

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

**Bayer CropScience  
Insect Resistant and Glufosinate Ammonium-Tolerant Cotton  
Transformation Event T303-3**

**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.

Bayer CropScience (BCS) submitted a request to APHIS in February 2012 for an extension of a determination of nonregulated status for a genetically engineered (GE) insect-resistant, glufosinate ammonium tolerant cotton event T303-3 (Event T303-3). 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 the regulations at 7 CFR 340. A person may request that APHIS extend a determination of nonregulated status to other organisms under § 340.6(e)(2) of the regulations. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question. 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 reviewed and analyzed the information submitted in the extension request by BCS (Bayer 2012) and has concluded that Event T303-3 is similar to the antecedent organism, event T304-40 and therefore, based on its Plant Pest Risk Assessment for TwinLink™ cotton (USDA-APHIS 2010) APHIS has concluded that Event T303-3 is unlikely to pose a plant pest risk (*see* Appendix A).

The petition for TwinLink™ Cotton Events GHB119 and T304-40 (08-340-01p) received a determination of non-regulated status from APHIS on October 12, 2011 (76 FR 63278-63279). TwinLink™ Cotton is a combined-trait cotton developed using conventional breeding techniques to link two deoxyribonucleic acid (DNA) transformation events; each developed using DNA recombinant techniques. By crossing BCS' Cry1Ab Cotton (event T304-40) with BCS' Cry2Ae Cotton (event GHB119), BCS has developed a cotton resistant to lepidopteran pests. The TwinLink™ Cotton also expresses a glufosinate ammonium herbicide tolerance trait based on LibertyLink® technology. In accordance with § 340.6(e)(2), BCS requests this determination of nonregulated status of TwinLink™ Cotton from APHIS be extended to Event T303-3 and any progeny derived from crosses of Event T303-3 with conventional cotton, and any progeny derived from crosses of Event T303-3 with other transgenic cotton varieties that have received a

determination of nonregulated status, no longer be considered regulated articles under 7 CFR Part 340. Event T303-3 is currently regulated under 7 CFR part 340. Interstate movements and field trials of Event T303-3 have been conducted under permits issued or notifications acknowledged by APHIS since 2001. Data resulting from these field trials are described in BCS application for extension (Bayer 2012).

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS completed an Environmental Assessment (EA) and NEPA Decision/FONSI that analyzed the potential impacts to the human environment<sup>1</sup> from a determination on the regulated status of a petition request (APHIS Number 08-340-01p) by BCS for their genetically engineered TwinLink™ Cotton Events GHB119 and T304-40 in 2011 (76 FR 63278-63279). The EA assessed alternatives to a determination of nonregulated status of TwinLink™ Cotton and analyzed the potential environmental and social effects that result from the proposed action and the alternatives. APHIS has carefully examined the existing NEPA documentation completed for TwinLink™ Cotton and has concluded that the BCS extension request for a determination of nonregulated status of Event T303-3 encompasses the same scope of environmental analysis as TwinLink™ Cotton. This conclusion is based on:

- Event T303-3 expresses the same Cry1Ab and PAT/bar proteins as event T304-40;
- Event T303-3 expresses the same resistance to lepidopteran pests and glufosinate ammonium herbicide tolerance as TwinLink™ Cotton;
- Event T303-3 does not exhibit any additional traits beyond what is expressed in TwinLink™ Cotton;
- the extension request for Event T303-3 encompasses the same regulatory action as TwinLink™ Cotton, that is a determination of nonregulated status under 7 CFR part 340;
- the affected environment, issues and alternatives described and analyzed in the existing NEPA documentation for TwinLink™ Cotton are applicable to the extension request of Event T303-3;
- no new alternatives have been identified that are relevant to this regulatory action;
- no substantive new environmental or social issues and impacts have been identified that are relevant to this regulatory action; and
- APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for TwinLink™ Cotton, including the proposed action or analysis of impacts in the EA;

Based on its similarity to the antecedent organism event T304-40, the BCS extension request for Event T303-3 has been subject to the previous NEPA review completed for TwinLink™ Cotton. Therefore, the existing NEPA documentation completed for TwinLink™ Cotton is being used to evaluate and determine if there are any potentially significant impacts to the human environment from APHIS' response to BCS extension request for a determination of nonregulated status of Event T303-3.

## **Regulatory Authority**

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<sup>1</sup> Under NEPA regulations, the “human environment” includes “the natural and physical environment and the relationship of people with that environment” (40 CFR §508.14).

“Protecting American agriculture” is the basic charge 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 GE varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated 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 mandated 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 is responsible for regulating GE organisms and plants under the plant pest provisions in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq.*) to ensure that they do not pose a plant pest risk to the environment.

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 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 USC 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 under 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 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 person may also request that APHIS extend a determination of nonregulated status to other organisms under § 340.6(e)(2). Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question. 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 Application for an Extension of Nonregulated Status**

Under the authority of 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 § 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as Event T303-3. When a request for an extension of nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to an antecedent organism which has previously been determined to be unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) of the antecedent organism that the genetically engineered organism identified in the extension request 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.

