NATIONAL ENVIRONMENTAL POLICY ACT FINDING OF NO SIGNIFICANT IMPACT

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

OECD Unique Identifier: TAM-66274-5

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

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has prepared this Finding of No Significant Impact (FONSI) consistent with the requirements of the National Environmental Policy Act (NEPA, 42 U.S.C. § 4321 et seq.), as amended, the Council of Environmental Quality's (CEQ) NEPA implementing regulations (40 CFR parts 1500-1508), and APHIS NEPA-implementing regulations (7 CFR part 1b, and 7 CFR part 372). This FONSI sets forth APHIS' NEPA decision with respect to potential impacts on the human environment that could derive from a determination of nonregulated status for Ultra-Low Gossypol TAM66274 Cotton.

Texas A&M University (hereinafter referred to as "TAMU") submitted a petition (17-292-01p) to the USDA APHIS requesting that genetically engineered (GE) TAM66274 cotton, and any cotton lines derived from crosses of TAM66274 cotton with other GE cotton varieties and conventional cotton, no longer be considered regulated articles under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). TAM66274, is a GE cotton variety that exhibits lower levels of gossypol in the seed which has been regulated by APHIS because it was developed using the plant pest *Agrobacterium tumefaciens*; a regulated article under 7 CFR part 340.2.¹

In support of APHIS' evaluation of TAMU's petition, APHIS conducted an Environmental Assessment (EA) to inform APHIS' decision regarding the regulatory status of GE TAM66274 cotton. The EA evaluates the potential impacts of APHIS' regulatory decision on the quality of the human environment.² The EA did not identify any significant impacts that would derive from either an approval or a denial of the petition. Therefore, the Agency has prepared this FONSI, pursuant to 40 CFR part 1508.13, which provides a summary of the EA, and the reasons why APHIS' decision to issue a determination of nonregulated status for GE TAM66274 cotton will not have a significant impact on the human environment.

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

² Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR part 1508.14).

APHIS Regulatory Authority

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

APHIS' Response to Petitions for Nonregulated Status

APHIS regulations at 7 CFR part 340 provide that any person may submit a petition to APHIS requesting that, because the GE organism does not pose a plant pest risk, it should not be regulated under 7 CFR part 340. As required by 7 CFR § 340.6 APHIS must respond to petitioners with a regulatory status decision. If APHIS determines, based on a Plant Pest Risk Assessment (PPRA) and other relevant information that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to regulation under 7 CFR part 340.

Public Involvement in Evaluation of the Petition and Environmental Assessment

On December 5, 2017, APHIS announced in the *Federal Register* that it was making TAMU's petition available for public review and comment to help identify potential environmental and interrelated economic issues that APHIS should consider in evaluation of the petition. ³ APHIS accepted written comments on the petition for a period of 60 days, until midnight February 5, 2018. At the end of the comment period APHIS had received a total of 47 comments on the petition; 44 were supportive, two opposed, and one was not related to the TAMU petition. A full record of each comment received on the petition is available online at www.regualtions.gov.⁴

On August 1, 2018, APHIS announced in the *Federal Register* it was making available the draft EA and PPRA for a 30-day public review and comment period.⁵ At the end of the comment period APHIS had received 2 comments, one from National Cotton Council in support of the petition, and one comment was not related to the petition. Comments received on the draft EA are available for public review at www.regulations.gov, Docket ID: APHIS-0217-0097.

