is being implemented to help control HR weed populations (Smith 2010; Hollis 2015). In the face of challenges in managing HR weeds and their development, producers have tended to increase 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). These trends may continue. There are various national and regional efforts to reduce contaminants from agricultural run-off, and run-off itself, such as the EPA's Mississippi River/Gulf of Mexico Hypoxia Task Force (US-EPA 2017c) and USDA-NRCS NWQI (USDA-NRCS 2017a), as well HR weed management information efforts (Norsworthy et al. 2012).

Preferred Alternative: Water Resources

Because the agronomic practices and inputs utilized for TAM66274 cotton crop production would the same as/similar to those commonly used for other cotton varieties, sources of potential impacts on water resources, namely NPS pollutants in agricultural run-off, would not be expected to substantially differ. The potential impacts of TAM66274 cotton crop production on water quality would be the same as those described for the No Action Alternative. As discussed, there is no additional acreage likely to be required for TAM66274 cotton crop production.

Consequently, no increase in agricultural inputs or land tilled, which can present risks to water quality, are expected. The various national, state, and regional efforts to mitigate the potential impacts of agriculture on water quality would continue as under the No Action Alternative, unaffected by approval of the petition (US-EPA 2017j; USDA-NRCS 2017b).

Growers that switch from planting GE cotton varieties with HR and/or IR resistance to planting TAM66274 cotton may need to change their pest management strategies, including the type of pesticide used, and the application time and frequency, unless they are planting hybrids of TAM66274 cotton and HR/IR varieties. In addition, growers may use tillage as part of their IWM. Growers have many choices in GE and non-GE cotton varieties and widespread planting of TAM66274 cotton that has not been crossed with other varieties is not expected. Therefore, changes in pesticide use as a sources of potential impact on water resources are not expected.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

Under the No Action Alternative, TAM66274 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.

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. Conservation tillage systems, including no-till, are highly advised, and promoted by USDA for use in commercial cropping systems as these practices contribute to higher soil quality and reduced erosion, as compared with conventional tillage. As discussed, HR weeds will likely remain a concern for cotton growers in the Southeast. Any continued development of HR weeds may incur increased tillage (Ashigh et al. 2012a), which can potentially affect soil quality, soil erosional capacity, and soil moisture retention.

Preferred Alternative: Soil Quality

The potential impacts of TAM66274 cotton production on soil quality are not expected to differ under the Preferred Alternative. TAM66274 cotton has been found to be compositionally, agronomically, and phenotypically equivalent to that of the non-GE parental line (TAMU 2017), consequently, cultivation of TAM66274 cotton would present the same potential impacts to soil quality as GE and non-GE cotton varieties currently produced. Growers that switch from HR GE cotton varieties to TAM66274 cotton may need to change their IWM strategies, potentially using tillage for weed management. Growers have many choices in GE and non-GE cotton varieties and widespread planting of TAM66274 cotton is not expected. Therefore, widespread impacts to soil quality are not expected.

4.3.3 Air Quality

No Action Alternative: Air Quality

The emission sources associated with cotton cultivation would be unaffected by a decision to deny the petition. Air quality would continue to be affected along current trends by emission sources such as tillage (PM), pesticide application (aerosols, spray drift), and use of farm equipment that combusts fossil fuels (NAAQS pollutants – O_3, NO_2, CO, SO_2, Pb, PM). The EPA and USDA efforts to reduce emissions, along with state and local efforts, would likewise continue (US-EPA 2017g). While conservation and no-till practices commonly used in cotton production limit airborne soil PM and fuel based emissions, the trend of increasing tillage in some areas of the South to manage HR weeds will likely continue, to some degree, contributing to minor increases in emissions (PM and NAAQS pollutants) from some cotton cropping systems.

Preferred Alternative: Air Quality

A determination of nonregulated status of TAM66274 cotton would have no effect on emission sources associated with cotton cultivation. Because agronomic practices and inputs would remain unchanged, no changes to emission sources or amounts (i.e., tillage, fossil fuel burning equipment, the application of fertilizers and pesticides) are expected. Growers who plant TAM66274 cotton may need to adjust their IWM strategies since this cultivar does not have GE herbicide resistance. These growers may employ tillage in their IWM, which would contribute PM and fossil fuel emissions. Growers have many choices in GE and non-GE cotton varieties and widespread planting of TAM66274 cotton is not expected. Therefore, widespread impacts to air quality from the planting of TAM66274 cotton are not expected.

4.4 Biological Resources

Potential impacts to biological resources considered in this EA are the effects of the GE trait genes and their gene products through gene flow to wild relative species, and consumption of TAM66274 cotton by wildlife. The potential for TAM66274 cotton to act as a weedy or invasive species are also considered.

4.4.1 Animal Communities

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 percent of which are GE (USDA-NASS 2017c) , including tillage, planting and harvesting, pesticide and fertilizer applications, and the use of agricultural equipment.

Preferred Alternative: Animal Communities

Under the Preferred Alternative, the direct and indirect impacts on wildlife would be similar to those under the No Action Alternative. The only difference in potential risks to wildlife, relative to TAM66274 cotton production, would be those potentially presented by the *dCS* RNAi and *nptII* transgenes and their gene products.

Safety of the NPTII Protein

The *nptII* gene/protein product (NPTII) is the most frequently used selectable marker gene for generating transgenic plants and is present in many of the crops currently in commercial production. International regulatory agencies have approved the commercial release of GE canola, corn, potato, tomato, flax, chicory, papaya, and cotton comprised of *nptII*/NPTII, many of which are commercially grown, including corn, cotton, papaya, and potato (CERA 2018). The amount of NPTII protein produced by TAM66274 cotton is very low, for example about a few billionths of a gram. NPTII expression is highest in leaves (253.3 ng/g (dry weight – DW)), lower in roots and seeds (58.5 ng/g and 41.1 ng/g DW, respectively), and it was not detected in pollen at a minimum detectable level of 25 ng/g DW. The NPTII protein represents no more than 0.0000041% of the seed of TAM66274 cotton (41 ng of NPTII variant protein per gram of seed tissue).

NPTII has been approved by the FDA as a food additive for tomato, cotton, and oilseed rape (US-FDA 1994). The FDA provides industry guidance for use of *nptII* as a marker gene in GE plants. The European Food Safety Authority concluded, on review, that the use of the *nptII* gene as a selectable marker in GE plants does not pose a risk to human or animal health or the environment (EFSA 2007).

Based on current scientific evidence, it is highly unlikely the NPTII expressed in TAM66274 cotton presents any risk to wildlife.

Safety of RNAi Transgene and Gene Products

The use of the RNAi for development of desired traits in GE crop plants has prompted discussion about the environmental safety of the technology. Provided here is an evaluation of the potential risks presented by RNAi mediated silencing of δ-cadinene synthase (*dCS*) genes that encode δ-cadinene synthase (dCS) – an enzyme involved in gossypol biosynthesis.

The RNAi cassette is comprised of a seed-specific gene promoter, derived from non-GE cotton, which results in the formation of double stranded RNA (dsRNA), and subsequently small interfering RNAs (siRNA) that govern the silencing of the *dCS* genes via RNAi. Expression of these RNAs and dCS silencing occurs only in seed tissue. Thus, conceptually, the only potential risk to wildlife, as a matter of hazard assessment, would be from exposure to the dsRNA/siRNA via consumption of the seed, this type of feeding is largely limited to insects and foraging rodents. Insects attack all parts of the cotton plant and feed throughout the growing season. Caterpillars of certain species of Lepidoptera, such as armyworms, and thrips and Lygus bugs, feed on cottonseed bolls. Voles, shrews, mice and other rodents may likewise consume the seed, although this would not be considered common practice, as cottonseed can be toxic to non-ruminant animals. Birds feed on insect pests of cotton, such as the boll weevil and cut worm, although are not commonly known to feed on cottonseed. In general, any animal that fed on the cottonseed would be considered a pest, which the grower would need to control.

Gene silencing via RNAi is a common, natural process in which dsRNA induces the inactivation of nucleic acid sequences via an RNA induced silencing complex. Small dsRNAs are ubiquitous among the diverse range of organisms in the plant and animal kingdoms consumed by wildlife as food. RNAs, as well other nucleic acid sequences, are a natural, albeit minor, component of all plant and animal derived foods. Fundamentally, wildlife regularly consume RNA (i.e., coding and non-coding: mRNAs, siRNAs, dsRNAs), as well as DNA, via animal and plant-derived foodstuffs.