BCS has submitted a request to APHIS for an extension of a determination of nonregulated status for an insect-resistant, glufosinate ammonium tolerant cotton event T303-3. In accordance with § 340.6(e)(2), BCS requests APHIS' determination of nonregulated status for TwinLink™ Cotton be extended to Event T303-3 and any progeny derived from crosses of Event T303-3 with

conventional cotton, and any progeny derived from crosses of Event T303-3 with other transgenic cotton varieties that have received a determination of nonregulated status, no longer be considered regulated articles under 7 CFR part 340. The antecedent organism identified in the extension request for Event T303-3 is Event T304-40 (Bayer 2012). The petition for TwinLink™ Cotton Events GHB119 and T304-40 (08-340-01p) received a determination of non-regulated status from APHIS on October 12, 2011 (76 FR 63278-63279).

### **BSC Cotton Event T303-3**

BCS has developed Event T303-3 as an insect-resistant and glufosinate ammonium tolerant cotton. *Gossypium hirsutum* transformation event T303-3 was produced by *Agrobacterium*-mediated transformation utilizing vector pTDL004 containing a *cry1Ab* gene construct, encoding insect-resistance, and the *bar* gene as a selectable marker conferring tolerance to glufosinate ammonium herbicides. The antecedent organism, cotton event T304-40 as described in petition 08-340-01p for TwinLink™ Cotton (Bayer 2010), was also generated through *Agrobacterium*-mediated transformation utilizing a slightly different vector (pTDL008). Both events produce the same insecticidal crystal protein (ICP) Cry1Ab (expression product of the *cry1Ab* gene) and PAT protein (expression product of the *bar* gene). A comparison of characteristics of events T303-3 and T304-40 is summarized in Table 1 of BCS application for extension (Bayer 2012).

### **Coordinated Framework Review**

#### *Food and Drug Administration*

Similar to the antecedent organism event T304-40, Event T303-3 is within the scope of the 1992 FDA policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA 1992). APHIS considers the FDA food and feed safety and nutritional assessment determination when assessing potential impacts that may result from a determination of nonregulated status of a GE organism. In the absence of a completed FDA determination, APHIS takes into consideration prior FDA reviews of comparable products to make a preliminary assessment of the potential impacts. Based on the similarity to the antecedent organism event T304-40, the conclusions made by FDA for TwinLink™ Cotton are being used to assess potential impacts that may result from a determination of nonregulated status of Event T303-3.

BCS provided the FDA with information on the identity, function, and characterization of the genes, for TwinLink™ Cotton, including expression of the gene products. FDA evaluated BCS submission to determine whether the developer's product raises any safety or regulatory issues with respect to the intended modification or with respect to the food itself. Based on the information provided by BCS and other information available to the agency, FDA did not identify any safety or regulatory issues under the Federal Food, Drug and Cosmetic Act or current FDA regulations that would require further evaluation at this time (US-FDA 2011). BCS has concluded that cotton derived from events T304-40 and GHB119 and the foods and feeds obtained from these events are as safe as conventional cotton varieties and with the exception of the plant-incorporated protectant proteins, are not materially different in composition or any other relevant parameter from other cotton varieties now grown, marketed, and consumed in the U.S. At this time, based on BCS' data and information, the FDA considers BCS' consultation on cotton derived from events T304-40 and GHB119 to be complete (US-FDA 2011). The FDA's oversight of the food and safety impacts associated with the incorporation and expression of

pesticidal substances, in this case, the Cry proteins associated with Bt, are more limited. EPA is the primary authority for the review of plant-incorporated protectants.

### *Environmental Protection Agency*

The EPA has authority over the use of pesticidal substances and plant-incorporated protectants (PIPs) under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.*). APHIS considers the EPA's regulatory assessment when assessing potential impacts that may result from a determination of nonregulated status of a GE organism. Note that EPA has issued a tolerance exemption for Cry1Ab protein in all crops (40 CFR §174.511; US-EPA 2010a), as well as for the PAT protein (40 CFR §174.522; US-EPA 2010c). A temporary exemption from the requirement of a tolerance has been issued for Cry2Ae (40 CFR §174.530; US-EPA 2010b).

BCS developed and sought EPA registration of two transgenic cotton (*Gossypium hirsutum*) PIPs, Event T304-40 and Event GHB119. Each expresses an insecticidal protein ("Cry" proteins) derived from the soil bacterium *Bacillus thuringiensis*. These cotton events are intended for use as PIPs for conventional breeding to produce a product, TwinLink™ Cotton that expresses both proteins. BCS applied for EPA pesticide registrations of Cry1Ab and Cry2Ae proteins as expressed in Events T304-40 and GHB119 cotton, respectively, and a new combination PIP product, TwinLink™ cotton, created through conventional breeding of these events for use as PIPs in 2009, under section 3 of the FIFRA. BCS concurrently filed a petition for a permanent exemption from the requirement of a tolerance for Cry2Ae protein residues in or on food and feed commodities in cotton. EPA believes that, based upon its assessment of the data and information submitted by BCS, it is in the interest of the public and the environment to issue the registrations proposed by BCS (US-EPA 2012).

