

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

**Dow AgroSciences
2,4-D and Glufosinate-Resistant DAS-81910-7 Cotton**

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

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR Part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 13-262-01p) by Dow AgroSciences (hereinafter referred to as "Dow") for their transgenic cotton, event DAS-81910-7 (hereafter referred to as DAS-81910-7 cotton), which is resistant¹ to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and glufosinate. DAS-81910-7 cotton was developed using *Agrobacterium*-mediated transformation to stably incorporate the *aad-12* gene and the *pat* gene into cotton. DAS-81910-7 cotton will enable additional choices of herbicides for the control of glyphosate-resistant (GR) and other economically important weeds. The herbicide application window for effective weed control can be lengthened because of the resistance to these two herbicides. This EA has been prepared in order to specifically evaluate the impacts on the quality of the human environment²

¹ "Resistance" to herbicides is defined by the Herbicide Resistance Action Committee (HRAC) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type (HRAC. 2014. Glossary. Herbicide Resistance Action Committee <http://www.hracglobal.com/Education/Glossary.aspx>, 2014). Several technologies are available that can be used to develop herbicide resistance in plants including classical breeding, tissue culture, mutagenesis and genetic engineering. "Tolerance" is distinguished from resistance and defined by (HRAC. 2013. Guideline to the management of herbicide resistance. Herbicide Resistance Action Committee 2013. <http://www.hracglobal.com/Education/ManagementofHerbicideResistance.aspx>) as the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. Throughout this EA, USDA-APHIS has used the terms "resistance" and "tolerance" consistent with the definitions of the HRAC. It should be noted however, that different terms for the same concept may be used interchangeably in some instances. In its petition to USDA-APHIS, Dow referenced the subject as "2,4-D and glufosinate-tolerant cotton," and used the term "herbicide tolerant" throughout its documentation to describe the cotton event. This terminology can be considered synonymous with "herbicide-resistant" (HR) used in this Environmental Assessment (EA).

² Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §508.14).

that may result from a determination of nonregulated status of DAS-81910-7 cotton. The EA assesses alternatives to a determination of nonregulated status of DAS-81910-7 cotton and analyzes the potential environmental and socioeconomic impacts that result from the proposed action and the alternatives.

Regulatory Authority

“Protecting American agriculture” is the basic mission of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those 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 required 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’s APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS has authority to regulate GE organisms and plants under the plant pest provisions in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq.*). APHIS regulates GE organisms and plants to ensure that they do not pose a plant pest risk based on requirements in 7 CFR Part 340.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a

consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

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

Regulated Organisms

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (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 Plant Protection Act 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 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 pursuant to Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated pursuant to the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may 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 Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Petition for Nonregulated Status

Pursuant to the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as DAS-81910-7 cotton. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism poses a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically

engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Dow has submitted a petition (APHIS Number 13-262-01p) to APHIS seeking a determination that their transgenic cotton, DAS-81910-7 cotton, is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article pursuant to regulations at 7 CFR Part 340.

DAS-81910-7 cotton

DAS-81910-7 cotton is a genetically engineered (GE) cotton line containing the aryloxyalkanoate dioxygenase-12 (*aad-12*) and phosphinothricin acetyltransferase (*pat*) genes, which confer resistance to the herbicides 2,4-D and glufosinate, respectively. DAS-81910-7 cotton was developed using *Agrobacterium*-mediated transformation to stably incorporate the *aad-12* gene and the *pat* gene into cotton. DAS-81910-7 cotton will enable additional choices of herbicides for the control of glyphosate-resistant (GR) and other economically important weeds. The herbicide application window for effective weed control can be lengthened because of the resistance to these two herbicides.

DAS-81910-7 cotton incorporates the *aad-12* gene, derived from the common soil bacterium derived from *Delftia acidovorana*. The *aad-12* gene in DAS-81910-7 cotton expresses the AAD-12 protein, which results in the metabolic inactivation of herbicides of the aryloxyalkanoate family. The AAD-12 protein degrades 2,4-D into herbicidally inactive 2,4-dichlorophenol (DCP). Additionally, this same protein has been demonstrated to degrade other phenoxy carboxylic acid herbicides, including (4-chloro-2-methylphenoxy) acetic acid (MCPA) and 4-(2,4-dichlorophenoxy) butyric acid (2,4-DB), and pyridine carboxylic acids herbicides, such as triclopyr and fluroxypyr.

The *pat* gene, also inserted into DAS-81910-7 cotton, encodes the PAT protein that inactivates the herbicide glufosinate. The *pat* gene is derived from *Streptomyces viridochromogenes*, a gram-positive soil bacterium. Glufosinate resistance allows growers to employ this ‘over-the-top’ broad spectrum herbicide.

DAS has plans to cross DAS-81910-7 cotton with other deregulated herbicide-resistant (HR) cotton varieties, such as those varieties expressing glyphosate and insect resistance (DAS, 2013b). Dow plans to market DAS-81910-7 cotton including a glyphosate resistance trait under the name Enlist™ cotton.

Coordinated Framework Review

Food and Drug Administration

DAS-81910-7 cotton falls within the scope of the 1992 FDA’s policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992). In compliance with this policy, on June 26, 2013, Dow submitted a safety and nutritional assessment summary document to the FDA to initiate a consultation on the food and feed safety and compositional assessment of DAS-81910-7 cotton which expresses the same AAD-12 protein as DAS-68416-4 and DAS-44406-6 soybean. Dow

received a completed consultation letter from the FDA on November 14, 2014. FDA concluded: “food and feed derived from DAS-81910-7 cotton are not materially different in composition, safety, and other relevant parameters from cottonseed-derived food and feed currently on the market, and that genetically engineered DAS-81910-7 cotton does not raise issues that would require premarket review or approval by FDA.”

Environmental Protection Agency

EPA has authority under FIFRA to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. The EPA Reregistration decision for 2,4-D was issued in 2005 (US-EPA, 2005). EPA concluded that 2,4-D and its metabolites were moderately nontoxic to practically nontoxic in ecological assessments. EPA concludes that the measures to control spray drift are expected to reduce the risk of 2,4-D to non-target plants. The EPA registration decision for glufosinate was issued in 2000 for crop use (US-EPA, 2008). The EPA is currently evaluating the proposed new uses of 2,4-D choline salt for use on cotton with DAS-81910-7 and has completed this evaluation for the 2,4-D choline salt for use on corn and soybean (US-EPA, 2013).