Plants encode hundreds of thousands of different small RNAs (Bonnet et al. 2006). APHIS is not aware of data in the scientific literature describing adverse effects on individuals or populations as a result of consumption of nucleic acids. Total plant RNA content is about 1 mg/g of plant tissue. Long dsRNAs from exogenous sources are particularly common in plants, due to infection from RNA-containing plant viruses. In addition to empirical data supporting the safety of consumption of RNA from plants (and animal products), there are data indicating that RNA molecules have a very short half-life in vertebrate systems, on the order of minutes, due to ribonucleases, clearance through excretory mechanisms (e.g., liver, kidney), and other factors (e.g., pH) (Petrick et al. 2013; Roberts et al. 2015). The weight of scientific evidence to date suggests that dietary intake of RNAs in foods, and biological effects resulting therefrom, does not normally occur in vertebrates (Petrick et al. 2013; Roberts et al. 2015; Chan and Snow 2017). Nevertheless, an evaluation of potential hazard presented by TAM66274 cotton is provided.

In order for consumption of an exogenous RNA expressed in a plant to result in any biological effect a series of physiological processes each must occur. If any of these processes do not occur, then the risk to wildlife from an RNAi-based GE plant is negligible. Immediately following consumption the dsRNA must resist degradation in the gut. Particularly the vertebrate digestive tract, the bio-availability of intact macromolecules is typically very low. The highly catabolic environment of the digestive tract that contains bile, stomach acids, and enzymes, few of any nucleic acids that might have been ingested remain intact after digestion. For the nucleic acids that are intact, the highly selective/protective uptake mechanisms of gut epithelial tissue, such as by transcytosis and protein transporters, serve as an impediment to translocation of RNA from the gut lumen to cell interior (Chan and Snow 2017). Transport between epithelial cells (intercellular) is likewise strictly regulated by tight junctions. Cellular tight junctions are localized cell to cell contact sites (see (Balda and Matter 1998)). If exogenous RNA does make its way into intracellular compartments, there must be uptake of dsRNA or other bioactive RNA in sufficient quantities to activate endogenous RNAi mechanisms. For example, the amount of RNA required to achieve biologically relevant effects on gene expression is currently thought to be 100–10,000 copies per target cell (Chan and Snow 2017). In order for any biological effect to occur, there would need to be sequence complementarity (homology) with an mRNA transcript in the target cells (Belles 2010; Petrick et al. 2013; Roberts et al. 2015). Finally, any silencing or modification of gene expression would need to result in harmful effects.

Considering the rapid breakdown of RNA in the gastro-intestinal GI system, the lack of evidence of intracellular uptake of intact RNA in vertebrate systems, the difficulty in assimilation of quantities of RNA that would be sufficient to elicit a biological response, and the fact that the dCS enzyme targeted in TAMU cotton only occurs in plants, the likelihood of dietary dsRNA or siRNA presenting a risk to vertebrate wildlife is extremely unlikely (Petrick et al. 2013; Roberts et al. 2015; Joga et al. 2016; Chan and Snow 2017).

On the other hand, dsRNA uptake in insects and worms is known to occur. These are two pathways in insects; the transmembrane Sid-1 channel protein-mediated pathway and the endocytic pathway (Joga et al. 2016). In nematodes (sometimes called roundworms), the Sid-2 gene encodes for a membrane protein, in the intestinal cells, this protein can transport dsRNA from the intestinal lumen to the cell's interior through endocytosis (Winston et al. 2006; McEwan et al. 2012). In addition, siRNA can also be exported to neighboring cells through Sid-1 channels by passive movement (Joga et al. 2016). While Sid-1 genes appear to be present in most insect species, to date, no Sid-2 genes have been identified in insects whose genomes have been sequenced. Studies in Drosophila (a type of fly) have confirmed dsRNA uptake through the endocytic pathway (Joga et al. 2016).

In invertebrates, susceptibility to dsRNA has been observed in many species, including cnidarians (Hydra), planaria (flatworms), and various arthropods (Roberts et al. 2015). Among arthropods, both coleopterans and lepidopteran insect species display a range of sensitivities to ingested dsRNA, with coleopterans showing greater sensitivity than other arthropod orders (Terenius et al. 2011; Ivashuta et al. 2015; Roberts et al. 2015; Joga et al. 2016).

While assimilation of exogenous dsRNA and biological response can occur in certain invertebrates, adverse effects resulting from consumption of TAM66274 cottonseed are considered improbable. The dCS enzyme targeted by the RNAi construct is only expressed in plants. Consequently, it is unlikely that the gene (nucleic acid) sequences in the dsRNA/siRNA in TAM66274 cottonseed are homologous to mRNA sequences expressed in animals that might consume TAM66274 cottonseed. Bioinformatic analyses were conducted for dCS, evaluating sequence homology among human, cow, pig, chicken, fish, shrimp, dog and cat gene sequences. No homology in any 20 base-pair contiguous span, the typical lower limit of siRNA molecules, was detected (TAMU 2017).

Considering the factors discussed, adverse effects on invertebrate species that feed on TAM66274 cottonseed are highly improbable.

4.4.2 Plant Communities

No Action Alternative: Plant Communities

Denial of the petition would have no effect on plant communities. Conventional and GE cotton production will continue as currently practiced while TAM66274 cotton remains a regulated article. Current agronomic practices, including the use of EPA registered pesticides will continue unchanged. Any pesticide used must be registered with the EPA and applied according to EPA label requirements. Potential impacts of GE and non-GE cotton production on plant communities would be unchanged.

Preferred Alternative: Plant Communities

Because the agronomic practices and inputs that will be used for TAM66274 cotton production are the same as those for the No Action Alternative, the potential impacts on vegetation close to cotton fields would be the same under both the Preferred and No Action Alternatives. The potential for TAM66274 to hybridize with cultivated, wild or feral cotton and persist in the environment is low due to the predominance of self-pollination in cotton, and absence of sexually compatible wild relative species (discussed below). In the event TAM66274 cotton presents as a volunteer, the risks to wild plants and commercial cotton crops from volunteer TAM66274 cotton are considered low; volunteer cotton can be easily managed with herbicides or hand pulling (Morgan et al. 2011), and TAM66274 cotton presents little risk for presenting as weedy or invasive plant (TAMU 2017).

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 TAM66274 cotton to *G. tomentosum* or to native or naturalized *G. barbadense*. There is no evidence that any of the genetic elements used in TAM66274 cotton would increase the rate of outcrossing or gene introgression of TAM66274 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 2018b). Thus, unassisted outcrossing and gene introgression could potentially occur in areas where these species are co-located.

The risk potential for gene flow, hybridization and introgression from TAM66274 cotton to sexually compatible relatives is discussed in the PPRA (USDA-APHIS 2018b). Based on the information presented in the petition and in relevant literature, APHIS has concluded that the *dCS* RNAi and *nptII* transgenes and their gene products present in TAM66274 cotton is not expected to increase the potential for gene flow, hybridization and/or introgression of genes from TAM66274 cotton to other sexually compatible relatives, including wild, weedy, feral or cultivated species in the United States and its territories. Therefore, TAM66274 is not expected to increase the weed risk potential of other species with which it can interbreed in theUnited States and its territories.

Silencing of gossypol production, if the event RNAi were extant in the hybrid, would have little effect on hybrid plants. *nptII*/NPTII presents no risk to plants; it is a widely used biomarker present in various GE crops (see discussion on wildlife above). 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 Biota

No Action Alternative: Soil Biota

Possible impacts to soil biota 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.

Preferred Alternative: Soil Biota

The potential impacts on soil biota under the Preferred Alternative are no different than those under the No Action Alternative. TAM66274 cotton has been determined to be agronomically and compositionally similar to other GE and non-GE cotton varieties. Based on the data presented by TAMU, the cultivation of TAM66274 cotton is unlikely to impact soil biota any differently than those cotton varieties currently cultivated.

4.4.4 Biodiversity

No Action Alternative: Biodiversity

Biological diversity, or the variety of all life forms in a given area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific geographic area, and which have been bred for a specific market. For cropping systems such as cotton, growers want to encourage high yields from their crop, and will intensively manage plant and animal communities through chemical and cultural controls to facilitate optimal yield, and protect the crop from damage. Consequently, the biological diversity in agricultural cropping systems (the agro-ecosystem) is typically lower than in surrounding habitats.