In addition to review of the crop with plant-incorporated protectants, 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 development of a transformed cotton crop providing tolerance to glufosinate ammonium may require a change in the EPA-approved label for this herbicide. The current glufosinate ammonium label provides for its use on transformed crops expressing resistance to glufosinate ammonium, and specifically references products marketed under the trade name "LibertyLink" (BCS 2010). Glufosinate ammonium-tolerant cotton was first available in the U.S. with the introduction of LibertyLink® Cotton in 2004. Although the glufosinate ammonium tolerance trait expressed in TwinLink™ cotton is the same as that expressed in the LibertyLink® Cotton, the EPA is expected to publish a new label for glufosinate ammonium that also references the TwinLink™ product varieties. APHIS used the current glufosinate label as the basis for its evaluation of the potential impacts associated with the use of and exposure to glufosinate ammonium.

### **Scope of the Environmental Analysis**

Based on the similarity to the antecedent organism event T304-40, APHIS has concluded that the BCS extension request for a determination on the regulated status for Event T303-3 encompasses the same scope of environmental analysis as TwinLink™ Cotton. APHIS reviewed and analyzed the information submitted in the extension request by BCS (Bayer 2012) and has concluded that Event T303-3 is similar to the antecedent organism, event T304-40 and therefore, based on its

Plant Pest Risk Assessment for TwinLink™ cotton (USDA-APHIS 2010) APHIS has concluded that Event T303-3 is unlikely to pose a plant pest risk (*see* Appendix A). Although a determination of nonregulated status of Event T303-3 would allow for new plantings of Event T303-3 to occur anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support cotton production. Similar to the antecedent organism event T304-40, a determination of nonregulated status of Event T303-3 is not expected to increase cotton production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE cotton acreage. To determine areas of cotton production, APHIS used data from the National Agricultural Statistics Service (NASS) 2007 Census of Agriculture to determine where cotton is produced in the U.S. (USDA-NASS 2007; USDA-NASS 2010). Cotton was produced in 17 states including Alabama, Arizona, Arkansas, California, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia.

### **Public Involvement**

APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for TwinLink™ Cotton, including the proposed action or analysis of impacts in the EA since the completion of the public involvement process for TwinLink™ Cotton. APHIS has not received any additional information or comments from the public specifically directed at the TwinLink™ Cotton petition, PPRA or NEPA documentation since a determination of non-regulated status was announced on October 12, 2011 (76 FR 63278-63279).

In preparing this NEPA decision/FONSI for Event T303-3, APHIS carefully reviewed and took into consideration all public input that was received during the public involvement process that was completed for Bayer CropScience petition 08-340-01p (TwinLink™ Cotton). On June 28, 2011, APHIS published a notice in the Federal Register (76 FR 37769-37770, Docket no. APHIS-2010-0102) announcing the availability of the Bayer CropScience petition 08-340-01p (TwinLink™ Cotton), and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before August 29, 2011. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 2 comment responses were received from individuals during the comment period. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. The 2 comments expressed opposition to a determination of nonregulated status of TwinLink™ Cotton, but did not change the analysis provided in the PPRA or draft EA. These individuals did not mention their specific disagreement with APHIS' analyses of TwinLink™ Cotton detailed in the EA or the PPRA (USDA-APHIS 2010); rather, they expressed their general opposition to genetically modified organisms (GMOs) or GE crops. Other claims suggest a negative impact of GE cotton and GE plants on human health and environmental safety in a general nature. Overall, people who expressed their opposition to a determination of nonregulated status did not provide any supporting evidence for their claims. Comment documents may be viewed at <http://www.regulations.gov/#!searchResults;dct=PS;rpp=10;po=0;s=aphis-2010-0102>

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

APHIS has concluded that the BCS extension request for a determination of nonregulated status of Event T303-3 encompasses the same scope of environmental analysis as

TwinLink™ Cotton. APHIS is not aware of any substantive new environmental or social issues associated with Event T303-3 that were not considered in the previous NEPA analysis completed for a determination on the regulated status of a petition request for TwinLink™ Cotton. Therefore, APHIS is using the same issues identified and analyzed in the existing NEPA documentation for TwinLink™ Cotton to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of an extension request by BCS for Event T303-3.

The issues considered in the TwinLink™ Cotton 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 TwinLink™ 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. These issues, including those regarding the agricultural production of cotton using various production methods, and the environmental and food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of TwinLink™ Cotton.

The TwinLink™ Cotton 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) for TwinLink™ Cotton. These same issues have been determined by APHIS to be relevant to APHIS' regulatory actions associated with Event T303-3 and therefore are being used in their entirety:

#### Management Considerations

- Acreage and Areas of Cotton Production
- Cropping Practices
- Seed Production
- Organic Farming
- Specialty Cotton Production

#### Environmental Considerations

- Water Resources
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Biological Diversity
- Gene Movement

#### Public Health Considerations

- Human Health
- Worker Safety

- Animal Feed

#### Socioeconomic Considerations

- Domestic Economic Environment
- Trade Economic Environment
- Social Environment