³ Public comments can be reviewed at: https://www.regulations.gov/document?D=APHIS-2017-0097-0001

⁴ See https://www.regulations.gov/document?D=APHIS-2017-0097-0050 [Docket No. APHIS-2017-0097 at www.regulations.gov]

⁵ https://www.regulations.gov/document?D=APHIS-2017-0097-0050

Scope of EA Analysis

Evaluating the deregulation which may lead to commercialization of GE TAM66274 cotton encompasses consideration of potential environmental, human health, and socioeconomic impacts. APHIS developed a list of topics for consideration in the EA based on issues identified in prior EAs for cotton varieties, public comments submitted on the petition for GE TAM66274 cotton, other EAs and Environmental Impact Statement (EIS) evaluating petitions for nonregulated status, the scientific literature on agricultural biotechnology, and issues specific to cultivated GE TAM66274 Cotton. The following topics were identified as relevant to the scope of analysis (40 CFR § 1508.25):

Agricultural Production

- Acreage and Areas of GE TAM66274 Cotton Production
- Agronomic Practices and Inputs

Environmental Considerations

- Soil Quality
- Water Resources
- Air Quality
- Soil Biota
- Animal and Plant Communities
- Herbicide Resistant Weeds
- Gene Flow and Weediness of GE TAM66274 cotton
- Biodiversity

Human Health

Consumer Health and Worker Safety

Animal Health

Animal Feed/Livestock Health

Socioeconomics

• Domestic Economic Environment and International Trade

The potential impacts on threatened and endangered species, as wells as adherence of the regulatory decision to executive orders, and environmental laws and regulations to which the regulatory status decision may be subject, were also analyzed.

Alternatives Evaluated in the EA

The EA considered two alternatives in response to the petition request, to either deny (No Action Alternative – required pursuant to CEQ regulations at 40 CFR part 1502) or to approve the request for non-regulated status (Preferred Alternative – described below). APHIS analyzed the potential environmental, human health, and socioeconomic impacts that may result from the two alternatives.

Preferred Alternative: Determination that TAM66274 Cotton is No Longer a Regulated Article Under this preferred alternative, TAM66274 cotton and progeny derived from it would no longer be subject to regulation under 7 CFR part 340. This alternative is preferred because APHIS

determined that, based on the scientific evidence before the Agency, TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018). Under this alternative, permits issued or notifications acknowledged by APHIS would no longer be required for introductions of TAM66274 cotton or its progeny into the environment. If developers commercialize TAM66274 cotton, growers could have access to TAM66274 cotton and progeny derived from it. This alternative best satisfies the purpose and need and responds appropriately to the petition pursuant to the requirements of 7 CFR part 340.6, the Agency's statutory authority under the PPA, and the shared biotechnology regulatory policies described in the Coordinated Framework for Regulation of Biotechnology⁶.

Alternatives Considered but Dismissed from Detailed Analysis

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

Environmental Consequences of APHIS' Selected Action

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

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 through confinement conditions for regulated field trials.	Determined by the plant pest risk assessment (USDA-APHIS 2018).
Agricultural Production		
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

⁶ https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles

		cotton varieties currently grown in the United States.
Change in 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 varieties resistant to either certain herbicides and/or insect pests. Denial of the petition would have no effect on the planting of existing varieties of GE cotton.	Approval of the petition would significantly reduce total gossypol levels in cotton seeds compared to that in non-transgenic seeds. This GE product would contain gossypol levels below the established safety standards for cottonseed products intended for use in human food (450 ppm) and for seed intended for monogastric animals feed (400 ppm).
Physical Environment		
Soils	Increased tillage to manage herbicide resistant (HR) weeds may continue to occur in some cotton cropping systems, potentially impacting soil quality and soil erosional capacity.	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 remain largely unchanged from current practices. Increased tillage, or adoption of more aggressive tillage practices to manage HR weeds, could exacerbate soil erosion and run-off, which can impair water quality.	Because TAM66274 cotton is agronomically similar to currently 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 impacts 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.
	Increased tillage to manage HR weeds may occur in some cotton cropping systems. This could reduce air quality as a result of increased NAAQS pollutant emissions from farm equipment.	