Under the No Action Alternative, growers and other parties who are involved in production, handling, and processing of cotton would continue to have access to conventional cotton varieties, including GE cotton varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Agronomic practices associated with conventional cotton production (both GE and non-GE) such as cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue unchanged. Life forms typically associated with cotton fields will continue to be affected by currently utilized management plans and systems, which include the use of mechanical, cultural, and chemical control methods. The consequences of current agronomic practices associated with cotton production, both traditional and GE varieties, on biodiversity is unlikely to be altered. Impacts to biodiversity associated with agronomic practices in cultivating cotton are not expected to change under the No Action Alternative.

Preferred Alternative: Biodiversity

Approval of the petition, and subsequent commercial production of TAM66274 cotton, would impact biodiversity in and around TAM66274 cotton crops no differently than that of current conventional and GE cotton cropping systems. Other than the introduced traits, TAM66274 cotton is agronomically and phenotypically equivalent to non-GE cotton. As previously discussed in Section 4.4.1 – Animal Communities, the trait genes and their gene products are unlikely to present any risk to soil biota, wildlife, or plant communities.

4.4.5 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

The United States 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 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 (cross with) 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 (e.g., (Andersson and de Vicente 2010)). 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). Denial of the petition would have no effect on potential matters concerning gene flow and weediness associated with commercial cotton production.

Preferred Alternative: Gene Flow and Weediness

Available evidence indicates that there is a low potential for introgression of transgenic material from TAM66274 cotton into wild *G. tomentosum* or native or naturalized *G. barbadense* (USDA-APHIS 2018b). (There is no evidence that any of the genetic elements used in TAM66274 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 (TAM66274) 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 2018b). . 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 TAM66274 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 TAM66274 cotton would not be expected to confer a selective advantage on the hybrid progeny, and hybrid breakdown[14] would be expected to eliminate introgressed genes from the *G. tomentosum* population. Thus, the transgenes present in TAM66274 cotton are unlikely to increase the rate of successful transgene introgression from TAM66274 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 TAM66274 cotton to native or naturalized *G. barbadense* can occur but is likely to be rare (USDA-APHIS 2018b). The *dCS* RNAi and *nptII* transgenes and their gene products in TAM66274 cotton are unlikely to increase the rate of successful transgene introgression from TAM66274 cotton into native or naturalized *G. barbadense* populations, relative to the rate of gene introgression from conventional cultivars, nor confer a selective advantage to any hybrid progeny that may result from outcrossing.

4.5 Human Health

Public health considerations are those related to (1) the safety and nutritional value of TAM66274 cotton, (2) the potential health effects of pesticides that may be used in the production of TAM66274 cotton. As for food safety, consumer health concerns are in regard to the potential toxicity or allergenicity of the introduced proteins, possibly altered levels of potential allergens in cottonseed products, or the expression of new antigenic proteins.

No Action Alternative: Human Health

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

Denial of the petition would have no effect on public health. GE and non-GE cotton would continue to be cultivated, supplies of cottonseed oil and fiber, and animal feed products, would be would be unaffected.

Preferred Alternative: Human Health

Approval of the petition would not be expected to present any risks to human health. The only potential human health risks are those associated with pesticide use –which is not expected to be different from the risk associated with the cotton varieties that are currently grown, and those potentially presented by the *dCS* RNAi and *nptII* transgenes and their products. As reviewed below, it is highly improbable that the *dCS* RNAi and *nptII* genes and their products present a hazard to human health.

TAMU initiated food safety consultations with the FDA in 2012 in accordance FDA policy and industry guidance (see1.3.3 – Food and Drug Administration). TAMU has prepared a safety and nutritional assessment of food and feed derived from TAM66274 cotton and states it will be submitting its findings to the FDA as part of the consultation process.

Safety of dCS RNAi and neomycin phosphotransferase II variant (nptII) expression cassette

Nucleic acids, including RNAs, are ubiquitous in plant and animal based foods. Plants possess thousands of functional dsRNAs and siRNAs (Khvorova et al. 2003). The exact number and prevalence of RNAs in plant cells has not been well quantified, although an evaluation of *Arabidopsis thaliana*, a model plant that is often used in biology and genetics research, described over 75,000 putative siRNAs and miRNAs expressed in the plant (Parrott et al. 2010). The *dCS* RNAi transgenes and gene products in TAM66274 cotton would be but one among many RNAs.

Due to the sheer number of plant RNAs, there is, in theory, the potential for some to be homologous (i.e., corresponding in structure but not necessarily in function) to mammalian gene sequences, thereby potentially biologically active. Similar reasoning can be applied to the abundant dsRNAs/ siRNAs present in animal tissues and consumed by humans as meat. However, bioinformatic analyses of the *dCS* RNAi transgene examining sequence homology among human, cow, pig, chicken, fish, shrimp, dog and cat expression sequences found no homology to any 20 base pair sequences among these genera (TAMU 2017).

There are no reports in the scientific literature describing dietary uptake and assimilation of functional RNA molecules, and subsequent biological effects, in higher animals. Reports describing dietary uptake of RNA, and subsequent detection in blood plasma, have found only trace levels of plant-derived miRNAs (Sherman et al. 2015). Researchers report in several studies that they have been unable to confirm that gastrointestinal uptake is a pathway of miRNA uptake and subsequent gene regulation (Witwer and Hirschi 2014). In general, based on dosage levels alone, RNAs present in the human diet are not numerous enough to achieve high enough levels in the bloodstream, and subsequently the cell interior, to affect gene regulatory functions (Sherman et al. 2015). Recent dietary miRNA studies report an absence of uptake of dietary miRNAs, and a lack of effects on gene regulatory functions (Dickinson et al. 2013; Witwer and Hirschi 2014; Sherman et al. 2015). Thus, while dietary assimilation of RNAs and potential effects on biological functions remains a subject of research, reproducible evidence of uptake and assimilation of diet-derived RNAs at biologically relevant levels, with any biological effect, has not emerged (Dickinson et al. 2013; Witwer and Hirschi 2014; Sherman et al. 2015).

Fundamentally, nucleotide (including various forms of RNA) biosynthesis is a highly regulated metabolic process. Complex feedback mechanisms sustain adequate quantities and regulate synthesis to meet physiological demands. Nucleotides such as RNA that are consumed in the diet are converted to nucleic acids (subunits) in the intestinal tract by proteolytic enzymes (Hess and Greenberg 2012). Nuclease enzymes can break nucleotides down into smaller subunits such as nucleosides. Nucleosides can be further degraded by nucleosidases to purines and pyrimidines. Once absorbed by intestinal cells (enterocytes), nucleosides are rapidly metabolized in the cell; however, approximately 5% may be incorporated into intracellular nucleotide pools (Hess and Greenberg 2012). The majority of absorbed nucleosides are extensively degraded and their end products excreted in the urine (Rudolph 1994).

Considering the rapid breakdown of RNA in the GI system (on the order of minutes, due to ribonucleases and pH), the lack of evidence of intracellular uptake of intact RNA in vertebrate systems, the difficulty in assimilation of quantities of RNA sufficient to elicit a biological response, the fact that the dCS enzyme targeted in TAMU cotton only occurs in plants (there is no sequence homology to human genes), and rapid clearance of endogenous RNAs in the blood stream through excretory mechanisms (e.g., liver, kidney), the likelihood of dietary dsRNA or siRNA presenting a risk to human health is highly unlikely (Petrick et al. 2013; Roberts et al. 2015; Joga et al. 2016; Chan and Snow 2017).

RNAi-mediated gene suppression has been used in a number of biotechnology-derived food crops including papaya, potato, plum, corn, canola, and soybean. These plant varieties have been previously evaluated by the FDA. Based on the compositional and safety assessment data presented, the FDA did not identify any safety or regulatory issues regarding food and feed derived from these varieties (US-FDA 2018). 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 and the Australia and New Zealand Food Standards Agency (FAO/WHO 2017). Most governments incorporate Codex Alimentarius principles and guidelines established by the World Health Organization and Food and Agriculture Organization of the United Nations in their review of foods derived from GE crop plants (FAO/WHO 2017). It is expected that if TAM66274 cotton is marketed outside of the United States, it would receive review by pertinent regulatory authorities as to food and feed safety.

Safety of the NPTII Protein

NPTII has been approved by the FDA as a food additive for tomato, cotton, and oilseed rape (US-FDA 1994). The FDA provides industry guidance for use of *nptII*/NPTII as a marker gene in GE plants. The EPA granted an exemption from the requirement of a tolerance for residues of NPTII in food commodities when used as an inert ingredient in a plant-incorporated protectant (40 CFR §174.521). The European Food Safety Authority concluded, on review, that the use of the *nptII* gene as a selectable marker in GE plants poses no risk to human or animal health (EFSA 2007). Based on current scientific evidence, it is highly unlikely the NPTII expressed in TAM66274 cotton presents any risk to human health. Humans may only be exposed through consumption of cottonseed oil. NPTII protein expression levels in TAM66274 cottonseed are extremely low, 41.1 ng/g (41 billionths of a gram per gram dry weight). Cottonseed oil processing will reduce if not remove proteins such as NPTII present in the unrefined oil. Consequently, exposure of humans to NPTII, even while safe for consumption, is unlikely.