#### **Alternatives that were analyzed**

APHIS has concluded that the BCS extension request for a determination of nonregulated status of Event T303-3 encompasses the same scope of environmental analysis and regulatory decision as TwinLink™ Cotton; that is a determination of nonregulated status under 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by BCS (Bayer 2012) and has concluded that Event T303-3 is similar to the antecedent organism, event T304-40 and therefore, based on its Plant Pest Risk Assessment for TwinLink™ cotton (USDA-APHIS 2010) APHIS has concluded that Event T303-3 is unlikely to pose a plant pest risk (*see* Appendix A). The comparison of characteristics of Event T303-3 to the antecedent organism, event T304-40, indicates that Event T303-3 expresses the same Cry1Ab and PAT/bar proteins as event T304-40; Event T303-3 expresses the same resistance to lepidopteran pests and glufosinate ammonium herbicide tolerance as TwinLink™ Cotton; and Event T303-3 does not exhibit any additional traits beyond what is expressed in TwinLink™ Cotton. Therefore, the proposed action identified in the existing NEPA documentation completed for TwinLink™ Cotton is being used to evaluate APHIS' action associated with a determination of nonregulated status of Event T303-3.

Based on the similarity to the antecedent organism event T304-40, APHIS has concluded that all the alternatives identified in the TwinLink™ Cotton EA to be relevant to APHIS' regulatory actions associated with Event T303-3 and therefore are being used in their entirety. APHIS is not aware of any new alternatives that are relevant to APHIS' decision on the regulatory status of Event T303-3 that were not considered in the previous NEPA analysis for TwinLink™ Cotton. Therefore, APHIS is using the same alternatives, including the proposed action, identified and analyzed in the existing NEPA documentation completed for TwinLink™ Cotton to evaluate and determine if there are any potentially significant impacts to the human environment from a determination of nonregulated status of Event T303-3.

#### ***Alternatives described in existing TwinLink™ Cotton EA***

The EA analyzes the potential environmental consequences of a determination of nonregulated status of TwinLink™ Cotton. To respond favorably to a petition for nonregulated status, APHIS must determine that TwinLink™ Cotton is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS 2010) APHIS has concluded that TwinLink™ Cotton is unlikely to pose a plant pest risk. Therefore, APHIS must determine that TwinLink™ 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 TwinLink™ 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. TwinLink™ Cotton and progeny derived from TwinLink™ Cotton would continue to be regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of TwinLink™ 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 TwinLink™ Cotton.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS 2010) that TwinLink™ 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 TwinLink™ Cotton is No Longer a Regulated Article

Under this alternative, TwinLink™ Cotton and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR Part 340. TwinLink™ Cotton is unlikely to pose a plant pest risk (USDA-APHIS 2010). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of TwinLink™ Cotton and progeny derived from this event. This alternative best meets the agency's 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 TwinLink™ Cotton is unlikely to pose a plant pest risk, a determination of nonregulated status of TwinLink™ 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 TwinLink™ Cotton and progeny derived from this event if the developer decides to commercialize TwinLink™ Cotton.

*Alternatives Considered but Rejected from Further Consideration*

APHIS assembled a list of alternatives that might be considered for TwinLink™ Cotton. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for TwinLink™ 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 TwinLink™ 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 of TwinLink™ Cotton, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that TwinLink™ Cotton is unlikely to pose a plant pest risk (USDA-APHIS 2010).

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 2010) and the scientific data evaluated therein, APHIS has concluded that TwinLink™ Cotton is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of TwinLink™ 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 lines described in a petition. Because APHIS has concluded that TwinLink™ 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 TwinLink™ 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 TwinLink™ Cotton from non-GE cotton production. However, because APHIS has concluded that TwinLink™ Cotton is unlikely to pose a plant pest risk (USDA-APHIS 2010), 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 regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of TwinLink™ 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 TwinLink™ Cotton, there are no geographic differences associated with any identifiable plant pest risks for TwinLink™ Cotton (USDA-APHIS 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that TwinLink™ 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 regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

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 effects. However, individuals might choose on their own to geographically isolate their non-GE cotton productions systems from TwinLink™ Cotton or to use isolation distances and other management practices to minimize gene movement between cotton fields.

Requirement of Testing For TwinLink™ 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 TwinLink™ Cotton does not pose a plant pest risk (USDA-APHIS 2010), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for TwinLink™ Cotton would not meet APHIS’ purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

**Environmental Consequences of APHIS’ Selected Action**

Based on the similarity of the antecedent organism event T304-40 to Event T303-3 (see Appendix A), APHIS has concluded that the previous analysis of impacts completed for TwinLink™ Cotton to be relevant to APHIS’ regulatory actions associated with responding to the BCS extension request for Event T303-3. The potential impacts of Event T303-3 on agricultural production of cotton, physical environment, animal and plant communities, public health, animal feed, socioeconomics, and threatened and endangered species are identical to those presented in the Final EA and FONSI for TwinLink™ Cotton and therefore are being used in their entirety to evaluate APHIS’ action associated with a determination of nonregulated status of Event T303-3. The TwinLink™ Cotton 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 A: No Action                        | Alternative B: Determination of Nonregulated Status |
|--|---|---|
| <b>Meets Purpose and Need and Objectives</b> | <b>No</b>                                       | <b>Yes</b>  |
| Unlikely to pose a plant pest risk           | Satisfied through use of regulated field trials | Satisfied – risk assessment (USDA-APHIS 2010)       |
| <b>Management Practices</b>                  |   |   |
| Acreage and Areas of Cotton Production       | Unchanged                                       | Unchanged   |
| Cropping Practices                           | Unchanged                                       | Unchanged   |
| Seed Production                              | Unchanged                                       | Unchanged   |
| Organic Farming                              | Unchanged                                       | Unchanged   |

