

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

**SYNGENTA BIOTECHNOLOGY, INC.
LEPIDOPTERAN-RESISTANT
EVENT COT67B COTTON**

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

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

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 07-108-01p) by Syngenta Biotechnology, Inc. (Syngenta) for their genetically engineered Event COT67B cotton (COT67B (OECD Unique Identifier SYN-IR67B-1)) that expresses a Cry1Ab protein to protect cotton plants from lepidopteran insect damage. 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 COT67B cotton. The EA assesses alternatives to a determination of nonregulated status of COT67B 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 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

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).

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 authorities 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) and 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 COT67B 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.

Syngenta Biotechnology, Inc. (Syngenta) has submitted a petition (APHIS Number 07-108-01p) to APHIS seeking a determination that their genetically engineered Event COT67B cotton is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

Syngenta Lepidopteran-Resistant Event COT67B Cotton

Syngenta has developed a new genetically engineered cotton event, COT67B cotton (OECD Unique Identifier SYN-IR67B-1) via recombinant DNA techniques with broad spectrum lepidopteran insect resistance. COT67B cotton produces a full-length Cry1Ab protein originally derived from *Bacillus thuringiensis* subsp. *kurstaki* HD-1 which has activity against several important lepidopteran pest species of cotton. These include, but are not limited to, *Helicoverpa zea* (cotton bollworm), *Heliothis virescens* (tobacco budworm), *Pectinophora gossypiella* (pink bollworm), and *Trichoplusia ni* (cabbage looper). Event COT67B, either alone or when combined by traditional breeding with other genetically-modified insect resistant cotton varieties, will provide growers with an additional pest management option for lepidopteran-insect pest control and will contribute to a reduction in the likelihood of insect resistance to Bt insect-resistant cotton varieties.

Coordinated Framework Review

COT67B cotton is designed for human and animal consumption and as such, may also be subject to regulation by the FDA. 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 biotechnology-derived food. Syngenta submitted a summary of its safety and nutritional assessment to FDA for COT67B cotton. Syngenta concluded that, with the exception of the intended change in fatty acid composition, the COT67B cotton and the foods and feeds derived from it are no different in composition, safety, or any other relevant parameter from cotton now grown, marketed, and consumed (Syngenta 2007). In February 2009, FDA completed Syngenta's consultation on COT67B cotton regarding the safety and nutritional assessment for the cotton and had no further questions (US-FDA No.000112). To view the text of the FDA's scientific and regulatory assessment response for COT67B cotton refer to Appendix A of the EA or <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing&page=1>.

Tolerance exemptions and conditional pesticide registrations have been granted for the plant-incorporated protectant in COT67B cotton and the genetic material necessary for its production. On July 16, 2008, the EPA granted an exemption from the requirement of a tolerance for residues of FLCry1Ab in or on food and feed commodities of cotton (73 FR 40760-40764). Likewise, on October 29, 2008, EPA approved the conditional registration of FLCry1Ab produced in COT67B cotton for use as a lepidopteran insecticide (73 FR 64323-64324) (US-EPA 2008).

Scope of the Environmental Analysis

Although a determination of nonregulated status of COT67B cotton would allow for new plantings of COT67B 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 COT67B 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 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 May 11, 2011, APHIS published a notice in the Federal Register (76 FR 27301-27303, Docket no. APHIS-2007-0130) announcing the availability of the Syngenta 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 July 11, 2011. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 7 comment responses were received from various groups and individuals during the comment period. An additional 4,045 names were submitted as an attachment to one of the comment documents. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. The 7 comments expressed opposition to a determination of nonregulated status of COT67B 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 COT67B cotton detailed in the EA

or the PPRA (USDA-APHIS 2009); 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. In addition, a single public comment generally claimed that the draft EA was inadequate. However, no explanation was provided for this reasoning. Responses to substantive comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination to 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 COT67B 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 COT67B 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 Use
- 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 COT67B cotton. To respond favorably to a petition for nonregulated status, APHIS must determine that COT67B cotton is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS 2009) APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk. Therefore, APHIS must determine that COT67B 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 COT67B cotton. APHIS has assessed the potential for environmental impacts for each alternative in the “Potential Environmental Consequences” section of the EA.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. COT67B cotton and progeny derived from COT67B 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 COT67B 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 COT67B cotton.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS 2009) that COT67B 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 COT67B cotton is No Longer a Regulated Article

Under this alternative, COT67B cotton and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. COT67B cotton is unlikely to pose a plant pest risk (USDA-APHIS 2009). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of COT67B 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 COT67B cotton is unlikely to pose a plant pest risk, a determination of nonregulated status of COT67B 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 COT67B cotton and progeny derived from this event if the developer decides to commercialize Syngenta COT67B cotton.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for COT67B 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 COT67B 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 COT67B 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 COT67B cotton, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk (USDA-APHIS 2009).