Scope of the Environmental Analysis

Although a determination of nonregulated status of DAS-81910-7 cotton would allow for new plantings of DAS-81910-7 cotton to occur anywhere in the U.S., APHIS limited the environmental analysis to those geographic areas that currently support cotton production. A determination of nonregulated status of DAS-81910-7 cotton is not expected to increase cotton production, or result in an increase in overall GE cotton acreage or cultivation in new regions. In the U.S., cotton is cultivated principally in 17 states, with over 9.7 million acres planted to cotton production in 2014, projected to slightly increase to nearly 10.4 million acres by 2023 (USDA-NASS, 2015; USDA-OCE, 2015). Table 1 in the EA presents an overview of the 2012 to 2014 acreage of cotton planted by state.

Relationship to Other Environmental Documents

USDA-APHIS prepared a Final EIS (FEIS) for the nonregulated status of 2,4-D- and ACCase inhibitor-resistant DAS-40278-9 corn; 2,4-D- and glufosinate-resistant DAS-68416-4 soybean; and 2,4-D-, glufosinate- and glyphosate-resistant DAS-44406-6 soybean (USDA-APHIS, 2014a). APHIS published a notice (79 FR 56555-56557) advising the public of the determinations of nonregulated status and availability of the Record of Decision (ROD) on September 22, 2014. The EA is tiered to that FEIS. Pertinent and current information available in the FEIS has been incorporated by reference into the EA and this decision document.

USDA-APHIS prepared a Final EIS (FEIS) for the nonregulated status of dicamba resistant MON-87708 soybean; and dicamba resistant MON 87701-3 cotton (USDA-APHIS-2014d). APHIS published a notice (79 FR 73890) advising the public of the determinations of nonregulated status and availability of the Record of Decision (ROD) on December 12, 2014. The EA is tiered to that FEIS. Pertinent and current information available in the FEIS has been incorporated by reference into the EA and this decision document.

Public Involvement

On March 18, 2014, APHIS published a notice in the Federal Register (79 FR 15096-15097, Docket no. APHIS-2011-0046) announcing the availability of the Dow AgroSciences petition for a 60-day public review and comment period. Comments were required to be received on or before May 19, 2014. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 193 comment responses were received from various groups and individuals during the comment period, with 7 comments providing support of the EA's preferred alternative including State Extension agents and representatives of large cotton growers associations as well as 186 comments in opposition, with one containing about 32,000 comments assembled by Organic Consumers Association. An announcement of the availability of an EA, PPRA and Preliminary FONSI was made May 28, 2015 (80 FR 30432-30433) and comments accepted until June 29, 2015. A total of 24 individual comments were received, of which one contained a submission of 33,071 mostly identical comments that were opposed to a decision of nonregulated status. Of the 24 unique comments, 10 were opposed to nonregulated status, and 14 were in favor. Comment documents may be viewed at <http://www.regulations.gov> for APHIS-2013-0113-0196. No new adverse issues, alternatives or substantive information new to USDA were identified in any of the EA comments received by APHIS.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status of DAS-81910-7 cotton. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. Issues raised in these public comments on the petition and the EA were focused on the nature of agronomic inputs associated with this new trait, potential impacts to plants from off-target drift, management of HR weeds, putative cumulative impacts from "herbicide loading" of multiple herbicides, and human health considerations from exposure to herbicides. Issues related to the use of herbicides, such as impacts on natural and physical resources are outside the scope of this EA. Also raised were concerns for the development of new herbicide resistant weeds and for possible economic impacts on domestic and international trade associated with the development and marketing of a new HR product. Issues raised in favor of the petition for nonregulated status were received from cotton agronomists and weed scientists, cotton growers, associations of cotton growers, professional cotton industry organizations, and Farm Bureau. These included identifying the needs for new options that would become available to control existing resistant and problem weeds, approval of a new system to help avoid additional herbicide resistant weeds, as well as a potential reduction in total herbicide use, the facilitation of reduced tillage and avoidance of resultant erosion, an extending of the effective life of other herbicide modes of action, and finally, support for existing economic benefits to growers pursuing sustainable and integrated weed control.

The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

Agricultural Production of Cotton

- Land Use for Cotton Production
- Acreage and Areas of Cotton Production
- Agronomic Cropping Practices
- Organic Cotton Production

Environmental Considerations

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Soil Microorganisms
- Weed Resistance and Management
- Biological Diversity

Human Health

- Public Health
- Worker Safety

Livestock Health

- Animal Feed/Livestock Health

Socioeconomic

- Domestic Economics
- Trade Economics

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of DAS-81910-7 cotton. To respond favorably to a petition for nonregulated status, APHIS must determine that DAS-81910-7 cotton is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2014c), APHIS has concluded that DAS-81910-7 cotton is unlikely to pose a plant pest risk. Therefore, APHIS must determine that DAS-81910-7 cotton is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of DAS-81910-7 cotton. APHIS has assessed the potential for environmental impacts for each alternative in the “Environmental Consequences” section of the EA.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. DAS-81910-7 cotton and progeny derived from DAS-81910-7 cotton would continue to be regulated articles pursuant to regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of DAS-81910-7 cotton and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of DAS-81910-7 cotton.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS, 2014c) that DAS-81910-7 cotton is unlikely to pose a plant pest risk. Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

Preferred Alternative: Determination that DAS-81910-7 Cotton is No Longer a Regulated Article

Under this alternative, DAS-81910-7 cotton and progeny derived from them would no longer be regulated articles pursuant to regulations at 7 CFR Part 340. DAS-81910-7 cotton is unlikely to pose a plant pest risk (USDA-APHIS, 2014c). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DAS-81910-7 cotton and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that DAS-81910-7 cotton is unlikely to pose a plant pest risk, a determination of nonregulated status of DAS-81910-7 cotton is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340 and the biotechnology regulatory policies in the Coordinated Framework. Under this alternative, growers may have future access to DAS-81910-7 cotton and progeny derived from this event if the developer decides to commercialize DAS-81910-7 cotton.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for DAS-81910-7 cotton. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and pursuant to regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for DAS-81910-7 cotton. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any DAS-81910-7 cotton from being released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release DAS-81910-7 cotton, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that DAS-81910-7 cotton is unlikely to pose a plant pest risk (USDA-APHIS, 2014c).