| <b>Attribute/Measure</b>                 | <b>Alternative A: No Action</b>                  | <b>Alternative B:<br/>Determination of<br/>Nonregulated Status</b> |
|--|--|--|
| Specialty Cotton Production              | Unchanged  | Unchanged  |
| <b>Physical Environment</b>              |  |  |
| Water Resources                          | Unchanged  | Unchanged  |
| Soil                                     | Unchanged  | Unchanged  |
| Air Quality                              | Unchanged  | Unchanged  |
| Climate Change                           | Unchanged  | Unchanged  |
| <b>Animal and Plant Communities</b>      |  |  |
| Animals                                  | Unchanged  | Unchanged  |
| Plants                                   | Unchanged  | Minimal  |
| Biological Diversity                     | Unchanged  | Minimal  |
| Gene Movement                            | Unchanged  | Unchanged  |
| <b>Public Health</b>                     |  |  |
| Human Health                             | Unchanged  | Unchanged  |
| Worker Safety                            | Unchanged  | Unchanged  |
| <b>Animal Feed</b>                       | Unchanged  | Unchanged  |
| <b>Socioeconomic Issues</b>              |  |  |
| Domestic Economic Environment            | Unchanged  | Unchanged  |
| Trade Economic Environment               | Unchanged  | Unchanged  |
| Social Environment                       | Unchanged  | Unchanged  |
| <b>Other Cumulative Effects</b>          | Unchanged  | Unchanged  |
| <b>Threatened and Endangered Species</b> | Unchanged  | Unchanged  |
| <b>Other U.S Regulatory Approvals</b>    | Unchanged for existing nonregulated GE organisms | FDA consultation complete; EPA biopesticide registration complete  |
| <b>Compliance with Other Laws</b>        |  |  |
| CWW, CAA, EOs                            | Fully compliant                                  | Fully compliant  |

Notes:

1. Unchanged – the current conditions will not change as a result of the selection of this alternative.
2. Minimal – the current conditions may change slightly as a result of the selection of this alternative, but the changes, if any, are not deemed significant.

### **Finding of No Significant Impact**

Based on the analysis of impacts in the existing TwinLink™ Cotton EA and the similarity of Event T303-3 to the antecedent organism event T304-40, a determination of nonregulated status of Event T303-3 will not have a significant impact, individually or cumulatively, on the quality of the human environment. I agree with this conclusion and therefore find that an environmental impact statement 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. Most of the cotton acreage in the U.S. is planted to GE cotton. Of the 11.3 million acres planted in cotton in 2010, 93% (10.5 million acres) were GE cotton. Of this, 73% of the GE cotton acreage was GE insect-resistant (Bt) cotton and 78% was herbicide-tolerant (USDA-ERS 2010a, 2010b). A determination of nonregulated status of Event T303-3 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 Event T303-3 will not 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.

Although a determination of nonregulated status of Event T303-3 would allow for new plantings of Event T303-3 to occur anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support cotton production. A determination of nonregulated status of Event T303-3 is not expected to increase cotton production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE cotton acreage.

*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 Event T303-3 will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty cotton varieties. Based on the discussions in Chapter 4 of the TwinLink™ Cotton EA and its similarity to the antecedent organism event T304-40, a determination of nonregulated status of Event T303-3 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 Event T303-3 will not 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. A determination of nonregulated status of Event T303-3 could add another GE cotton variety to the conventional cotton market and is not expected to change the market demands for GE cotton or cotton produced using organic methods or specialty systems. Most of the cotton acreage in the U.S. is planted to GE cotton. Of the 11.3 million acres planted in cotton in 2010, 93% (10.5 million acres) were GE cotton. Of this, 73% of the GE cotton acreage was GE insect-resistant (Bt) cotton and 78% was herbicide-tolerant (USDA-ERS 2010a, 2010b). Based upon recent trend information, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share. Between 2000 and 2008, although 12 GE cotton events or lines were no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, the acreage associated with the organic production of cotton remained at slightly above 15,000 acres (USDA-ERS 2010c). Based on the data provided by BCS on the antecedent organism T304-40 cotton (Bayer 2010), as well as previous experience with other Bt cotton varieties that have been widely adopted by growers since their introduction in 1996 (USDA-ERS 2010a), APHIS has concluded that the availability of Event T303-3 would