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 2009) and the scientific data evaluated therein, APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of COT67B 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 COT67B 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 COT67B 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 COT67B cotton from non-GE cotton production. However, because APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk (USDA-APHIS 2009), 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 COT67B 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 COT67B cotton, there are no geographic differences associated with any identifiable plant pest risks for COT67B cotton (USDA-APHIS 2009). This alternative was rejected and not analyzed in detail because APHIS has concluded that COT67B 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 COT67B cotton or to use isolation distances and other management practices to minimize gene movement between cotton fields.

Requirement of Testing For COT67B 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 COT67B cotton does not pose a plant pest risk (USDA-APHIS 2009), 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 COT67B 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
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Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS 2009)
Management Practices		
Acreage and Areas of Cotton Production	Unchanged	Unchanged
Cropping practices	Unchanged	Unchanged
Pesticide use	Unchanged	Minimal
Seed Cotton Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Impact to Specialty Cotton	Unchanged	Unchanged
Environment		
Water use	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Gene Movement	Unchanged	Unchanged
Human and Animal Health		
Risk to Human Health	Unchanged	Unchanged
Risk to Worker Safety	Unchanged	Minimal
Risk to Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Other Regulatory Approvals		
U. S.	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted
Compliance with Other Laws		
CWW, CAA, EOs	Fully compliant	Fully compliant

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 total cotton acres planted in 2009, 88% were GE cotton and 65% of that GE cotton acreage was GE insect-resistant (Bt) cotton (USDA-ERS 2010). A determination of nonregulated status of COT67B 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 COT67B 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 COT67B cotton would allow for new plantings of COT67B 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 COT67B 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 COT67B 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 COT67B 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 COT67B 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 COT67B 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 total cotton acres planted in 2009, 88% were GE cotton and 65% of that GE cotton acreage was GE insect-resistant (Bt) cotton (USDA-ERS 2010). 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 2009). A determination of nonregulated status of COT67B cotton will not result in changes in the current practices of crop rotation, tillage, and overall pesticide use. As discussed in Chapter 4 of the EA, cotton production practices are expected to be unchanged, except for the availability of an additional Bt cotton variety to those that are currently available to farmers. A determination of nonregulated status of COT67B cotton is not expected to increase the total acreage of cotton production or the use of Bt cotton. Syngenta anticipates that COT67B cotton will primarily replace some of the Bt cotton cultivars already on the market today (Syngenta 2007). However, if a grower replaces a non-Bt cotton variety with COT67B cotton then it would be expected that there would be a reduction in the use of budworm/bollworm insecticides. This has been the case with the adoption of other Bt cotton cultivars (Benbrook 2009). Studies demonstrate COT67B cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Syngenta 2007). COT67B cotton would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE seed production, nor pose a plant pest risk (USDA-APHIS 2009).

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

A determination of nonregulated status of COT67B cotton would have no significant impacts on human or animal health. The food/feed nutritional and safety assessment for COT67B cotton has been reviewed by the FDA. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from COT67B cotton must be in compliance with all applicable legal and regulatory requirements. FDA completed their consultation on COT67B cotton on February 13, 2009 and concluded that it had “no further questions concerning food and feed derived from cotton event COT67B” (US-FDA BNF No. 0112). The FDA considers Syngenta’s consultation on COT67B cotton and its expression of FLCry1Ab to be complete (see Appendix A of the EA). The Cry1Ab protein is also present in a number of *B. thuringiensis* cotton plant incorporated protectants registered by the US-EPA since 1996 and re-registered in 2001 and 2006. The FDA completed food and feed safety consultations for these products and the EPA,

through its statutory authority under the Federal Food Drug and Cosmetic Act, established a permanent exemption from the requirement of a tolerance for the FLCry1Ab protein and the genetic material necessary for its production in all plants (40 CFR 180.1173). The health and safety of children and minorities were also considered in the establishment of this exemption from the requirement of a tolerance. Based on the analysis of field and laboratory data and scientific literature provided by Syngenta (Syngenta 2007), and safety data available on earlier insect-resistant GE cotton, along with the completion of the consultation process with FDA, APHIS has concluded that a determination of nonregulated status of COT67B cotton would have no significant impacts on human or animal health.