In enacting the Plant Protection Act, 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 our Plant Pest Risk Assessment (USDA-APHIS, 2014c) and the scientific data evaluated therein, APHIS has concluded that DAS-81910-7 cotton is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of DAS-81910-7 cotton.

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 events described in a petition. Because APHIS has concluded that DAS-81910-7 cotton is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

Isolation distance between DAS-81910-7 cotton and non-GE cotton and geographical restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating DAS-81910-7 cotton from non-GE cotton production. However, because APHIS has concluded that DAS-81910-7 cotton is unlikely to pose a plant pest risk (USDA-APHIS, 2014c), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and the regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of DAS-81910-7 cotton based on the location of production of non-GE cotton in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for DAS-81910-7 cotton, there are no geographic differences associated with any identifiable plant pest risks for DAS-81910-7 cotton (USDA-APHIS, 2014c). This alternative was rejected and not analyzed in detail because APHIS has concluded that DAS-81910-7 cotton does not pose a plant pest risk, and will not exhibit a

greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act, and the regulations codified in 7 CFR Part 340.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR Part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Nevertheless, APHIS is not expecting significant impacts. However, individuals might choose on their own to geographically isolate their non-GE cotton productions systems from DAS-81910-7 cotton or to use isolation distances and other management practices to minimize gene movement between cotton fields.

Requirement of Testing for DAS-81910-7 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. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because DAS-81910-7 cotton does not pose a plant pest risk (DAS, 2013; USDA-APHIS, 2014c), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR Part 340. Therefore, imposing such a requirement for DAS-81910-7 cotton would not meet APHIS' purpose and need to respond appropriately to the petition.

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	Alternative 1: No Action (Deny the Petition)	Alternative 2: Preferred Alternative-Determination of Nonregulated Status for DAS- 81910-7 Cotton
Meets Purpose and Need	No	Yes
Land Use	Acreage of cotton plantings are anticipated to increase modestly after 2015 through 2024 (USDA-OCE, 2015). Cotton plantings are anticipated to fluctuate as market prices change. Locations of cotton production are not expected to change.	Acreage of plantings generally the same as No Action Alternative The nonregulated cotton variety might replace other cotton varieties currently grown in the United States. Locations of production unchanged.
Agronomic Practices	Weeds resistant to glyphosate and other herbicides will continue to increase. As HR weeds become	Use of 2,4-D and glufosinate in cotton cropping systems is expected to increase, but 2,4-D use

Attribute/Measure	Alternative 1: No Action (Deny the Petition)	Alternative 2: Preferred Alternative-Determination of Nonregulated Status for DAS- 81910-7 Cotton
	more prevalent, growers are expected to shift to more costly alternative weed control measures or other HR crops that are economically viable. Conventional growers are likely to use additional herbicides or abandon conservation tillage practices and return to more aggressive conventional tillage systems to maintain yields.	is contingent on EPA's decision to approve the new uses of 2,4-D on DAS-81910-7 cotton. More efficient weed control is expected to reduce the need for more aggressive tillage. Conventional growers are likely to continue the use of herbicides and retain or increase conservation tillage practices if resistant weeds do not develop over time.
Organic Production Systems	Planting of organic cotton is not likely to change.	Planting of organic cotton is not likely to change.
Use of GE Crops: Herbicide and Resistant Weeds	Planting of GE HR crops is likely to remain at current levels with adoption of GE crops high.	Planting of GE HR crops is likely to remain at current levels with adoption of GE crops high.
Human Health and Safety	Cotton varieties are associated with all the normal risks of agricultural production. The EPA label use restrictions are designed to protect humans during herbicide use in cotton cropping systems to achieve a standard of a "reasonable certainty of no harm".	This variety does not present any additional risks to workers. The revised EPA label use restrictions for Enlist cotton are designed to achieve the same level of human health and safety as those that currently exists for non-GE varieties.
Biological Diversity	Cropping systems generally are not expected to change, so biodiversity in regions where cotton are produced will not change. Herbicide use may decrease weed prevalence or modify the weed species complex in some regions. These changes could modify the species complex of organisms that rely on these weeds as a food source or habitat.	Crop biodiversity is not expected to substantially change relative to the No Action Alternative. Use of DAS-81910-7 cotton varieties will allow for stable levels of conservation tillage, which will not decrease biodiversity and might increase it. Use of DAS-81910-7 cotton will likely allow decreased use of some non-glyphosate herbicide uses as 2,4-D substitutes for these, which will not reduce biodiversity and might increase it. Selection pressure for 2,4-D and

Attribute/Measure	Alternative 1: No Action (Deny the Petition)	Alternative 2: Preferred Alternative-Determination of Nonregulated Status for DAS- 81910-7 Cotton
		glufosinate resistance in weed populations may modify the weed species complex in some regions, which might modify the species complex of organisms that rely on these weeds as a food source or habitat.
Animal Communities	Cultivated cotton currently provides limited food and habitat for wildlife in regular cropping situations.	Expected to be the same as No Action Alternative because toxicological studies and studies of allergenicity of the added traits did not reveal any impacts on animals.
Plant Communities / Weed Complexes	Currently cultivated cotton varieties are not potential plant pests because they do not compete with native plant species, so do not adversely impact natural plant communities. Selection pressure for HR weed development will continue.	DAS-81910-7 cotton is not a potential plant pest because it does not compete with native plant species and lack the potential to do so, so will not adversely impact natural plant communities. If growers fail to adopt best management practices and diversify weed control methods, selection pressure to develop 2,4-D and glufosinate resistance in weed populations will increase, including the potential for development of weeds with multiple resistance to more than one herbicide mode of action.
Soil Quality	Increased tillage to manage HR weeds may occur in cotton cropping systems and cause decreased soil quality from increased soil erosion.	New options to avoid tillage would be accompanied by decreased soil erosion. This cotton variety is not expected to change the existing composition of soil microflora in cropping systems.
Water Quality	Increased tillage to manage HR weeds may occur in cotton cropping systems. This could increase evaporative water loss and demand on water resources for irrigation, and cause increased soil	This cotton variety will support continued use of current conservation tillage practices in the short term. In the long term, unless growers follow practices of best