not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE seed production. A determination of nonregulated status of Event T303-3 will not require a change to seed production practices. A determination of nonregulated status of Event T303-3 is not expected to result in changes in the current cotton cropping practices. As discussed in Chapter 4 of the TwinLink™ Cotton EA, studies demonstrate the antecedent organism T304-40 cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Bayer 2010). If Event T303-3 is adopted, a continued reduction in the use of budworm/bollworm insecticides applications and the number of acre-treatments per year as reported in Benbrook's trend analysis (Benbrook 2009) is expected to occur. A determination of nonregulated status of Event T303-3 will provide growers with another alternative Bt cotton variety to cultivate. Herbicide use patterns have the potential to change as well. The introduction of Event T303-3 provides a cotton variety, expressing Bt-based lepidopteran resistance combined with tolerance to glufosinate ammonium, an alternative herbicide. Event T303-3 provides growers with an alternative to those cotton varieties resistant to glyphosate, thus expanding options in the field for weed control. In those fields where glyphosate-resistant weeds have emerged, glufosinate ammonium tolerance provides the grower with an option to transition away from glyphosate herbicides to a different post-emergent herbicide. The transition to glufosinate ammonium could reduce applications of those other herbicides needed to manage glyphosate-resistant weeds.

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

A determination of nonregulated status of Event T303-3 would have no significant impacts on human or animal health. As discussed in Chapter 4 of the TwinLink™ Cotton EA, similar products were no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 beginning in 1996 with the introduction of Bt products and followed shortly after by the introduction of the various "Liberty" products which provided tolerance to glufosinate ammonium. In each case, FDA and EPA reviews and approvals determined that the products met the agency's review criteria for approval. The cultivation of these existing crop products would not change under either alternative. Both characteristics have been successfully cultivated in multiple crops in the ensuing years with no evidence of human health impacts. BCS provided the FDA with information on the identity, function, and characterization of the genes, for TwinLink™ Cotton, including expression of the gene products. FDA evaluated BCS submission to determine whether the developer's product raises any safety or regulatory issues with respect to the intended modification or with respect to the food itself. Based on the information provided by BCS and other information available to the agency, FDA did not identify any safety or regulatory issues under the Federal Food, Drug and Cosmetic Act or current FDA regulations that would require further evaluation at this time (US-FDA 2011). BCS applied for EPA pesticide registrations of Cry1Ab and Cry2Ae proteins as expressed in Events T304-40 and GHB119 cotton, respectively, and a new combination PIP product, TwinLink™ cotton, created through conventional breeding of these events for use as PIPs in 2009, under section 3 of the FIFRA. BCS concurrently filed a petition for a permanent exemption from the requirement of a tolerance for Cry2Ae protein residues in or on food and feed commodities in cotton. EPA believes that, based upon its assessment of the data and information submitted by

BCS, it is in the interest of the public and the environment to issue the registrations proposed by BCS (US-EPA 2012). Based on the analysis of field and laboratory data and scientific literature provided by BCS on TwinLink™ Cotton (Bayer 2010); the safety data available on other GE cotton; FDA' conclusions on the TwinLink™ Cotton; EPA' registration of Cry1Ab and Cry2Ae proteins as expressed in Events T304-40 and GHB119 cotton, respectively, and a new combination PIP product, TwinLink™ cotton; and its similarity to the antecedent organism event T304-40, APHIS has concluded that a determination of nonregulated status of Event T303-3 would have no adverse 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 Event T303-3. Similar to the antecedent organism T304-40, 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 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 Event T303-3. Similar to the antecedent organism T304-40, 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 Event T303-3, 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 Event T303-3, 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.*

The effects on the quality of the human environment from a determination of nonregulated status of Event T303-3 are not highly controversial. Although there is some opposition to a determination of nonregulated status of Event T303-3, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. Based on the discussions in Chapter 4 of the TwinLink™ Cotton EA and its similarity to the antecedent organism event T304-40, a determination of nonregulated status of Event T303-3 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 Event T303-3 will not 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. Similar to the antecedent organism T304-40, Event T303-3 is not expected to increase the total acreage of cotton production or

current cotton cropping practices. It is anticipated that the trend of reduced broad-spectrum insecticide use by cotton growers will continue due to the adoption of Bt cotton and other cultural practices. There is the potential that the introduction of glufosinate ammonium tolerance may result in a reduction in total herbicide use as growers adopt different herbicide treatment strategies involving glufosinate ammonium as a post-emergent crop treatment, thereby reducing the use of some of the other herbicides which have been required in response to the emergence of glyphosate-resistant weeds. Similar to the antecedent organism T304-40, the effect of Event T303-3 on wildlife or biodiversity is no different than that of other GE or non-GE cotton produced in conventional agriculture in the U.S. Although Event T303-3 does provide the grower with a new choice for a herbicide-tolerant and insect-resistant variety, based on the similarity to the antecedent organism T304-40, cultivation of Event T303-3 does not otherwise require a change in the rates of fertilizer application, tillage, planting, or harvesting from existing commercial cotton varieties, including other GE cotton varieties providing either insect resistance, herbicide tolerance, or stacked with both (Bayer 2010). During the public comment period for TwinLink™ Cotton, APHIS received comments opposing a determination of nonregulated status of TwinLink™ Cotton. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. These individuals did not mention their specific disagreement with APHIS' analyses of TwinLink™ Cotton detailed in the EA or the PPRA (USDA-APHIS 2010); rather, they expressed their general opposition to genetically modified organisms (GMOs) or GE crops. Other claims suggest a negative impact of GE cotton and GE plants on human health and environmental safety in a general nature. Overall, people who expressed their opposition to a determination of nonregulated status did not provide any supporting evidence for their claims. APHIS has not received any additional information or comments from the public specifically directed at the TwinLink™ Cotton petition, PPRA or NEPA documentation since a determination of non-regulated status was announced on October 12, 2011 (76 FR 63278-63279).