·	Increased use of herbicides may occur to manage HR weeds. This could increase herbicide volatilization and drift that could reduce air quality. Biological Resources	
Animal Communities	Commercial cotton fields provide limited food and habitat for wildlife. Also, the current levels of gossypol in cottonseed limits consumption by rodents and other pests due to the toxicity of gossypol.	Potential impacts of TAM66274 cotton crop production on animal communities are expected to be the same as No Action Alternative. The δ -Cadinene synthase genes (dCS) Ribonucleic acid interference (RNAi) and Neomycin phosphotransferase II gene from <i>Escherichia coli</i> Tn5 ($nptII$) transgenes and their gene products present negligible risks 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 managed as such. Plant communities surrounding cotton fields are generally encouraged as the 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 nptll transgenes and their gene products present in TAM66274 are not expected to increase the potential for gene flow, hybridization and/or introgression of genes from TAM66274 to other sexually compatible relatives, including wild, weedy, feral or cultivated species in the U.S. 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 varieties currently used by growers. Consequently, commercial production of TAM66274 cotton and hybrid crops are not expected to present impacts to soil biota.
Biological Diversity	Under the No Action Alternative, cropping systems generally are not expected to change, so biodiversity in regions where cotton are 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 effect on gene flow and weediness	The introduction of the transgenes and the associated gene products in

	associated with commercial cotton production.	TAM66274 cotton does not alter its weediness characteristics (USDA-APHIS 2018), 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.	
Herbicide Resistant (HR)	Weeds with an evolved resistance to	Weed, including HR weeds,	
Weeds	herbicides are expected to continue	management practices would be	
	to increase. As these HR weeds	unaffected by approval of the	
	become more prevalent, growers are expected to shift to other, possibly	petition. HR cotton varieties stacked with TAM66274 cotton could provide	
	more costly, weed control measures	an additional weed management	
	and/or switch to other HR crops in	tool.	
	order to control weeds and remain		
	economically viable.		
	Cotton growers are likely to use		
	additional herbicides and may		
	abandon conservation tillage		
	practices and return to more		
,	aggressive conventional tillage		
	systems to manage weeds and		
	protect yields.		
Human and Animal Health			
Human Health and Safety	Denial of the petition would have no	Approval of the petition would not	
	impacts on human health or worker safety.	be expected to present risks to human health. RNAi-mediated gene	
	Consumer use of cotton and cottonseed products will continue similarly to current uses. The use of cottonseed products other than oil in human food will continue to be limited due to the concentration of gossypol. EPA regulation of pesticides and	suppression has been used in a number of GE food crops including papaya, potato, plum, corn, canola, and soybean. These plant varieties have been previously evaluated by the FDA, which had no concerns regarding the safety of these foods for human consumption (US-FDA 2018).	
	worker protection standards would remain unchanged.		

		The FDA has approved Neomycin phosphotransferase II protein (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 plantincorporated protectant (40 CFR § 174.521).
Animal Health and Welfare	Denial of the petition would no effect on animal health and welfare.	TAM66274 cotton, which has low levels of gossypol in the seed, is intended to expand the uses of cottonseed products as food and feed. This would benefit livestock and aquaculture production, and in turn processors and end users of those 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 impact domestic or international markets. TAM66274 cotton facilitates cottonseed oil refining, use of cottonseed oil in the food industry, and use of whole seed, oil, and crushed meal in the livestock and aquaculture feed industries. Consequently, its introduction could potentially benefit 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.
Coordi	nated Framework for the Regulation of	Biotechnology
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,

		and has prepared a safety and nutritional assessment of food and feed derived from TAM66274 cotton and expects to submit its findings in 2018.
	Regulatory and Policy	Compliance
Endangered Species Act, Clean Water Act, Clean Air Act, Safe Drinking Water Act, National Historic Preservation Act, Executive Order	Compliant	Compliant

Finding of No Significant Impact

Based on the analysis presented in the EA, a determination of non-regulated status for TAM66274 cotton will not have a significant impact, individually or cumulatively, on the quality of the human environment. Assessment of significant impacts, as required by NEPA regulations (40 CFR § 1508.27), entails the consideration of both the context and intensity of potential impacts. The EA considered and this FONSI is based upon the following factors.