Attribute/Measure	Alternative 1: No Action (Deny the Petition)	Alternative 2: Preferred Alternative-Determination of Nonregulated Status for DAS- 81910-7 Cotton
	erosion accompanied by diminished water quality from sedimentation.	management for weeds, development of HR weeds may be accompanied by increased tillage with negative impacts (as described in the No Action Alternative).
Air Quality	Increased tillage to manage HR weeds may occur in cotton cropping systems. This could reduce air quality from increased air particulates and exhaust from farm equipment. Increased use of herbicides may occur to manage HR weeds. This would increase drift from herbicides that would reduce air quality.	Use of this cotton variety is expected to stabilize current tillage trends. This will be accompanied by a reduction in airborne particulates from current tillage practices as well as exhaust emissions, which will increase air quality. Overall use of herbicides will remain the same or be reduced by better management of HR weeds. Drift incidents from herbicide use will remain the same but damage from drift may be reduced with the substitution of the Enlist formulation for 2,4-D.
Climate Change	Increased tillage to manage HR weeds may occur in cotton cropping systems. This would Increase the release of GHGs (primarily CO ₂ and methane).	Use of this cotton variety is expected to stabilize current conservation tillage. This will be accompanied by a reduction in the release of GHGs (primarily CO ₂ and methane).
Socioeconomic Resources	The U.S. will continue to be an exporter of cotton. The percentage of GE varieties in the market is not expected to change.	DAS has submitted or is planning to submit requests for regulatory approvals in the main export markets for the proposed variety of cotton. These traits and this variety are not substantially different from those already in commerce. Their presence in exported commodities is not likely to affect trade differently than that of other currently approved GE traits in commerce.

Attribute/Measure	Alternative 1: No Action (Deny the Petition)	Alternative 2: Preferred Alternative-Determination of Nonregulated Status for DAS- 81910-7 Cotton
		The percentage of GE varieties in the market is not expected to change. The percentage of GE varieties in the market is not expected to change.
Other U.S. Regulatory Approvals: FDA Consultations and EPA Registrations	Consultations with the FDA and changes to the EPA registrations would be unnecessary.	Dow completed consultations with the FDA for DAS-81910-7 cotton on November 14, 2014 (BNF No. 00142). The EPA reregistration decision for 2,4-D was issued in 2005 (US-EPA, 2005). EPA concluded that 2,4-D and its metabolites were moderately nontoxic to practically nontoxic in ecological assessments. EPA concludes that the measures to control spray drift are expected to reduce the risk of 2,4-D to non-target plants. The EPA registration decision for glufosinate was issued in 2000 for crop use (US-EPA, 2008). The EPA is currently evaluating the proposed new uses of 2,4-D choline salt for DAS-81910-7 cotton.
Applicable U.S. Laws	Compliant	Compliant

Finding of No Significant Impact

APHIS has analyzed the potential impacts from the use of 2,4-D and agricultural practices associated with cotton production in the 2,4-D herbicide resistant corn and soybean FEIS (USDA-APHIS, 2014a) and dicamba herbicide resistant cotton and soybean FEIS (USDA-APHIS, 2014b) to which the EA is tiered. Specifically, the potential for 2,4-D resistant crops to facilitate the development of 2,4-D resistant weeds, potential new use of 2,4-D to cause unintended herbicide damage to adjacent 2,4-D sensitive crops, and the potential for 2,4-D resistance-developing weeds to interfere with existing weed control in cotton rotation crops using 2,4-D for weed control has been fully analyzed in these two EISs and summarized in the EA. This Finding of No Significant Impact focuses on the analysis of potential impacts associated

with DAS-81910-7 cotton that were not analyzed in the 2,4-D herbicide resistant corn and soybean FEIS and dicamba herbicide resistant cotton and soybean FEIS. Pertinent information from the two EISs has been incorporated by reference into this Finding of No Significant Impact.

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

Context – The term “context” recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic cotton production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets. According to USDA-NASS data, cotton was planted on approximately 11 million acres in the United States in 2014 (USDA-NASS, 2015). GE-derived varieties of cotton, containing either herbicide resistance, insect resistance, or both traits, comprised 96 percent of all cotton acreage in 2014 (USDA-ERS, 2014a). Cotton is planted in 17 states across the southern United States, identified as the Cotton Belt. These states include Alabama, Arizona, Arkansas, California, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia (USDA-NASS, 2015). Figure 1 in the EA shows U.S. Upland cotton (short staple cotton) planted acres in 2013, while Figure 2 in the EA shows the planted Pima cotton (extra-long staple) acres in the United States in 2013 (USDA-NASS, 2013a; USDA-NASS, 2013b).

Plantings of GE HR cotton expanded from about 10 percent of U.S. acreage in 1997 to 91 percent in 2014 (USDA-ERS, 2014b). Plantings of cotton with insect-resistant *Bacillus thuringiensis* (Bt) traits also expanded rapidly, from 15 percent of U.S. cotton acreage in 1997 to 84 percent in 2014 (USDA-ERS, 2014b). Adoption of cotton varieties stacked with both traits has accelerated in recent years. Adoption of GE cotton stacked with both HR and Bt traits reached 79 percent of cotton acreage in 2014 (USDA-ERS, 2014a). A determination of nonregulated status of DAS-81910-7 cotton is not expected to directly cause an increase in agricultural acreage devoted to cotton production or those cotton acres devoted to GE cotton cultivation. The availability of DAS-81910-7 cotton is not expected to change cultivation areas for cotton production in the U.S., because it is not substantially different from existing cotton, and will not likely cause changes in the economic costs of that production. Consequently there are no anticipated changes to the availability of GE and non-GE cotton varieties on the market.

Although a determination of nonregulated status of DAS-81910-7 cotton would allow for new plantings of DAS-81910-7 cotton to occur anywhere in the U.S., APHIS limited the environmental analysis to those geographic areas that currently support cotton production. A determination of nonregulated status of DAS-81910-7 cotton is not expected to increase cotton production, or result in an increase in overall GE cotton acreage or cultivation in new regions.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

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

A determination of nonregulated status of DAS-81910-7 cotton will have no significant environmental impact in relation to the availability of GE, conventional or organic cotton varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of DAS-81910-7 cotton is not expected to directly cause an increase in agricultural acreage devoted to cotton production or those cotton acres devoted to GE cotton cultivation. The availability of DAS-81910-7 cotton is not expected to change regional cultivation patterns for cotton production in the U.S. There are no anticipated changes to the availability of GE and non-GE cotton varieties now on the market.