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 TwinLink™ Cotton EA and its similarity to the antecedent organism event T304-40, the possible effects on the human environment from a determination of nonregulated status of Event T303-3 are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. Based on the discussions in Chapter 4 of the TwinLink™ Cotton EA and its similarity to the antecedent organism event T304-40, a determination of nonregulated status of Event T303-3 is not expected to directly cause an increase in agricultural acreage devoted to cotton production, or those cotton acres devoted to GE cotton cultivation. Similar to the antecedent organism T304-40, a determination of nonregulated status of Event T303-3 is not expected to result in changes in the current cotton cropping practices. BCS' studies demonstrate TwinLink™ Cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Bayer 2010; USDA-APHIS 2010). Although Event T303-3 does provide the grower with a new choice for a herbicide-tolerant and insect-resistant variety, based on the similarity to the antecedent organism T304-40, the cultivation of Event T303-3 does not otherwise require a change

in the rates of fertilizer application, tillage, planting, or harvesting from existing commercial cotton varieties, including other GE cotton varieties providing either insect resistance, herbicide tolerance, or stacked with both (Bayer 2010). It is anticipated that the trend of reduced broad-spectrum insecticide use by cotton growers will continue due to the adoption of Bt cotton and other cultural practices. There is the potential that the introduction of glufosinate ammonium tolerance may result in a reduction in total herbicide use as growers adopt different herbicide treatment strategies involving glufosinate ammonium as a post-emergent crop treatment, thereby reducing the use of some of the other herbicides which have been required in response to the emergence of glyphosate-resistant weeds. Similar to the antecedent organism T304-40, the effect of Event T303-3 on wildlife or biodiversity is no different than that of other GE or non-GE cotton produced in conventional agriculture in the U.S. As described in Chapter 4 of the TwinLink™ Cotton 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), Event T303-3, or produce cotton using organic methods or specialty systems, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural cotton production. Additionally, most of the cotton acreage in the U.S. is planted to GE cotton. Of the 11.3 million acres planted in cotton in 2010, 93% (10.5 million acres) were GE cotton. Of this, 73% of the GE cotton acreage was GE insect-resistant (Bt) cotton and 78% was herbicide-tolerant (USDA-ERS 2010a, 2010b). 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 Event T303-3. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE cotton products, the possible effects to the human environment from the release of an additional GE cotton product are already well 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 Event T303-3 would not establish a precedent for future actions with significant effects 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 on 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 specific to a particular GE organism and undergoes this 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 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 Event T303-3. When a request for an extension of nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to an antecedent organism which has previously been determined to be unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk

Assessment of the antecedent organism that the genetically engineered organism identified in the extension request 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 under 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 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 person may also request that APHIS extend a determination of nonregulated status to other organisms under § 340.6(e)(2). Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question. 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.*

Based on the similarity of the antecedent organism T304-40 to Event T303-3, no significant cumulative effects were identified through this assessment. The TwinLink™ Cotton EA discussed cumulative effects on cotton management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is included for each environmental issue analyzed in Chapter 4 of the TwinLink™ Cotton EA. In the event of a determination of nonregulated status, similar to the antecedent organism T304-40, Event T303-3 may be stacked (combined) with non-GE and GE cotton varieties by traditional breeding techniques, resulting in a plant that, for example, may also be resistant to other herbicides, or may present a different combination of insect pest-resistant, but may also have progeny with no transgenes at all. Similar to the antecedent organism T304-40, there is no guarantee that Event T303-3 will be stacked with any particular non-GE or GE cotton varieties 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. Thus, predicting 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. Based on the analysis documented in the TwinLink™ Cotton EA and its similarity to the antecedent organism event T304-40, in the event of a determination of nonregulated status of Event T303-3, APHIS has not

identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of Event T303-3 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.* Based on the analysis documented in the TwinLink™ Cotton EA and its similarity to the antecedent organism event T304-40, a determination of nonregulated status of Event T303-3 is not expected to adversely impact cultural resources on tribal properties. Any farming activities that may be taken 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. Similar to the antecedent organism T304-40, a determination of nonregulated status of Event T303-3 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 Event T303-3. Similar to the antecedent organism T304-40, standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to Event T303-3, 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. A determination of nonregulated status of Event T303-3 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 effects on the character or use of historic properties. For example, there is potential for audible effects 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 effects 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 Event T303-3 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 Chapter 4 of the TwinLink™ Cotton EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of TwinLink™ 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. APHIS has obtained and reviewed the USFWS list of Threatened and Endangered Species ([http://ecos.fws.gov/tess\\_public/StateListing.do?state=WV&status=listed](http://ecos.fws.gov/tess_public/StateListing.do?state=WV&status=listed)) and based on