Pesticide Use

The EPA regulates the use pesticides, conducts human and ecological risk assessments for pesticides, and provides label use instructions and restrictions that are intended to be protective of human health. Pesticides must be used in strict accordance with their label instructions. Any pesticide use with TAM66274 cotton would be subject to EPA approval and label use requirements. The FDA and USDA monitor foods for pesticide residues to enforce tolerance limits and ensure protection of human health (USDA-AMS 2015). The EPA uses the USDA Pesticide Data Program (PDP) to prepare pesticide dietary exposure assessments, and establish pesticide residue limits (thresholds) pursuant to the Food Quality Protection Act. These pesticide residue limits, or food tolerances, are intended to be protective of human health. Periodically, and depending on the specific pesticide tolerance in question, the EPA will reexamine the risk assessments used to set tolerances to ensure that tolerances accurately reflect actual or anticipated residue levels in foods. This reexamination, in conjunction with a review of other exposure routes for that pesticide (from drinking water and residential uses of the pesticide), will ensure "a reasonable certainty that no harm will result from aggregate exposure."

4.6 Worker Safety

No Action Alternative: Worker Safety

Denial of the petition for TAM66274 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 pesticides on cotton crops, both in terms of the types of chemistries and quantity of pesticides 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 TAM66274 cotton can occur through inhalation and dermal contact at workplaces where these compounds are produced or used. The potential for exposure of workers to pesticides under the Preferred Alternative is not expected to differ from that which may occur under the No Action Alternative.

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. Used in accordance with the EPA label requirements, pesticides used with TAM66274 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 TAM66274 cotton will adhere to these label use and WPS requirements.

Considering these factors, worker health and safety risks under both alternatives are substantially the same. A determination of nonregulated status for TAM66274 cotton presents no more risk to worker safety than that of the No Action Alternative.

4.7 Animal Health

Cottonseed meal, cottonseed hulls, and whole cottonseed are utilized in the animal feed industry as sources of protein, fiber, and energy. Cottonseed meal is a common source of protein mostly for adult ruminants, who are relatively tolerant to gossypol. It can also be utilized for feed for monogastrics, provided that feed is rationed to limit uptake of gossypol.

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 in Sections 4.4.1– Animal Communities and 4.5 – Human Health, it is highly unlikely that TAM66274 cotton would present any risk to animal health and welfare. To the contrary, TAM66274 cotton, which has very low levels of gossypol, is intended to provide for expanded uses of cottonseed products in the food and feed industries. This would be considered a benefit to livestock and aquaculture, as well as processors and end users in the livestock and aquaculture industries.

TAMU initiated food safety consultations with the FDA in 2012 in accordance FDA policy and industry guidance (see1.3.3 – Food and Drug Administration). TAMU has prepared a safety and nutritional assessment of food and feed derived from TAM66274 cotton. As a part of its process, TAMU submitted its food and feed safety and nutritional assessment finding of TAM66274 to FDA on September 22, 2017 (TAMU 2017)

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, winter cover cropping, and other control methods. These costs would be unaffected by denial of the petition.

Preferred Alternative: Domestic Socioeconomic Environment

Approval of the petition would not be expected to present any risks to domestic markets. TAM66274 cottonseed, low in gossypol (e.g., 3% of that in conventional cottonseed varieties (TAMU 2017), facilitates cottonseed processing (e.g., oil refining), use of cottonseed products in the food industry, and use of whole seed, oil, and crushed meal in the livestock and aquaculture feed industries. Consequently, its introduction would be considered of potential benefit to domestic food and feed markets. In general, TAM66274 cotton potentially expands opportunities for cottonseed use in the food and feed sectors, without adversely affecting the quality or value of the fiber or other byproducts such as hulls and linters. It is assumed that growers would adopt and produce TAM66274 cotton commensurate with market demand for cottonseed products low in gossypol.

An important consideration in the marketing of agricultural commodities is the preservation of crop and crop commodity identity across GE, organic, and conventional production and marketing systems. This is not an environmental safety or health issue per se; rather, it is an economic marketing issue associated with agronomic and industry practices. This is particularly important for the identity-preserved (IP) and organic markets, which are required to maintain the genetic integrity of their crop commodities. The unintended presence of foreign GE plant material in an IP or organic crop product can occur not only as a result of cross-pollination and seed dispersal, but also due to failed segregation of crop products during harvesting, shipping, and post-harvest processing. Thus, the maintenance of crop product identity is fundamental to ensuring the sustainability of GE, organic, and conventional crop production systems, maintenance of commodity price premiums in the market, and avoidance of market disruption impacts on suppliers, manufacturers, and consumers.

IP is a process for ensuring segregation and channeling of agricultural commodities to respective buyers and markets (e.g., human foods, animal feeds, cosmetics, pharmaceuticals, industrial uses), requiring strict separation be maintained at all times (Sundstrom et al. 2002). IP applies to commodities derived from conventional, organic, and GE crops alike. For example, commodities with unique traits such as specialty grains, high-oleic canola, blue corn, and various cotton fiber quality grades require IP programs to channel these commodities to specific markets in order realize their added value. It should be noted that IP and USDA organic certification are not the same processes. Organic commodities that use an IP program must still be produced according to specific criteria and segregated in the marketplace in order to receive price premiums.

For these reasons, TAMU states that an IP program will be used for production and marketing of TAM66274 cotton to segregate TAM66274 cottonseed products from conventional cottonseed commodities, and preserve the added value of TAM66274 cottonseed commodities in food and animal feed industries. TAMU states that dedicated cottonseed mills will process TAM66274 cotton (TAMU 2017).

Fundamentally, it is in the best interest of the provider of TAM66274 cotton, TAMU, to steward the production and marketing of TAM66274 cotton, and ensure compliance with legal requirements and industry standards for the successful, sustainable commercialization of their product.

Considering these factors, adverse impacts on domestic markets are unlikely to derive from approval of the petition. While TAM66274 cotton would require strict segregation in supply chains, it would present no more risk for commingling than do other IP products (e.g., canola, corn, cotton).

4.8.2 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 effects on the trade of cotton commodities. As with domestic markets, because TAM66274 cottonseed is low in gossypol, its introduction would be considered of potential benefit to export markets.

The trade of TAM66274 cotton products would be subject to the laws, regulations, and policies of the importing country, which are impacted by international treaties, agreements, and other arrangements. International trade is facilitated by the World Trade Organization (WTO) and the Organization for Economic Cooperation and Development (OECD 2015; WTO 2015c). Standards and guidelines for the safety evaluation and trade of GE crop commodities are established under international policy and agreements such as the Codex Alimentarius (FAO

2009), the WTO International Plant Protection Convention (WTO 2015b), WTO Sanitary and Phytosanitary Measures (WTO 2015a), WTO Technical Barriers to Trade Agreement (WTO 2015c), and the Cartagena Protocol on Biosafety (CBD 2015a).

As with all GE crop commodities, there exists the potential for low level presence (LLP) occurring in countries importing U.S. agricultural commodities. LLP situations occur in the importing country when there is asynchrony between the authorization of the exporting country and that of the importing country; an issue described as an "asynchronous approval" (AA). LLP is generally described as a situation where there is authorization of a particular GE commodity by one or more exporting countries, but authorization is still pending or has not been requested in the importing country. The issue of AA, and resulting LLP situations, can lead to trade delays, shipment rejection, and costs to traders (FAO 2014). AA can also result in the diversion of shipments to other markets by some exporters, and rejection of agricultural products by importers due to zero tolerance policies for the presence of unauthorized GE materials in shipments (Frisvold 2015; WTO 2015c). Incidents of LLP can lead to income loss for exporters and importers, and consequently for producers. Consumers in importing countries can also, potentially, face higher domestic commodity prices when an import is deterred or directed to another trading partner (Atici 2014).

In addition to situations arising from AA and LLP, trade can also be impacted by moratoria, or bans on the import or use of GE crops or crop products. These bans can be explicit as a result of legislation, or de facto. De facto bans may occur if a country does not have a GE product decision making framework, or chooses to take no action regardless of its existing decision making framework.