Based upon recent trend information, adding GE cotton varieties to the market appears unrelated to the ability of organic production systems to maintain their market share. In 2014, 96 percent of the cotton grown in the United States was genetically engineered (USDA-ERS, 2014a), an increase of 61% from the percentage grown in 2000. The first HR GE cotton was introduced in 1996 (glyphosate-resistant) and after 2003 a second (glufosinate-resistant) introduced. Organic cotton has been produced in the United States since 1991 (Funtanilla et al., 2009) and increased 3-fold from 1991 to the most recent eight years. Since 1996, organic cotton production has averaged 10,880 acres yearly, rising to 16,635 acres in 2014 (Table 8). A determination of nonregulated status of DAS-81910-7 cotton will add another GE variety to the existing cotton market and is not expected to change the market demands for GE cotton produced using organic methods. In addition to absence of impacts from new GE variety on organic cotton production, general cotton market factors may similarly affect production of both types of cotton. Between 2009 and 2014, planted organic cotton acreage varied between 10,521 acres and 16,635 acres (EA, Table 8), and total U.S. acreage dedicated to cotton fluctuated between 9.1 million and 11 million acres (USDA-NASS, 2015), both showing an increasing trend in cotton production acreage. In 2011, both planted organic cotton with 16,050 acres and U.S. total planted cotton acres at 14.7 million acres registered a coordinate increase (36% for organic and 12% for total cotton) from 2010; in the next year both organic and total cotton production steeply declined. The acreage devoted to organic cotton is expected to remain small regardless of whether new varieties of GE or non-GE cotton varieties, including DAS-81910-7 cotton, become available for commercial cotton production. DAS-81910-7 cotton should not present any new or different issues and impacts for organic cotton producers and consumers. Based on demonstrated agronomic characteristics and cultivation practices, the market share of organic cotton varieties is unlikely to change by the introduction of DAS-81910-7 cotton. APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact organic cotton producers and consumers.

DAS-81910-7 cotton is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterparts (DAS, 2013; USDA-APHIS, 2014c). No differences were observed in pollen diameter, weight, and viability (DAS, 2013; USDA-APHIS, 2014c). Consistent with the lack of difference in agronomic properties, DAS-81910-7 cotton is not expected to have an increased ability to cross pollinate other cotton varieties. Changes in the agronomic practices and locations for cotton seed production using DAS-81910-7 cotton are not expected. A determination of nonregulated status of DAS-81910-7 cotton is not expected to result in changes in the current cotton cropping practices. Other agronomic changes may include use of different herbicides, and a

possible reversal of increasing tillage to control weeds, although in general, production practices are not likely to change. The anticipated registration changes for DAS-81910-7 cotton would facilitate a wider window of application for 2,4-D in cotton, which is expected to provide a tool for improved control of broadleaf weeds (including some with resistance to other herbicides such as glyphosate and ALS). The Dow cotton trait and the herbicides 2,4-D and glufosinate (as well as glyphosate) can be integrated within weed management programs conducted under no-till, reduced tillage or conventional tillage. Because an additional herbicide is now available with a different mode of action which has not been previously available, growers will be able to rotate use of existing herbicides that may have been overexposing weeds to these other modes of action (USDA-APHIS, 2014a; USDA-APHIS, 2014b). Thus, DAS-81910-7 cotton may be relieving selection pressure on weeds from these herbicides. In addition, new modes of action can be additively applied using existing options to prevent weed resistance from developing (see EA and USDA-APHIS (2014a)). A determination of nonregulated status of DAS-81910-7 cotton is expected to facilitate post-emergent control of problem weeds with 2,4-D, which has not previously been possible in cotton. Such cotton applications would be made at crop developmental stages that could expose other potentially adjacent crops to 2,4-D application drift which have not previously received such exposure. However, the combination of a new less volatile formulation of 2,4-D, EPA mandated spraying using large droplet size and rigorous environmental conditions required before spraying will limit the potential for impacts of herbicide drift and volatilization. APHIS has concluded that most growers are cognizant of the consequences of not strictly following 2,4-D application protocols (see EA and USDA-APHIS (2014a)).

Because of the improved efficacy of 2,4-D in control of glyphosate resistant weeds, several other herbicides will be less frequently used, and mechanical tillage also may decline. Planting DAS-81910-7 is not expected to affect the use of glyphosate as a post-emergent weed herbicide because the 2,4-D herbicide required by grower agreements is Enlist, which contains both glyphosate and 2,4-D (USDA-APHIS, 2014a); the Dow variety will likely replace glyphosate-only varieties, and glyphosate use will likely not change when Enlist herbicide is used instead. The rate of application of glyphosate in the Enlist mixture is only about half of a typical POST application, but the average number of Enlist applications cannot be easily predicted. DAS-81910-7 cotton will also likely be a replacement for glufosinate-resistant-only varieties. It is unclear whether 2,4-D/Enlist will be more commonly applied to cotton than glufosinate for control of problem weeds. The mechanism for glufosinate resistance of DAS-81910-7 is the same as that expressed by other cotton varieties, so the application rates for glufosinate are not expected to change (DAS, 2013). It is anticipated that herbicide use will continue the trends associated with the wide adoption of herbicide resistant crops which include the potential emergence of herbicide-resistant weeds, the potential for increased herbicide use and a possible eventual increase in costs for weed management (Beckie and Hall, 2014; USDA-APHIS, 2014a). As discussed in Chapter 4 of the EA, studies demonstrate DAS-81910-7 cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (USDA-APHIS, 2014c). Dow did not identify any differences between DAS-81910-7 cotton and conventional in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity (DAS,

2013; USDA-APHIS, 2014c). The absence of variety differences will make unlikely any new impacts deriving from management practices in cotton production.

