

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

**Bayer CropScience
Insect Resistant and Glufosinate Ammonium-Tolerant
(TwinLink™) Cotton, Events T304-40 x GHB119**

**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 08-340-01p) by Bayer CropScience (BCS) for their genetically engineered TwinLink™ Cotton Events GHB119 and T304-40. 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. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment¹ that may result from a determination of nonregulated status of TwinLink™ Cotton. The EA assesses alternatives to a determination of nonregulated status of TwinLink™ Cotton and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

“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

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

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 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 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 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 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

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 TwinLink™ Cotton. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose 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.

Bayer CropScience has submitted a petition (APHIS Number 08-340-01p) to APHIS seeking a determination that their genetically engineered TwinLink™ Cotton Events GHB119 and T304-40 are unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

BSC TwinLink™ Cotton Events GHB119 and T304-40

BCS has developed the TwinLink™ Cotton as an alternative insect-resistant and herbicide-tolerant cotton product. BCS has developed upland or Mexican cotton (*Gossypium hirsutum*) plants that express two insecticidal crystalline proteins, Cry1Ab and Cry2Ae, derived from the common soil bacterium, *Bacillus thuringiensis* (*Bt*). The Cry1Ab and Cry2Ae proteins in TwinLink™ Cotton are effective in controlling lepidopteran larvae such as bollworm (CBW),

Helicoverpa zea), tobacco budworm (TBW, *Heliothis virescens*), and fall armyworm (FAW, *Spodoptera frugiperda*) which are common pests of cotton. The rationale for using two *Bt* genes is that target insects are much less likely to develop resistance to both proteins simultaneously than to develop resistance to one toxic protein. In addition to the Cry1Ab and Cry2Ae proteins, the TwinLink™ Cotton contains the modifying phosphinothricin-acetyl-transferase (PAT) enzyme, encoded by the *bar* gene which confers tolerance to glufosinate ammonium-based herbicides. The *bar* gene, derived from *Streptomyces hygroscopicus*, encodes the PAT enzyme which acts to convert glufosinate ammonium into its inactive form, thus rendering the plant tolerant to the herbicide. This is the same enzyme that is expressed in BCS LibertyLink® Cotton (LLCotton25) that also confers tolerance to glufosinate ammonium herbicides.

Coordinated Framework Review

Food and Drug Administration

TwinLink™ Cotton (events T304-40 x GHB119) 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). BCS has provided the FDA with information on the identity, function, and characterization of the genes, for TwinLink™ Cotton, including expression of the gene products. The FDA is currently reviewing the information submitted by the applicant.

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. Note that with regard to the expression of glufosinate ammonium tolerance, the gene construct in the Bayer TwinLink™ Cotton is the same as that approved by the FDA in June 2003 for the LibertyLink® Cotton product (US-FDA, 2003). In that approval, the FDA noted that the transformational event in LibertyLink® Cotton was not materially different in composition, safety, or any other relevant parameter in cotton grown, marketed, and consumed at that time (US-FDA, 2003). This previous FDA review was used by APHIS to analyze the food and safety impacts associated with the incorporation and expression of glufosinate ammonium tolerance in TwinLink™ Cotton. 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 under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.*). EPA is currently reviewing information submitted by the applicant on the efficacy and potential environmental concerns associated with the use of TwinLink™ Cotton.

APHIS considers the EPA's regulatory assessment when assessing potential impacts that may result from a determination of nonregulated status of a GE organism. In the absence of a completed EPA determination, APHIS takes into consideration prior EPA reviews of comparable

products to make a preliminary assessment of the potential impacts. 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). These previous EPA reviews were used by APHIS to analyze the food and safety impacts associated with the incorporation and expression of the Cry proteins in TwinLink™ Cotton.

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

Although a determination of nonregulated status of TwinLink™ Cotton would allow for new plantings of TwinLink™ Cotton 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 TwinLink™ Cotton 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

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, 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

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 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 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):

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 fully analyzed

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

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 A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2010)
Management Practices		
Acreage and Areas of Cotton Production	Unchanged	Unchanged
Cropping Practices	Unchanged	Unchanged
Seed Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Specialty Cotton Production	Unchanged	Unchanged
Physical Environment		
Water Resources	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animal and Plant Communication		
Animals	Unchanged	Unchanged
Plants	Unchanged	Minimal
Biological Diversity	Unchanged	Minimal
Gene Movement	Unchanged	Unchanged
Public Health		
Human Health	Unchanged	Unchanged
Worker Safety	Unchanged	Unchanged
Animal Feed	Unchanged	Unchanged
Socioeconomic Issues		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Unchanged
Other Cumulative Effects	Unchanged	Unchanged
Threatened and Endangered Species	Unchanged	Unchanged
Other U.S Regulatory Approvals	Unchanged for existing nonregulated GE organisms	FDA consultation pending, EPA tolerance exemptions and conditional pesticide registrations being reviewed
Compliance with Other Laws		
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