As discussed for potential impacts on domestic markets, TAMU states that growers of TAM66274 cotton will produce and market products derived from this variety in a closed-loop IP system to ensure that all commodities are isolated to maintain product identity throughout production and marketing processes. In general, developers have various legal, quality control, and marketing motivations to implement rigorous stewardship measures to ensure IP, prevent commingling, and avoid AA and LLP. By necessity, all international regulatory and industry standards and requirements must be met for marketing of TAM66274 cotton commodities, and it is assumed that there will be strict adherence to requirements to maintain the integrity TAM66274 cotton crop commodities so as to reduce legal exposure, and loss of standing in the market. TAMU states they will be examining opportunities to market TAM66274 cotton in other countries and may seek import clearances (TAMU 2017).

Considering these factors, while there is the potential for instances of LLP, adverse effects of the trade of U.S. cotton commodities is considered unlikely.

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."

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.

If APHIS approves the petition for TAM66274 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. It is possible, if not likely, 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. TAMU states, and APHIS assumes, that TAM66274 cotton will likely be crossed and commercialized in stacked-trait varieties through private sector breeding programs (TAMU 2017). These varieties would be low in gossypol, and may be resistant to one or more herbicide MOAs, and/or insect resistant, and/or possess other agronomically beneficial traits.

5.2 Land Use and Acreage

There are no direct or indirect impacts on the areas or acreage used for cotton crop production that would derive from either alternative, consequently cumulative impacts on land use are improbable. Market factors such as demand for cotton fiber, cottonseed meal, cottonseed oil, domestic and international supplies of cotton, subsidies provided to cotton farmers, and the suitability of land for cotton production are the primary factors that influence land use.

5.3 Agronomic Inputs and Practices in Cotton Production

5.3.1 Pesticide Use

TAM66274 cotton, if commercially produced, would not be expected to contribute in a cumulative manner to any changes or increase in pesticide use. Region-specific patterns of pesticide use will vary relative to the prevalence and variety of pests, weeds, and HR weeds present in any given area, as well as the tillage and other practices employed for weed management. This is further discussed in Section *5.3.5 – Insect and Weed Resistance Management*.

5.3.2 Tillage

As previously discussed, HR weeds in cotton are partially responsible for increases in conventional tillage and declines in conservation tillage (CAST 2012), particularly in the Mid-south states. Under either alternative, increased or more extensive tillage may continue to occur in certain regions where HR weed populations have evolved, and continue to evolve. 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. However, because TAM66274 cotton, the plant itself, and the agronomic practices and inputs used in cultivation, are no different than other cotton varieties (other than low gossypol in the seed), there are no potential cumulative impacts on tillage, soils, and water quality that would derive from approval of the petition.

5.3.3 Fertilizer Use

There are no cumulative impacts associated with fertilizer requirements for TAM66274 cotton cultivation.

5.3.4 Insect and Weed Management

TAM66274 cotton could potentially be crossed with IR traits. In areas where cultivation of IR cotton is high, 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 European corn borer and pink bollworm, respectively (e.g., see review by (Fernandez-Cornejo et al. 2014c). These trends in decreased insecticide use in the United States are likely to continue under both the No Action and Preferred Alternatives(NAS 2016)(NAS 2016)(NAS 2016)(NAS 2016).

TAM66274 cotton varieties stacked with HR traits would, if stacked with more than one HR trait, help growers manage weeds if applied consistent with best management practices recommended by EPA and the Weed Science Society of America (WSSA). If TAM66274 cotton is crossed with other HR varieties, the resulting combination would allow growers to plant a crop that is resistance to multiple herbicide MOAs. Such varieties would allow growers to use herbicides with different MOAs, which have been shown to be beneficial to weed management, as well as to management of herbicide resistant weeds (discussed below). If IWM strategies are employed with cultivation of future TAM66274 cotton stacked-trait HR varieties, fewer growers would be expected to use tillage for weed control, which can reduce tillage-induced soil erosion and agricultural run-off.

Considering the potential benefits of stacked-trait TAM66274 cotton to insect and weed management, adverse cumulative impacts on crop production and management are unlikely.

5.3.5 Insect and Weed Resistance Management

By its very nature, the development of insect and weed resistance is a cumulative effect, particularly when adjacent cropping systems do not implement recommended IWM/IPM programs. TAM66274 cotton cropping systems, to include progeny, will have the potential to contribute in a cumulative manner to the emergence of HR weed populations, IR pest populations, and resistant pathogen populations, just as all other cropping systems that use pest and weed controls do. But, by itself, TAM66274 cotton will not cause an increase in HR, IR, or pathogen resistance.

As discussed above, future TAM66274 cotton varieties stacked with multiple HR traits would help growers manage HR weeds and their development is grown as part of n integrated pest management program.. Such varieties would allow growers to use herbicides with different MOAs, in combination and rotation and other strategies, thereby reducing or delaying HR weed populations. However, such stacked-trait varieties need to be used within an IWM program to be, and remain, effective. The benefits of stacked-trait varieties to resistance management will be relative to the efficacy of IWM/IPM programs employed in the cultivation of these varieties. Approval nor denial of the petition would not have any effect on grower options or choices in the management of pests, diseases, and weeds over the coming years. As discussed in Sections 3.2 and 4.2, academia, weed and pest specialists, and the EPA through further refining of IWM and IPM strategies, are addressing resistance management. In 2017, the EPA issued PR Notice 2017-2, *Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship* (US-EPA 2017h). The EPA guidance is part of a more holistic, proactive approach involving crop consultants, agricultural commodity organizations, professional /scientific societies, researchers, and the pesticide registrants themselves. PRN 2017-2 provides 11 elements focused on labeling, education, training, and stewardship strategies. The EPA also issued PR Notice 2017-1, *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling* (US-EPA 2017a). PRN 2017-1 is aimed at improving information on pesticide labels about how pesticide users can minimize and manage pest resistance.

It is assumed that the majority of growers who adopt TAM66274 cotton and any progeny will employ management practices recommended by the EPA, the Weed Science Society of America (WSSA), and university extension services to help deter the development of HR weeds, and development of insect and pathogen resistance, as there are economic and practical incentives for doing so (Fernandez-Cornejo et al. 2014d; Fernandez-Cornejo and Osteen 2015; Livingston et al. 2015).

5.4 Physical Environment

5.4.1 Soil Quality

A determination of nonregulated status of TAM66274 cotton, and subsequent commercial production, is unlikely to contribute to any cumulative impacts on soil quality. The phenotypic and agronomic characteristics of TAM66274 cotton are not substantially different from other cotton varieties (TAMU 2017). The cultivation of a cotton variety stacked with resistance to herbicides with multiple MOAs may be of benefit to soil quality. This benefit could result from growers' ability to manage difficult to control weeds, to include HR weeds, facilitating the continued use of, and in some instances a return to, conservation tillage, an agricultural practice with direct and positive effects on soil quality and erosional capacity.

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 pesticides and fertilizers will be used with TAM66274 cotton. Since TAM66274 cotton is agronomically similar to currently cultivated cotton varieties, the total amount of pesticides and fertilizers used on U.S. cotton would not be expected to increase or decrease as a result of cultivation of this variety. As discussed previously, insecticide use may very well be less with stacked-trait IR varieties. Consequently, cumulative increases in pesticide use and associated increases in potential surface and groundwater contamination are considered unlikely.

Over the long term, any further development of HR weed populations in cotton cropping systems could result in growers continuing to abandon conservation and no-till and adopting more aggressive tillage practices, which, via run-off, can adversely affect surface water quality. In terms of cumulative impacts, this could present a problem in those areas where HR weeds are currently, and will continue to be, difficult to manage. This is a possibility under both alternatives, and no more likely or unlikely under either. To the extent stacked-trait HR/IR varieties contributed to management of weeds, and limited tillage and insecticide use, cumulative benefits to water quality would be expected.

The EPA determines the use requirements for pesticides, which are intended to be protective of water quality and aquatic biota (US-EPA 2018d, c). The EPA considers the potential impacts to water resources from the agricultural application of pesticides, 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. APHIS assumes that applicators will adhere to EPA label use requirements for all pesticides.

5.4.3 Air Quality

Air pollution is fundamentally the result of cumulative emissions from multiple sources. TAM66274 cotton production would entail the application of pesticides and fertilizers, and use of tillage to some extent, which will contribute to potential cumulative impacts on air quality, as does current cotton production. Use of tillage and fossil fuel combusting farm equipment would contribution to the cumulative emissions of NAAQS pollutants and greenhouse gases. While

TAM66274 cotton production would contribute to cumulative impacts on air quality, these impacts are expected to be no different, in nature, from that already occurring with current cotton production.