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

A determination of nonregulated status of DAS-81910-7 cotton would have no significant impacts on human or animal health. Dow AgroScience's intention in developing DAS-81910-7 cotton is enabling the use of additional herbicides to control glyphosate-resistant and other problem weeds. Because the herbicides used in Enlist for soybean and corn have been approved by EPA for use with these other herbicide resistant crops (US-EPA, 2014) and FDA has no questions about food safety of DAS-81910-7 cotton (US-FDA, 2014b), no human health impacts are anticipated for use of Enlist resistant cotton. The FDA has completed its consultation on DAS-81910-7 cotton and has concluded that the product is not materially different in any respect relevant to food safety compared to cotton varieties currently on the market (US-FDA, 2014c). The FDA's conclusions are based on an evaluation of two introduced proteins, AAD-12 that degrades 2,4-D into 2,4-dichlorophenol (DCP) that is inactive as an herbicide and PAT that inactivates the herbicide glufosinate. Neither the AAD-12 nor PAT proteins have relevant amino acid sequences similar to known allergens, toxins or other proteins that may have adverse effects on mammals. Furthermore, the AAD-12 and PAT proteins in DAS-81910-7 cotton are rapidly digested in simulated gastric and intestinal fluids, and these studies did not show any observable adverse effects in mouse acute oral toxicity analyses. According to Dow AgroSciences, the low level or negligible content of these proteins presents a low exposure risk to humans and animals (DAS, 2013). Consultation with the FDA for DAS-81910-7 cotton (US-FDA, 2014a) has been completed on October 31, 2014, and the FDA has no further questions about food and feed derived from this cotton variety. Additionally, the PAT protein, expressed in DAS-81910-7 cotton has already been reviewed by the FDA and has been available in numerous commercially produced crops including cotton. An FDA biotechnology consultation on cotton lines containing the PAT protein (BNF No. 000086) (US-FDA, 1998) was completed on April 2, 2003 (US-FDA, 1998) and does not require reevaluation. Additionally, EPA previously concluded, after reviewing data on the acute toxicity and digestibility of the PAT protein, that there is a reasonable certainty that no harm will result from aggregate exposure of the U.S. population, including infants and children, to the PAT protein and the genetic material necessary for its introduction (US-EPA, 1997). Accordingly, DAS-81910-7 cotton is anticipated to be safe for human and animal consumption with reference to the *aad-12* and *pat* genes. Based on the FDA's consultation (US-FDA, 2011), our analysis of field and laboratory data and scientific literature provided by Dow (DAS, 2013) and safety data available on other GE cotton varieties, APHIS has concluded that a determination of nonregulated status of DAS-81910-7 cotton would have no significant impacts on human or animal health.

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

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of DAS-81910-7 cotton.

The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property; do not cause any new alterations of property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of DAS-81910-7 cotton. The product will be deployed on agricultural land currently suitable for production of cotton and is not expected to increase the acreage of cotton production. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to DAS-81910-7 cotton, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of DAS-81910-7 cotton, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to cotton production sites.

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

From public comments, APHIS understands there is some opposition to a determination of nonregulated status of DAS-81910-7 cotton because of additional use of 2,4-D in agriculture and the likely high percentage of growers who may choose this new trait. The new use may be accompanied by possible development of 2,4-D resistant weeds (USDA-APHIS, 2014a). Possible impacts on the natural or physical environment are also mentioned by those who are opposed to nonregulated status for DAS-81910-7 cotton (Section 1.5 of EA). The environmental impacts of new use of 2,4-D is assessed by EPA, and if the impacts are unreasonable, EPA will not approve use with DAS-81910-7. As discussed in Chapter 4 of the EA, a determination of nonregulated status of DAS-81910-7 cotton is not expected to directly cause an increase in agricultural acreage devoted to cotton production or those cotton acres devoted to GE cotton cultivation. The availability of DAS-81910-7 cotton is not expected to change cultivation areas for cotton production in the U.S., and there are no anticipated changes to the availability of GE and non-GE cotton varieties on the market. DAS-81910-7 cotton is not expected to result in changes in the current cotton cropping practices, although the types of herbicides used will change, as well as the frequency of use of some may decline. DAS-81910-7 cotton would be both a new herbicide resistant cotton and an additional glufosinate-resistant variety. Importantly, Dow states that they will develop and market DAS-81910-7 cotton with glyphosate resistance (DAS, 2013) consistent with their plan to enable use of Enlist as an herbicide, which is a mixture of 2,4-D and glyphosate. This resistance will be accomplished by traditional breeding. DAS-81910-7 cotton is not expected to affect the use of glyphosate as a post-emergent weed herbicide, since it will still be a component of Enlist when used on the crop, and DAS-81910-7 cotton will likely replace existing glyphosate resistant varieties. The mechanism for glufosinate resistance is the same as that expressed by other varieties, so the application rates for glufosinate are not expected to change (DAS, 2013). It is anticipated that herbicide use will continue the trends noted by Beckie and Hall (2014) associated with the wide adoption of glyphosate-

resistant crops and the emergence of glyphosate-resistant weeds (USDA-APHIS, 2014a). The impact of DAS-81910-7 cotton on wildlife or biodiversity is no different than that of other GE or non-GE cotton produced in conventional agriculture in the U.S. Cultivation of DAS-81910-7 cotton is highly unlikely to have direct toxic effects on non-target organisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE cotton. During the public comment period, APHIS received comments opposing a determination of nonregulated status of DAS-81910-7 cotton. No new issues, alternatives or new substantive information were identified in any of the comments received by APHIS following publication of the petition. APHIS has addressed substantive comments in the EA accompanying this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