Context

The term "context" means identification of the locations and resources that could potentially be affected by the Agency's action. The EA identified the areas in which cotton is and may be cultivated in the United States, and those aspects of the human environment potentially affected by the Agency's regulatory status decision. This action has the potential to affect GE and non-GE cotton cropping systems; environments adjacent to and associated with TAM66274 cotton cropping systems; cotton fiber and seed oil post-harvest processing systems; and domestic and foreign commodity markets. According to USDA-NASS data, cotton has been planted on approximately 10 to 12 million acres over the last several years (USDA-NASS 2015). GE-derived varieties of cotton, containing either HR, insect resistance (IR), or both traits, comprised 96 percent of all cotton planted in 2017 (USDA-ERS 2017). Cotton is mostly grown in 17 states across the southern United States. These states include Alabama, Arizona, Arkansas, California, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia (USDA-NASS 2015).

A determination of non-regulated status for TAM66274 cotton is not expected to result in any increase in agricultural acreage utilized for cotton production, or change in the areas where cotton is grown, because it is not substantially different, phenotypically and agronomically, from existing cotton, and will be used to provide the same cotton commodities, fiber and oil, as non-GE varieties.

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⁷ https://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2017.pdf

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

1. Impacts that may be both beneficial and adverse.

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

Potentially Beneficial: Approval of the petition would likely result in availability of TAM66274 cotton to commercial markets. TAM66274 cottonseed, low in gossypol (e.g., 3% of that in conventional cottonseed varieties context (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 a potential benefit to domestic and international 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.

Potentially Adverse: There are no potentially adverse impacts, of a unique nature, that would derive from approval of petition. The EA concluded that cultivation of TAM66274 cotton, to include the use of pesticides and fertilizers, and to some extent tillage, could contribute, but not increase, cumulative impacts on soil, air, and water quality, as well as, if crossed with IR/HR varieties, on selection for insecticide-resistant pest and herbicide-resistant weed populations. Any commercial cultivation of TAM66274 cotton or hybrid progeny would have the same potential impacts on water, soil, and air quality as that of currently cultivated cotton varieties. Any use of pesticides would be subject to EPA as well as state requirements (e.g., (US-EPA 2017)).

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

Approval of the petition would have no effect on public health or safety. The only potential human health risks are those associated with pesticide use, and those potentially presented by the dCS RNAi and nptII transgenes and their products. As reviewed in the EA, it is highly improbable that the dCS RNAi and nptII transgenes and their products present a risk to humans.

Any pesticide use with TAM66274 cotton will be regulated by the EPA. The EPA conducts human health and environmental risk assessments for pesticide active ingredients and provides use restrictions that are intended to be protective of human and environmental health. TAMU initiated food safety consultations with FDA in 2012 in accordance with FDA's policy statement and industry guidance. TAMU has prepared a safety and nutritional assessment of food and feed derived from TAM66274 and will submit its findings to FDA as part of marketing of TAM66274 cotton.

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

The EA concluded that it is unlikely that historic or cultural resources, park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas would be significantly impacted by approval of the petition. Volunteer cotton plants may occur in areas where TAM66274 cotton is cultivated and due to spilling of seed during transport. However, invasion of park lands, wetlands, wild and scenic areas, or ecologically critical areas by TAM66274 cotton or feral hybrids is considered unlikely. APHIS conducted a PPRA and concluded that it is unlikely that TAM66274 cotton will become weedy or invasive, nor would gene introgression from TAM66274 cotton to wild cotton populations increase the weediness wild cotton hybrids (USDA-APHIS 2018)

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

APHIS received public comments opposing the petition, however, approval of the petition for non-regulated status for TAM66274 cotton and its progeny is not an action considered highly controversial in nature. There would be no significant changes to the agricultural practices and inputs used for cotton production, nor the potential impacts of these practices and inputs on the human environment. The potential sources of impacts of TAM66274 cotton production on physical and biological resources are similar to that of currently cultivated cotton varieties. There are no potential impacts on the human environment that would derive from approval of the petition that are controversial in nature.