5.5 Biological Resources

5.5.1 Animal, Plant, and Microbial Communities

Approval of the petition and subsequent commercial cultivation of TAM66274 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 TAM66274 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 *dCS* RNAi and *nptII* transgenes and their gene products, expressed in the seed of TAM66274 cotton, present any risk to wildlife. Because the agronomic practices and inputs that will be used for TAM66274 cotton production will be similar to those for the No Action Alternative, the potential cumulative impacts on animal and plant communities proximate to cotton fields are the same under both the Preferred and No Action Alternatives, as are potential cumulative impacts on biodiversity. Because potential direct and indirect impacts on biological resources do not differ between the No Action and Preferred Alternatives, there are no reasonably foreseeable cumulative impacts that would derive from the commercial cultivation of TAM66274 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 Alternatives in regard to matters concerning potential gene flow and weediness. TAM66274 cotton presents no weediness risk (USDA-APHIS 2018b). The risk of gene flow among TAM66274 cotton, currently cultivated upland and Pima cotton, and sexually compatible wild relatives, is no more or less than that of conventional cotton varieties. The *dCS* RNAi and *nptII* transgenes and their gene products present no risk to wild cotton populations. The only risk of these transgenes to commercially cultivated upland and Pima cotton is economic in nature, discussed in Section 5.8 – Socioeconomics.

5.6 Human Health and Worker Safety

There are no reasonably foreseeable cumulative impacts on human health and worker safety that would derive from approval of the petition. The *dCS* RNAi and *nptII* transgenes and their gene products present no risk to human health. The agronomic inputs and practices, which are the source of potential impacts on public health and workers, are the same under both alternatives.

5.7 Animal Health and Welfare

TAM66274 cotton, which has very low levels of gossypol, would be considered of potential benefit to animal health and welfare, as well as the livestock and aquaculture industries on the whole. While there are potentially direct and indirect benefits to these industries, and animals reared within them, there are no further cumulative impacts associated with the commercial availability of TAM66274 cotton in the way of animal health and welfare.

5.8 Socioeconomics

One of the challenges among organic, GE, and conventional crop production systems is preventing the accidental comingling among commodities derived from these cropping systems in order to protect product identity and price premiums. Potential adverse impacts to non-GE crop producers are those related to cross-pollination and commingling of GE crop material with non-GE crops or crop products, leading to instances of unintended presence. This is particularly important for IP and organic crop commodities.

As of 2016, there were 36 USDA certified and exempt organic cotton farms in the United States, 1 in New Mexico, and 35 in Texas (Morris and Maggiani 2016). Total organic cotton acreage in the United States is 14,599 acres, with crop sales valued at $8.24 million (AgWeb 2017).

Similar to the organic cotton market, there is an expanding non-GMO market. These are products verified to contain GE trait material below an established threshold (e.g, food < 0.9% GE material by weight, feed < 5%), but are not necessarily USDA certified organic products – non-GMO cotton may be produced via conventional or organic means. The non-GMO verified market has expanded rapidly since 2007. According to the Non-GMO Project, Non-GMO Project Verified is the fastest growing label in the natural products industry, with more than 3,000 verified brands representing around 43,000 products, and annual sales of around $19.2 billion. It should be noted that "Non-GMO" verified does not necessarily mean it was produced via an IP program. While Non-GMO products are considered here, there are currently no Non-GMO verified cotton products on the market that APHIS is aware of.

Because TAM66274 cotton is phenotypically similar to existing GE and non-GE cotton cultivars (apart from the low levels of seed gossypol), it would present the same potential risks for cross-pollination and commingling with organic and conventional cotton crops as current GE and non-GE cotton varieties. If TAM66274 cotton were to cross-pollinate a cotton produced for the organic or Non-GMO markets, or commingle with commodities derived from these crops, it would reduce the value of that crop commodity (these crops could still be sold to buyers of GE cotton). TAM66274 cotton potentially adds to the number and variety of GE traits in commerce that need to be segregated among GE, organic, conventional post-harvest processing chains. In this sense, there could be an additive cumulative effect on commercial cotton and cottonseed supply chains – costs incurred for segregation of TAM66274 cotton commodities from other cotton supply chains. It is possible that other cotton varieties with enhanced seed quality traits, or fiber traits, may also be commercialized. An increase in development and adoption of new varieties of GE or non-GE cotton varieties would necessitate maintaining segregation, identity preservation, of cotton crop products produced via GE, conventional, and organic cropping systems and supply chains.

This potential impact considered, the availability of TAM66274 cotton, or its progeny, to commercial producers, is not expected to have a significant influence, in a cumulative manner, on organic/non-GMO cotton markets. Current and future cotton producers targeting IP, organic, and non-GMO markets are expected to use a variety of measures to preserve the integrity of their production systems and commodities, to include those required by USDA organic standards; measures that would be unaffected by approval of the petition. TAM66274 cotton is expected to be produced using standard industry practices for IP crops (TAMU 2017), which segregates the harvesting and post-processing food chains to ensure integrity of the crop product (Sundstrom et al. 2002). Crop varieties with unique product quality traits, such as TAM66274 cotton, require IP programs to channel these commodities to specific markets to capture their added value. Similarly, organic commodities must be produced according to specific criteria and segregated in the marketplace in order to receive price premiums. Because TAM66274 cotton will be produced using standard industry IP practices (TAMU 2017), contamination of other crops or their products (unintended presence), and contamination of TAM66274 cotton by other crops, is no more likely than that which exists among current cotton commodity supply chains. If such occurred, these events would be expected to be of low incidence.

The economic impact to growers of organic, non-GMO, and IP commodities from such unintended presence would depend on the price premium affected. For instance, organic commodities can receive a price premium in the food and personal care products markets (e.g., from 30% to 500%) relative to the price of commodities derived from conventionally grown crops. Because “organic” and “non-GMO” commodities can always be sold as “conventional” commodities, it is the price premium above the conventional price that represents a measure of the value affected by the unintended presence of GE plant material.

If APHIS approves the petition but TAM66274 cotton is not approved for import by other countries, this could theoretically present the opportunity for LLP incidents. However, adverse cumulative impacts on U.S. exports via LLP under this scenario is considered unlikely. To preclude LLP events other countries, subsequent to any approval of the petition, will need to approve TAM66274 cotton for import. It is expected that approvals for the commercial production or import of TAM66274 cotton in other countries would be pursued by TAMU as require. TAMU states they are examining opportunities to market TAM66274 cotton in other countries and will seek import clearances as required (TAMU 2017). It is also assumed that developers of future cotton varieties derived from TAM66274 cotton progeny would consult with foreign regulatory authorities if they intended to market food and feed to international markets.

As with domestic markets, TAM66274 cotton could prove valuable to international markets where there is a demand for cottonseed with reduced levels of gossypol. Growers will cultivate TAM66274 cotton and its progeny, in lieu of or in addition to other GE cotton varieties, as well as conventional cultivars, to the extent it can meet global demand, and it provides growers benefits in the way of yields, production efficiencies, and net-returns. Considering these factors, there are no reasonably foreseeable cumulative effects on international trade that would likely derive from entry of TAM66274 cotton into commercial markets.

6 THREATENED AND ENDANGERED SPECIES

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

Before a plant or animal species can receive protection provided by the ESA, it must be added to the Federal list of threatened and endangered plants and animals. 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 USFWS/NMFS 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 (a process 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 PPA (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.

After completing a PPRA and presenting relevant information for public comment, APHIS may determine that TAM66274 cotton "regulated articles" (e.g., cotton seeds, plants, or parts thereof) do not pose a plant pest risk. If so, then these articles would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340. In that case, APHIS would not have jurisdiction over these articles and can no longer regulate them. As part of its review in this EA, APHIS is analyzing the potential effects of TAM66274 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.

As described below, in following this review process, APHIS has evaluated the potential effects that a determination of nonregulated status of TAM66274 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 TAM66274 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 TAM66274 cotton are essentially indistinguishable from practices used to grow other cotton varieties (TAMU 2017). Although TAM66274 cotton may replace certain other varieties of cotton that are cultivated currently, APHIS does not expect the introduction of TAM66274 cotton to result in new cotton acres 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 TAM66274 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 the Affected Environment section of the EA (Chapter 3), 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.