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

Based on the analysis documented in the EA, the possible impacts on the human environment are well understood. The impacts of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of DAS-81910-7 cotton is not expected to directly cause an increase in agricultural acreage devoted to all cotton production or those cotton acres devoted to GE cotton cultivation. A determination of nonregulated status of DAS-81910-7 cotton is not expected to result in changes in the current cotton cropping practices, including pesticide use. As discussed in Chapter 4 of the EA, studies demonstrate DAS-81910-7 cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (DAS, 2013). Dow did not identify any differences between DAS-81910-7 cotton and conventional in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity (DAS, 2013). A determination of nonregulated status of DAS-81910-7 cotton is not expected to affect the use of glufosinate as a post-emergent weed herbicide, because growers will likely plant DAS-81910-7 cotton as a replacement for other cotton with glufosinate-resistant traits. Growers already appreciate the efficacy of glufosinate where glyphosate resistant weeds are an important agronomic problem (USDA-APHIS, 2014a). The mechanism for glufosinate resistance is the same as that expressed by other varieties, so the application rates for glufosinate are not expected to change (DAS, 2013). Dow states that they will develop and market DAS-81910-7 cotton with glyphosate resistance (DAS, 2013) using conventional crossing techniques because they plan to enable use of Enlist (glyphosate + 2,4-D) herbicide on this crop. Concurrently Dow has requested an EPA permit for this new usage. Glyphosate resistance will be incorporated by traditional breeding methods. A determination of nonregulated status of DAS-81910-7 cotton is not expected to affect the use of glyphosate either as a post-emergent weed herbicide because Enlist herbicide (containing glyphosate) will be used on DAS-81910-7 cotton and the new cotton variety would replace other cotton varieties with glyphosate-resistant traits. (DAS, 2013) It is anticipated that herbicide use will continue the trends noted by Benbrook associated with the wide adoption of glyphosate-resistant cotton and the emergence of glyphosate-resistant weeds (Benbrook, 2009; USDA-APHIS, 2014a). The effect of DAS-81910-7 cotton on wildlife or biodiversity is no different than that of other

GE or non-GE cotton produced in conventional agriculture in the U.S. Cultivation of DAS-81910-7 cotton is highly unlikely to have direct toxic effects on non-target organisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE cotton. As described in Chapter 4 of the EA, well established management practices, production controls, and production practices (GE, conventional and organic) are currently being used in cotton production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional cotton (GE and non-GE varieties), DAS-81910-7 cotton, or produce cotton using organic methods, will continue to use these reasonable and commonly accepted best management practices for their chosen systems and varieties during agricultural cotton production. DAS-81910-7 cotton will add another GE variety to the existing cotton market and is not expected to change the market demands for GE cotton or cotton produced using organic methods. Cultivation of DAS-81910-7 cotton as a new GE cotton variety should not present any new or different issues and impacts for organic cotton producers and consumers. Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of organic cotton varieties is unlikely to change by the introduction of DAS-81910-7 cotton, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact organic cotton producers and consumers. Additionally, most of the cotton acreage in the U.S. is planted to GE cotton. DAS-81910-7 cotton would be an additional herbicide resistant variety. Currently 96 percent of the cotton grown in the United States is genetically engineered, an increase of 61% since 2000 (USDA-ERS, 2014a). Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of DAS-81910-7 cotton. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE cotton products and organic cotton varieties, and the experience with 2,4-D resistant soybean and corn varieties by the developer (DAS, 2013), the possible impacts to the human environment from the release of an additional GE cotton product are already known and understood. Therefore the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
A determination of nonregulated status of DAS-81910-7 cotton would not establish a precedent for future actions with significant impacts or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based upon an independent determination of whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR Part 340. Each petition that APHIS receives is for a specific GE organism and undergoes an independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the Plant Protection Act and pursuant to 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as DAS-81910-7 cotton. When a petition for nonregulated status is submitted, APHIS must make a determination whether the GE

organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR Part 340. APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated pursuant to Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or pursuant to regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may 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 Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

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

No significant cumulative impacts were identified through this assessment. The EA discussed cumulative impacts on cotton management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative impacts analysis is included for each environmental issue analyzed in Chapter 4 of the EA. In the event of a determination of nonregulated status, DAS-81910-7 cotton may be stacked (combined) with non-GE and GE cotton traits by traditional breeding techniques, resulting in a plant that, for example, may also be resistant to other herbicides, but may also have progeny with no transgenes at all. There is no assurance that DAS-81910-7 cotton will be stacked with any particular non-GE or GE cotton traits that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, as company plans and market demands play a significant role in those business decisions. However, glyphosate resistance will be incorporated by traditional breeding because Dow has requested EPA to grant a permit for use of Enlist herbicide (glyphosate + 2,4-D) with DAS-81910-7 cotton. Extensively foreseeing all potential combinations of stacked varieties that could be created using both non-GE and GE cotton varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR Part 340 is hypothetical and purely speculative. In the event of a determination of nonregulated status of DAS-81910-7 cotton APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of DAS-81910-7 cotton when added to other past, present, and reasonably foreseeable future actions.

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.* A determination of nonregulated status of DAS-81910-7 cotton is not expected to adversely affect cultural resources on tribal properties. Any farming activities that may be undertaken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of DAS-81910-7 cotton would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of DAS-81910-7 cotton. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to DAS-81910-7 cotton, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential significant impacts to the human environment. A determination of nonregulated status of DAS-81910-7 cotton is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in impacts on the character or use of historic properties. For example, there is potential for audible impacts on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary impacts on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the cotton production regions. The cultivation of DAS-81910-7 cotton does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.
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.* As described in Chapters 4 and 7 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of DAS-81910-7 cotton on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible impacts of a determination of nonregulated status of DAS-81910-7 cotton, APHIS has concluded that a determination of nonregulated status of DAS-81910-7 cotton would have no effect on federally listed threatened or endangered species and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

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

The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that DAS-81910-7 cotton is unlikely to pose a plant pest risk, a determination of nonregulated status of DAS-81910-7 cotton is a response that is consistent with the plant pest provisions of the PPA and the regulations codified in 7 CFR Part 340. DAS-81910-7 cotton falls within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992). In compliance with this policy, Dow AgroSciences initiated a consultation with the FDA on the food and feed safety and nutritional assessment summary for DAS-81910-7 cotton. FDA agreed with Dow's safety assessment, and concluded that "DAS-81910-7, and food and feed derived from it are as safe as conventional cotton varieties and are not materially different in composition or any other relevant parameter from other cotton varieties now grown, marketed, and consumed in the United States." A copy of the completed FDA review can be found at FDA's website³. EPA has authority under FIFRA to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. DAS submitted a registration request for a 2,4-D formulation with glyphosate (Enlist Duo) for use with DAS-81910-7 cotton and a tolerance petition to EPA on July 30, 2014. The AAD-12 protein expressed in DAS-81910-7 cotton is identical to the AAD-12 trait in other Enlist® crops including Enlist® soybean (DAS-68416-4 and DAS-44406-6) and functionally similar to Enlist® corn (DAS-40278-9) with the AAD-1 trait (USDA-APHIS, 2014a) and FDA review concluded that they had no further questions about the safety of these proteins that express the trait for 2,4-D resistance (US-FDA, 2014b). The new protein expressed in DAS-81910-7 cotton is the same as that previously reviewed by the FDA and the safety of the expressed PAT protein has likewise been previously reviewed. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that DAS-81910-7 cotton is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

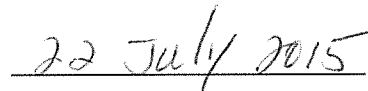
As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations.