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. 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 TwinLink™ 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 TwinLink™ Cotton 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 TwinLink™ Cotton would allow for new plantings of TwinLink™ Cotton 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 TwinLink™ Cotton 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 TwinLink™ Cotton will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty cotton varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of TwinLink™ 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 TwinLink™ Cotton 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 TwinLink™ Cotton 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 for TwinLink™ 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 TwinLink™ Cotton would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE seed production (USDA-APHIS, 2010). A determination of nonregulated status of TwinLink™ Cotton will not require a change to seed production practices. A determination of nonregulated status of TwinLink™ Cotton is not expected to result in changes in the current cotton cropping practices. As discussed in Chapter 4 of the EA, studies demonstrate TwinLink™ Cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Bayer, 2010). If TwinLink™ Cotton 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 TwinLink™ Cotton will provide growers with another alternative Bt cotton variety to cultivate. Herbicide use patterns have the potential to change as well. The introduction of TwinLink™ Cotton provides a stacked variety, expressing Bt-based lepidopteran resistance combined with tolerance to glufosinate ammonium, an alternative herbicide. TwinLink™ Cotton 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 TwinLink™ Cotton would have no significant impacts on human or animal health. As discussed in Chapter 4 of the 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. Based on the analysis of field and laboratory data and scientific literature provided by BCS (Bayer, 2010), and safety data available on other GE cotton, APHIS has concluded that a determination of nonregulated status of TwinLink™ Cotton 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 TwinLink™ 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 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 TwinLink™ 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 TwinLink™ 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 TwinLink™ 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.*

The effects on the quality of the human environment from a determination of nonregulated status of TwinLink™ Cotton are not highly controversial. Although there is some opposition to a determination of nonregulated status of TwinLink™ Cotton, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of TwinLink™ 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 TwinLink™ Cotton 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. TwinLink™ Cotton 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. The effect of TwinLink™ 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. Although TwinLink™ Cotton does provide the grower with a new choice for a herbicide-tolerant and insect-resistant variety, cultivation of TwinLink™ Cotton 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, 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.

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 effects on the human environment 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. As discussed in Chapter 4 of the EA, a determination of nonregulated status of TwinLink™ 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. A determination of nonregulated status of TwinLink™ Cotton 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 TwinLink™ Cotton does provide the grower with a new choice for a herbicide-tolerant and insect-resistant variety, cultivation of TwinLink™ Cotton 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. The effect of TwinLink™ 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. 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), TwinLink™ Cotton, 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 TwinLink™ Cotton.

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 a 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 TwinLink™ Cotton 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 TwinLink™ Cotton. When a petition for nonregulated status is submitted, APHIS must make a determination if 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 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 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 effects were identified through this assessment. The 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 EA. In the event of a determination of nonregulated status, TwinLink™ Cotton 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. There is no guarantee that TwinLink™ Cotton 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. In the event of a determination of nonregulated status of TwinLink™ 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 TwinLink™ 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 TwinLink™ Cotton is not expected to adversely impact cultural resources on tribal properties. Any farming activity 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. A determination of nonregulated status of TwinLink™ 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 TwinLink™ Cotton. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to TwinLink™ 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. A determination of nonregulated status of TwinLink™ 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 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 TwinLink™

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 Chapter 4 of the 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. After reviewing possible effects of a determination of nonregulated status of TwinLink™ Cotton, APHIS has reached a conclusion that a determination of nonregulated status 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 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. TwinLink™ Cotton (events T304-40 x GHB119) 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). Bayer has provided the FDA with information on the identity, function, and characterization of the genes, for TwinLink™ Cotton, including expression of the gene products. 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 FFDCFA (21 USC §301, *et seq.*). EPA is currently reviewing information submitted by the applicant on the efficacy and potential environmental concerns associated with the use of this product. 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 TwinLink™ 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. As APHIS has not identified any plant pest risks associated with TwinLink™ Cotton, the continued regulated status of TwinLink™ 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 TwinLink™ Cotton will not have any significant environmental effects.

Michael C. Gregoire

9/23/2011

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Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
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Date:

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