As discussed in further detail elsewhere in this EA and in the petition (TAMU 2017), TAM66274 cotton has been genetically engineered with the *dCS* RNAi cassette that silences *dCS* genes encoding dCS enzyme (protein) involved in gossypol synthesis and with a neomycin phosphotransferase II (NPTII) variant protein which is encoded by *nptII* gene variant and serves as a marker. For its analysis of effects on T&E animals, APHIS focused on the implications of exposure to the GE plants resulting from the novel proteins expressed in the plants as a result of the transformation (resulting in low levels of gossypol in the seeds) as well as the ability of the TAM66274 cotton plants to serve as a host for a T&E species.

6.1 Potential Effects of TAM66274 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), and is not considered to be a problem plant or a common weed in the United States. It is not listed as a Federal Noxious weed (USDA-NRCS 2010a, 2018b), nor as invasive by any state other than Hawaii, nor as a weed in the major weed references (Crockett 1977; Holm LG et al. 1979; Muenscher 1980). Modern upland cotton is a domesticated perennial, typically grown as an annual crop that is not generally persistent in unmanaged or undisturbed environments without continued human intervention. Modern cultivars of upland cotton 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; they do not exhibit vegetative propagation or over-wintering structures, or rapid vegetative growth; and do not compete effectively with other cultivated plants (OECD 2008). In areas where freezing does not occur, cotton plants can occur as volunteers in the following growing season in crop fields. These volunteers can be controlled by herbicides, rotation to different crops and the production practices used to produce those crops that would not be compatible with cotton, and/or mechanical means. Cotton can become locally feral or naturalized in suitable areas, such as southern Florida, Hawaii, and Puerto Rico (Fryxell 1984; Coile and Garland 2003; Wunderlin 2008). However, TAM66274 cotton is expected can be controlled by the same herbicides as other cotton varieties should individual plants or populations occur where they are not wanted.

The agronomic and morphologic characteristics data provided by TAMU were used in the APHIS analysis of the weediness potential for TAM66274 cotton and evaluated for the potential to impact T&E species and critical habitat. Agronomic studies conducted by TAMU tested the hypothesis that the plant pest risk and weediness potential of TAM66274 cotton does not differ from conventional cotton (TAMU 2017). TAMU conducted field trials in eight locations representative of the major cotton-growing areas of the United States to evaluate phenotypic, agronomic and ecological characteristics relative to non-transgenic cv. Coker 312 in 2014 and 2015 (TAMU 2017). In its petition, TAMU provided evaluations of 40 phenotypic, agronomic, and ecological characteristics, comparing TAM66274 cotton to non-transgenic cv. Coker 312, which were measured six times in-season, as well as at harvest. The characteristics TAMU evaluated represent six general categories: 1) seed germination, dormancy, and stand count; 2) vegetative growth; 3) reproductive development; 4) fiber quality; 5) plant mapping and 6) plant susceptibility to diseases and insect pests and to rodents. TAMU also conducted laboratory studies on germination of seeds harvested from the field studies. In a few instances, statistical differences were seen between the TAM66274 cotton and non-transgenic cv. Coker 312, but these differences were inconsistent across the two seasons and therefore do not appear agronomically meaningful. TAMU detected no statistically significant or biologically meaningful differences in seed germination (both in laboratory and field studies), stand count, vegetative growth, or plant susceptibility to disease and insect pests or rodents for TAM66274 cotton relative to non-transgenic cv. Coker 312. Of all the parameters measured, only fiber length consistently statistically differed between the treatments over the two field trial seasons. Fiber length of TAM66274 cotton was slightly shorter than non-transgenic cv. Coker 312 (within commercially acceptable limits), but this does not contribute to increased weediness or plant pest risk (TAMU 2017). Data from these studies show that TAM66274 cotton is phenotypically, agronomically and ecologically equivalent to non-transgenic cv. Coker 312 and, therefore, is likely comparable to other conventional cotton varieties. The results demonstrate that the cultivation of TAM66274 cotton poses no greater weediness risk or plant pest risk than does the cultivation of non-transgenic cv. Coker 312 and, therefore, is unlikely to pose greater weediness risk or plant pest risk than other conventional cotton varieties (TAMU 2017; USDA-APHIS 2018b).

The seed dormancy characteristic is often associated with plants that are considered weeds. Lab studies found no significant differences in germination (an indicator of dormancy) of TAM66274 cottonseed compared with the control, non-transgenic cv. Coker 312, under cool conditions from any of the eight field sites. Percent germination of seed varied greatly across the field locations for both TAM66274 cotton and Coker 312. Under warm conditions, there were no statistical differences in percent germination between TAM66274 cotton and Coker 312 for seven of the eight sites. However, percent germination at the Perquimans County, NC site was greater for TAM66274 cotton than for Coker 312. This difference may have arisen from the variation in seed quality across the field sites due to especially high rainfall in two of the sites (including the site in Perquimans County) during boll formation (TAMU 2017). Thus, the statistically significant difference in this one site was not considered biologically relevant (TAMU 2017). In summary, no agronomically meaningful differences were detected between TAM66724 cotton and the non-transgenic cotton in growth, reproduction, or interactions with pests and diseases or with rodents (TAMU 2017; USDA-APHIS 2018b). Extensive post-harvest monitoring of field trial plots planted with TAM66274 cotton under USDA-APHIS notifications did not reveal any differences in survivability or persistence relative to other varieties of cotton currently being grown (TAMU 2017).

Based on the agronomic field and laboratory data and a search of the technical and scientific literature that was focused on the weediness potential of cotton, APHIS believes that TAM66274 cotton is unlikely to persist as a weed or impact weed control practices (USDA-APHIS 2018b). TAM66274 cotton volunteer plants and feral populations can be managed using a variety of currently available methods and herbicides. From these data, APHIS determined that TAM66274 cotton is no more likely to become a weed than those varieties of cotton that are currently in use (USDA-APHIS 2018b).

As part of its analysis of effects on species and habitat, APHIS evaluated the potential of TAM66274 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 2012b). Naturalized populations of *G. barbadense* grow in Puerto Rico, the Virgin Islands and several Hawaiian Islands (Fryxell 1984; Bates 1990). 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; USDA-NRCS 2018a). *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 CL 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 2018b).

For transgene introgression from TAM66274 cotton to occur, the recipient variety or species would have to be both near TAM66274 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 CL 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 CL et al. 1993). Various mechanisms have been suggested to account for this difference (Percy and Wendel. 1990; Brubaker CL et al. 1993; Jiang and PW Chee 2000; OGTR 2008). While none of these mechanisms leads to complete isolation between the two species, the reported asymmetry in gene flow suggests that gene introgression from cultivated *G. hirsutum* varieties such as TAM66274 cotton to native or naturalized *G. barbadense* should be rare (USDA-APHIS 2018b).

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). The wild cotton tetraploid species *G. tomentosum* is sexually compatible with upland cotton. However, *G. tomentosum* populations are limited to the Hawaiian Islands. The flowering period for *G. tomentosum* corresponds to the end of the rainy season and may begin as early as January, possibly extending as late as August in a very wet year (Pleasants and Wendel 2010). Therefore, any cultivated cotton that blooms between January and August could potentially overlap temporally with *G. tomentosum*. The work of Pleasants (2010) also suggests that there may be overlap of flowering during time of day, as well. The two species of cotton also overlap in potential pollinators, including honeybees, which may travel up to six miles from their nests (Pleasants and Wendel 2010). 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 (Saha et al. 2006). Therefore, gene introgression into wild relatives is extremely unlikely (USDA-APHIS 2018b). But even if it were to occur, suppression of the genes that normally result in the synthesis of gossypol does not cause any major changes in the phenotype of cotton plants other than a reduction in gossypol levels in the seeds (TAMU 2017; USDA-APHIS 2018b), and the transgenic material in TAM66274 cotton is unlikely to confer a selective advantage on any hybrid progeny that may result from outcrossing (USDA-APHIS 2018b).

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 TAM66274 cotton to naturalized *G. hirsutum* in Florida is highly unlikely. Accordingly, a decision to no longer regulate TAM66274 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 TAM66274 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 TAM66274 cotton would comprise those T&E species that inhabit cotton fields and potentially feed on TAM66274 cotton. To identify potential effects on T&E animal species, APHIS evaluated the risks to T&E animals from consuming TAM66274 cotton.