³ <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/UCM427610>

As APHIS has not identified any plant pest risks associated with DAS-81910-7 cotton, the continued regulated status of DAS-81910-7 cotton would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR Part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of DAS-81910-7 cotton will not have any significant environmental impacts.



Michael J. Firko, Ph.D.
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture



Date:

Literature Cited:

Beckie, H.J., and L.M. Hall. 2014. Genetically-modified herbicide-resistant (GMHR) crops a two-edged sword? An Americas perspective on development and effect on weed management. *Crop Protection*. 66:40-45.

Benbrook, C. 2009. Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years. Critical Issue Report Number 3. The Organic Center.

DAS. 2013. Petition for Determination of Nonregulated Status for Herbicide Tolerant DAS-81910-7 Cotton. OECD Unique Identifier: DAS-81910-7. Company Full Name. 215. G. Rudgers.

Funtanilla, M., C. Lyford, and C. Wang. 2009. An Evaluation of the Organic Cotton Marketing Opportunity. Agricultural and Applied Economics Association's 2009 AAEA and ACCI Joint Annual Meeting. Milwaukee, WI.
<http://ageconsearch.umn.edu/bitstream/49359/2/2009%20aaea%20paper%2004-30-09.pdf>.

HRAC. 2013. Guideline to the management of herbicide resistance. Herbicide Resistance Action Committee 2013.
<http://www.hracglobal.com/Education/ManagementofHerbicideResistance.aspx>

HRAC. 2014. Glossary. Herbicide Resistance Action Committee
<http://www.hracglobal.com/Education/Glossary.aspx>.

Phosphinothricin acetyltransferase and the genetic material necessary for its production in all plants; Exemption from the requirement of a tolerance on all raw agricultural commodities. US-EPA.

US-EPA. 2005. Reregistration Eligibility Decision for 2,4-D. EPA 738-R-05-002.
http://www.epa.gov/pesticides/reregistration/REDs/24d_red.pdf.

US-EPA. 2008. Glufosinate Summary Document. Registration Review: Initial Docket, March 2008. S.R.a.R. Division. Docket No. EPA-HQ-OPP-2008-0190.
http://www.epa.gov/oppsrrd1/registration_review/glufosinate_ammonium/.

US-EPA. 2013. EFED Environmental Risk Assessment of the Proposed Label for Enlist (2,4-D Choline Salt), Ne Uses on Soybean with DAS 68416-4 (2,4-D Tolerant) and Enlist (2,4-D + Glyphosate Tolerant) Corn and Field Corn.
<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2014-0195-0002>.

US-EPA. 2014 Final Registration of Enlist Duo Herbicide.
http://www2.epa.gov/sites/production/files/2014-10/documents/final_registration_-_enlist_duo.pdf.

US-FDA. 1992. Statement of Policy - Foods Derived from New Plant Varieties.
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm>

US-FDA. 1998. Biotechnology Consultation Agency Response Letter BNF No. 000055. U.S. Food and Drug Administration.
<http://www.fda.gov/Food/Biotechnology/Submissions/ucm161092.htm>

US-FDA. 2011. Biotechnology Consultation - Note to File No. 000121. Department of Health and Human Services, Food and Drug Administration.

US-FDA. 2014a. Biotechnology Consultation Agency Response Letter NPC 000142 - DAS-81910-7 cotton U.S. Food and Drug Administration, CFSAN/Office of Food Additive Safety.
<http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/UCM427612>

US-FDA. 2014b. Biotechnology Consultation Note to the File BFN No. 000142, DAS-81910-7, herbicide-tolerant cotton. C.O.o.F.A. Safety.

<http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm427610.htm>.

US-FDA. 2014c. Biotechnology Consultation Note to the File BNF No. 000142.

<http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/UCM427610>

USDA-APHIS. 2014a. Final EIS. Dow AgroSciences Petitions (09-233-01p, 09-349-01p, 11-234-01p) for Determinations of Nonregulated Status for 2,4-D Resistant Corn and Soybean Varieties

USDA-APHIS. 2014b. Final EIS. Monsanto Petitions (10-188-01p and 12-185-01p) for Determinations of Nonregulated Status for Dicamba-Resistant Soybean and Cotton Varieties

USDA-APHIS. 2014c. Plant Pest Risk Assessment - Dow AgroSciences LLC Petition (13-262-01p) for Determination of Nonregulated Status of Event DAS-8191Ø-7 Cotton. USDA-APHIS. Data Base Online Database.

http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml. April 1, 2014.

USDA-ERS. 2014a. Adoption of Genetically Engineered Crops in the U.S.

<http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>.

USDA-ERS. 2014b. Adoption of Genetically Engineered Crops in the U.S. - Recent Trends in GE Adoption. United States Department of Agriculture Economic Research Service.

<http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx>

USDA-NASS. 2013a. Map: Pima Cotton 2013 Harvested Acres by County for Selected States. U.S. Department of Agriculture, National Agricultural Statistics Service.

USDA-NASS. 2013b. Map: Upland Cotton 2013 Harvested Acres by County for Selected States.

http://www.nass.usda.gov/Charts_and_Maps/graphics/cotnacm.pdf. U.S. Department of Agriculture, National Agricultural Statistics Service.

USDA-NASS. 2015. Crop Production 2014 Summary. N.A.S.S. U.S. Department of Agriculture.

January 2015. http://www.nass.usda.gov/Statistics_by_Subject/result.php?CDC03D5A-502B-344F-9014-F3F3729512C1§or=CROPS&group=FIELD%20CROPS&comm=COTTON.

USDA-OCE. 2015. USDA Agricultural Projections to 2024. I.A.P. Committee. Long-term Projections Report OCE-2015-1.

http://www.usda.gov/oce/commodity/projections/USDA_Agricultural_Projections_to_2024.pdf.