the analysis documented in the TwinLink™ Cotton EA and its similarity to the antecedent organism event T304-40, APHIS has reached a conclusion that a determination of nonregulated status of Event T303-3 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, a determination of nonregulated status of Event T303-3, would be in compliance with all federal, state, and local laws. Because the agency has concluded that Event T303-3 is unlikely to pose a plant pest risk, a determination of nonregulated status of Event T303-3 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. Similar to the antecedent organism event T304-40, Event T303-3 is within the scope of the 1992 FDA policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA 1992). EPA has authority over the use of pesticidal substances and plant-incorporated protectants under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCAs (21 USC §301, *et seq.*). 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 existing NEPA documentation completed for TwinLink™ Cotton, including input from the public involvement process. Based on APHIS' conclusion that Event T303-3 encompasses the same scope of environmental analysis and regulatory decision as TwinLink™ Cotton; that is a determination of nonregulated status under 7 CFR part 340, I believe the issues identified and analyzed in the existing NEPA documentation for TwinLink™ Cotton are relevant to this regulatory action and best addressed by extending a determination of nonregulated status to Event T303-3. This regulatory action 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." A determination of nonregulated status of Event T303-3 has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, a determination of nonregulated status of Event T303-3 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. As APHIS has not identified any plant pest risks associated with Event T303-3, the continued regulated status of Event T303-3 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 Event T303-3 will not have any significant environmental effects.

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Michael C. Gregoire  
Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Services  
U.S. Department of Agriculture

Date:

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## Appendix A. Similarity of Cotton Event T303-3 to the Antecedent Organism T304-40

APHIS-BRS has received an extension request (APHIS number 12-033-01p) from Bayer CropScience for nonregulated status of genetically engineered (GE) cotton event T303-3. The extension request refers to Bayer TwinLink™ cotton as the comparator or antecedent organism. GE cotton event T304-40 is one of the parents of Bayer CropScience TwinLink™ cotton, which was submitted for nonregulated status December 22, 2008 (APHIS petition number 08-340-01p) and received a determination of non-regulated status from APHIS on October 12, 2011 (76 FR 63278-63279). A comparison of a variety of characteristics of T303-3 and T304-40 cottons follow this text.

Functionally, the two cotton varieties are resistant to the identical types of pests as well as the same herbicide. They are similar in that they both express a Cry1Ab protein from *Bacillus thuringiensis* and a phosphinothricin acetyltransferase (PAT) protein from *Streptomyces hygroscopicus*. The primary difference between these two cotton varieties is the presence of a Ps7s7 subterranean clover stunt virus promoter in T304-40 versus a P35S2 cauliflower mosaic virus promoter in T303-3. Both promoters drive expression of the Cry1Ab gene in their respective varieties, and the difference in promoters does not change the similarity in the proteins produced between the two varieties. Because the Cry1Ab and PAT proteins are similar between the two varieties, the protein in T303-3 cotton will not be substantively different than that found in T304-40.

Disease and pest susceptibility: Similar to results from field trials with TwinLink™ cotton, no significant differences were noted in diseases or pests between GE T303-3 lines and the appropriate comparator lines over several years of trials (Bayer CropScience, 2012, Section VII.C. and Appendix 1, pp 57-86).

Outcrossing to wild relatives: Similar to observations made on TwinLink™ cotton, the T303-3 line produces heavy, sticky pollen and is considered to be primarily self-pollinating. As such, outcrossing to other cotton (*Gossypium hirsutum*, *G. tomentosum*, *G. barbadense*, *G. thurberi*) can be expected to be the same (Bayer CropScience, 2012, Section VIII.A., p. 49).

Weediness potential: Similar to phenotypic observations made on TwinLink™ cotton, observations and data collected for T303-3 did not indicate any increased potential for T303-3 to become a weed (Bayer CropScience, 2012, Sections VII.B. and VI.B.1., pp 41-45; Section VIII.B., p. 50). Relevant data collected related to plant emergence, height, number of nodes, seed production, etc).

Nontarget or beneficial organisms: The functional proteins produced in TwinLink™ cotton and T303-3 (Cry1Ab and PAT) are identical. As such, it can be anticipated that potential impacts on nontarget and/or beneficial organisms will be identical. Those assessments were conducted by Bayer and noted minimal to no risk to nontarget organisms (Bayer 2008, Section IX, pp. 79-85).

Transfer of genetic material to organisms with which it cannot interbreed: Bayer notes nothing significant about either of these plants that would increase the potential for horizontal gene transfer (Bayer 2008, p 79; Bayer 2012, p. 49).

After a thorough review of the BCS extension request, BRS concludes that Event T303-3 is similar to the antecedent organism, event T304-40 and therefore, the plant pest risk assessment developed for TwinLink™ cotton (USDA-APHIS 2010) will be used to determine if Event T303-3 is unlikely to pose a plant pest risk. Similar to the conclusions found in the plant pest risk assessment for TwinLink™ cotton (USDA-APHIS 2010), that is, due to the lack of plant pest risk from the inserted genetic material, the lack of weediness characteristics, the lack of atypical responses to disease or plant pests in the field, the lack of deleterious effects on non-targets or beneficial organisms in the agro-ecosystem, and the lack of horizontal gene transfer, APHIS has concluded that Event T303-3 is unlikely to pose a plant pest risk.

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