TAM66274 cotton differs phenotypically from other varieties of cotton in that its seeds have lower concentrations of gossypol, with about 3% of the normal amount. The other plant parts retain normal levels of gossypol, which protect the plants from insect pests and other animals that limit their consumption of gossypol (TAMU 2017); see also see Section 1.2). 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. The North Carolina survey did not specify which plant parts were consumed. However, 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 (Taylor et al. 2013a). 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 white-tailed 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 TAM66274 cotton in the field more than they consume other varieties currently in production. TAM66274 cotton seeds having lower gossypol concentrations compared to currently grown cotton varieties does not suggest that deer or any other animal will eat more cotton in the field because (a) all plant parts other than the seed will continue to have typical levels of gossypol protection and (b) deer will not easily extract the seeds from the growing plant; and (c) the seed is only present for a relatively short time before it is harvested, which limits potential grazing time.

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 other food items in cotton fields, such as the 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.

TAMU conducted compositional analyses on TAM66274 cotton, including proximates, fiber (total dietary, crude, acid and neutral detergent fibers), fatty acids, amino acids, minerals, alpha-tocopherol, and anti-nutrients (total and free gossypol, gossypol isomers, cyclopropenoid fatty acids and phytic acid), and mycotoxins. With the exception of reduction in gossypol levels in TAM66274 cottonseed, compositional analyses demonstrated that TAM66274 cottonseed is compositionally and nutritionally equivalent to parental variety cv. Coker 312 (TAMU 2017; USDA-APHIS 2018b). Therefore, other than its low gossypol seed concentrations, TAM66274 cotton should not present any nutritional differences to T&E animal species compared to other commonly grown varieties of cotton.

TAMU also conducted bioinformatics analyses related to the dCS gene and protein. Results demonstrate the unlikelihood of adverse non-target effects of the dCS RNAi across a range of animal taxa (TAMU 2017). The amount of NPTII variant protein in TAM66274 cottonseed is extremely low with no more than 0.0000041% dry weight (compared to the parental non-transgenic Coker 312 plants, in which NPTII was not detected) (TAMU 2017). The low concentration and history of safe use of NPTII in other commercial crops strongly suggests that these two proteins in TAM66274 cotton will have no effect on T&E animal species.

Section 4.4.1 discusses in greater detail the *dCS* RNAi and *nptII* transgenes and their gene products and the mechanisms by which they might pose risks to both invertebrate and vertebrate animals. It shows that these mechanisms are unlikely to adversely affect animals. Therefore, in the unlikely event that T&E animal species consume TAM66274 cottonseed, they are very unlikely to experience any adverse effects.

The RNAi-mediated suppression in TAM66274 cotton shares no homology to genes in other plant or animal species, nor do they encode a protein toxin or allergen (TAMU 2017). The *nptII* gene in TAM66274 cotton is widely distributed in nature and has previously been evaluated for human and environmental safety (TAMU 2017). Therefore neither of these genetic changes or their products would likely cause any adverse effects through allergic responses in T&E animal species (See also Section 4.4.1).

The FDA approved a maximum allowable level of free gossypol in roasted or baked glandless cottonseed kernels used as human food at 450 ppm (US-FDA 1976). This decision followed FDA prior approval of modified cottonseed products for human consumption derived from glanded cottonseed varieties that are mechanically or chemically processed to reduce free gossypol to less than 450 ppm (Rathore et al. 2012; Gadelha et al. 2014). As part of the consultation process, TAMU submitted a food and feed safety and nutritional assessment for TAM66274 cotton to FDA on September 22, 2017 (TAMU 2017).

In summary, APHIS has determined that contact and ingestion of TAM66274 cotton plants or plant parts is unlikely to affect T&E species. There is no evidence of allergenicity with TAM66274 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 TAM66274 cotton. Based on this analysis, APHIS concludes that contact with or consumption of TAM66274 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 species proposed for listing.

APHIS did consider the possibility that TAM66274 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 TAM66274 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 TAM66274 cotton on designated critical habitat or habitat proposed for designation. Compared to other cotton varieties that are currently in use, APHIS determined that TAM66274 cotton production would not differentially affect critical habitats. Like many crops, cotton has been selected for yield rather than its ability to compete and persist in the environment. TAM66274 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 TAM66274 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 TAM66274 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 draft EA in order to document the potential consequences 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 TAM66274 cotton. APHIS determined that the cultivation of TAM66274 cotton would not lead to the increase in or expansion of the area in cotton production. Because TAM66274 cotton is agronomically and phenotypically equivalent to other non-GE and GE commercially cultivated cotton (TAMU 2017), the potential impacts to water and air quality from the commercial cultivation of TAM66274 cotton would be no different than that of currently cultivated cotton varieties. The *dCS* RNAi and *nptII* transgenes and their gene products are not expected to result in any changes in water usage for cultivation or post-harvest processing of seed and lint. Pesticides must be used in strict accordance with their label instructions. To do otherwise is a violation of law. APHIS assumes any use of pesticides will be compliant with EPA registration and label use requirements. Based on these analyses, APHIS concludes that a determination of nonregulated status for TAM66274 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 NHPA of 1966 and its implementing regulations (36 CFR part 800) requires federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

Approval of the petition is not a decision that would directly or indirectly result in alteration of the character or use of historic properties protected under the NHPA, nor would it result in any loss or destruction of cultural or historical resources. Where TAM66274 cotton is cultivated there may be the potential for increased noise during the operation of machinery and other equipment, however, crop production activities would have only temporary effects on historic sites in the way of noise, with no consistent long-term effects on the enjoyment of a historical site.

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 TAM66274 cotton would not lead to the increase in or expansion of the area in cotton production. A determination of nonregulated status of TAM66274 cotton is not likely to impact cultural resources on tribal properties. On December 11, 2017, APHIS sent a letter to tribal leaders and natural resource managers to review the petition (USDA-APHIS 2017). APHIS received one response from the Comanche Nation stating that no properties have been identified as being impacted by the proposed petition. 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 TAM66274 cotton is not expected to impact cultural resources on tribal properties.

Based on the information submitted by TAMU and reviewed by APHIS, TAM66274 cotton is agronomically, phenotypically, and compositionally comparable to conventional cotton except for the presence of the introduced *dCS* RNAi and *nptII* variant genes expressed in the seed. As reviewed in Chapter 4, the transgenes and gene products present no risk to human health, this includes that of minorities, low-income populations, children, and Tribal entities who might be exposed to TAM66274 cotton through agricultural production and/or processing. TAMU states they will consult with the FDA as to the safety of food products derived from TAM66274 cotton.

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

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

The outcrossing and weediness potential of TAM66274 cotton are discussed in the PPRA (USDA-APHIS 2018b) 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. APHIS concluded based in the PPRA that TAM66274 cotton is unlikely to present as a weedy or invasive species, nor any progeny derived from it (TAMU 2017).

- **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.

Migratory birds may visit cotton fields during periods of migration, although would not be present during normal farming operations. If migratory birds did visit TAM66274 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. TAMU data shows no substantial difference in composition or nutritional quality of TAM66274 cotton compared with other GE or non-GE cotton, apart from the presence of the introduced *dCS* RNAi and *nptII* variant genes and the low gossypol levels in the cottonseed. As discussed in Chapter 4, it is highly unlikely that the *dCS* RNAi and *nptII* genes and their products, which occur naturally in the environment, present any risk to wildlife, to include birds. Based on these factors, it is unlikely that the determination of nonregulated status of TAM66274 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.

The United States is a member of the WTO, which facilitates harmonizing the global rules of trade between nations. The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement"), entered into force with the establishment of the WTO on January 1, 1995, sets out the basic rules for food safety and animal and plant health standards. The SPS agreement recognizes three international organizations/frameworks that have established standards and guidelines related to SPS measures (WTO 2015a). These are: the Codex Alimentarius Commission (Codex), the World Organization for Animal Health, and the International Plant Protection Convention (IPPC). Any international trade of TAM66274 cotton or products derived from it following a determination of nonregulated status would be subject to national phytosanitary requirements and be in accordance with international SPS standards, inclusive of the Codex (food safety) and IPPC (plant pests and disease). Approvals for the commercial use of TAM66274 cotton will be sought by TAMU as needed (TAMU 2017).

All crop production can potentially have adverse impacts on soils, and air and water quality. Any cultivation of TAM66274 cotton outside of the United States, its territories, or possessions would utilize the same (or similar) agronomic practices and inputs as those utilized in the United States. Consequently, the sources and degree of environmental impacts that derive from crop production would not differ for those described for the United States, as discussed in this EA. In the event APHIS approves the petition for TAM66274 cotton, significant adverse environmental impacts outside the United States as a result of cultivation of this cotton variety are unlikely.

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 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 NOP prohibitions on excluded methods, then organic producers cannot not 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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