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

There are no unique or unknown risks associated with TAM66274 cotton. Since 1994, APHIS has evaluated over 15 different GE cotton varieties. As discussed in the EA, the mechanisms by which the *dCS* RNAi and *nptII* transgenes and their products govern gossypol production in the cottonseed are well understood. The transgenes and respective enzymes present in TAM66274 cotton pose negligible risk to plants, animals, and other taxa.

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

Approval of TAMU's petition would not establish a precedent for future actions that would result in significant impacts on the human environment, nor would it represent a decision in principle about a future decision. Approval of the petition is based upon an

independent determination of whether TAM66274 cotton is unlikely to pose a plant pest risk (USDA-APHIS 2018) pursuant to 7 CFR part 340, and an environmental analysis consistent with NEPA and CEQ implementing regulations. APHIS has reviewed and approved petitions for non-regulated status since 1992; each of these petitions reviewed independent of the others, and determinations of regulatory status is based on the plant pest risk assessments for the GE organism. Each petition that APHIS receives is specific for a particular GE organism-trait combination and undergoes an independent review to determine if the regulated article may pose a plant pest risk.

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

The EA discusses potential cumulative impacts on agricultural practices and inputs, human and animal health, physical and biological resources, and on the selection pressure toward insecticide-resistant pest and herbicide-resistant weed populations. Cultivation of TAM66274 cotton will contribute to, but not increase, cumulative impacts on air, water, and soil quality. These impacts would not be considered significant, because they not different than those that occur with the production of currently cultivated cotton varieties.

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

The EA concluded approval of the petition is not an action that would directly or indirectly alter the character or use of properties protected under the National Historic Preservation Act. It would have no impact on districts, sites, highways, structures, or objects listed in, or eligible for listing in, the National Register of Historic Places, nor cause any loss or destruction of significant scientific, cultural, or historic resources. TAM66274 cotton would be cultivated on lands zoned for agricultural uses. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of cotton would be used in cultivation of TAM66274 cotton, including the use of EPA registered pesticides. The crop production practices used in the cultivation of cotton do not introduce significant visual impairments, or noise, in a manner that would impact the use and enjoyment of historic properties. Any farming activities that may be undertaken on tribal lands are only conducted under the Tribe's approval; Tribes have control over any potential conflict with cultural resources on tribal properties.

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

APHIS analyzed the potential effects of TAM66274 cotton on threatened and endangered species and critical habitat in Chapter 6 of the EA. APHIS concluded that approval of the petition for non-regulated status for TAM66274 cotton, and any subsequent commercial

production of this cotton variety, will have no effect on listed species or species proposed for listing, nor would it affect designated habitat or habitat proposed for designation. Because of this no-effect determination, neither consultation under Section 7(a)(2) of the Act nor the concurrences of the U.S. Fish and Wildlife Service and National Marine Fisheries Services are required.

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

The EA evaluated the federal, state, and local laws and regulations, executive orders, and policy related to TAMU's petition. The EA concluded that approval of the petition would not violate federal and state laws and regulations governing environmental and human health protections.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for the proposed action of granting the petition and the input from the public involvement process. In light of the FONSI, APHIS will implement Alternative 2 as described in the EA (Determination that TAMU's cotton event TAM66274 is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of GE organisms, and is consistent with the plant pest provisions of the PPA.

As stated in CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The Preferred Alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, the Preferred Alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect the health and value of American agriculture and natural resources using a science-based regulatory framework that allows for the safe development and use of GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As a result of the analyses conducted in the EA and summarized in this FONSI, I have concluded that granting nonregulated status to TAMU's cotton even TAM66274 will have no significant impacts on the human environment as a result of making a determination of nonregulated status.

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Deputy Administrator

Biotechnology Regulatory Services

Animal and Plant Health Inspection Services

U.S. Department of Agriculture

Date:

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