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

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of COT67B 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 COT67B cotton. The product will be deployed on agricultural land currently suitable for production of cotton, will replace existing varieties, and is not expected to increase the acreage of cotton production. Progeny of this variety that express the identified traits of the COT67B cotton will be retained by Syngenta or licensed users. 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 COT67B 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 COT67B 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 COT67B cotton are not highly controversial. Although there is some opposition to a determination of nonregulated status of COT67B 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 COT67B 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 COT67B 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. COT67B cotton is not expected to

increase the total acreage of cotton production or the use of Bt cotton. Syngenta anticipates that COT67B cotton will primarily replace some of the Bt cotton cultivars already on the market today (Syngenta 2007). A determination of nonregulated status of COT67B cotton will not result in changes in the current practices of crop rotation, tillage, and overall pesticide use. Studies demonstrate COT67B cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Syngenta 2007). The effect of COT67B 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. During the public comment period, APHIS received comments opposing a determination of nonregulated status of COT67B 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 COT67B cotton detailed in the EA or the PPRA (USDA-APHIS 2009); 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 addressed substantive comments in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

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

Based on the analysis documented in the EA the possible 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 COT67B 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. Syngenta anticipates that COT67B cotton will primarily replace some of the Bt cotton cultivars already on the market today (Syngenta 2007). A determination of nonregulated status of COT67B cotton will not result in changes in the current practices of crop rotation, tillage, and overall pesticide use. Studies demonstrate COT67B cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Syngenta 2007). The effect of COT67B 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), COT67B 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 total cotton acres planted in 2009, 88% were GE cotton and 65% of that GE cotton acreage was GE insect-resistant

(Bt) cotton (USDA-ERS 2010). 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 COT67B 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 COT67B 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 COT67B 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 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.

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, COT67B 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 herbicides, but may also have progeny with no transgenes at all. There is no guarantee that COT67B 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.

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 COT67B cotton will not 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 COT67B 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 COT67B cotton. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of COT67B 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 COT67B 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 cultivation of COT67B cotton and its progeny 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 COT67B 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 COT67B cotton is unlikely to pose a plant pest risk, a determination of nonregulated status of COT67B 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. Syngenta submitted a summary of its safety and nutritional assessment to FDA for COT67B cotton. In February 2009, FDA completed Syngenta's consultation on COT67B cotton regarding the safety and nutritional assessment for the cotton and had no further questions (US-FDA No.000112)(see Appendix A of the EA). Tolerance exemptions and conditional pesticide registrations have been granted for the plant-incorporated protectant in COT67B cotton and the genetic material necessary for its production. On July 16, 2008, the EPA granted an exemption from the requirement of a tolerance for residues of FLCry1Ab in or on food and feed commodities of cotton (73 FR 40760-40764). Likewise, on October 29, 2008, EPA approved the conditional registration of FLCry1Ab produced in COT67B cotton for use as a lepidopteran insecticide (73 FR 64323-64324) (US-EPA 2008). 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 COT67B 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)

regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of COT67B cotton will not have any significant environmental effects.

Michael C. Gregoire

8-24-11

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Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
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Date:

Literature Cited:

Benbrook, C. (2009). Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years, The Organic Center: 69.

Syngenta (2007). Petition for the Determination of Nonregulated Status for Event COT67B. Submitted by J. N. Reed, Regulatory Affairs Manager. Syngenta Biotechnology, Inc. (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

US-EPA (2008). Biopesticides Registration Action Document Bacillus thuringiensis modified Cry1Ab (SYN-IR67B-1) and Vip3Aa19 (SYN-IR102-7) insecticidal proteins and the genetic material necessary for their production in COT102 XCOT67B cotton.

USDA-APHIS (2009). Plant pest risk assessment for Syngenta COT67B cotton. Riverdale, MD, USDA APHIS Biotechnology Regulatory Services.

USDA-ERS (2009). "Data Sets: Organic Production." Retrieved January 20, 2010, from <http://www.ers.usda.gov/data/organic/#national>.

USDA-ERS (2010). "Adoption of Genetically Engineered Crops in the U.S." Retrieved April 29, 2010, from <http://www.ers.usda.gov/Data/BiotechCrops/>.

USDA-NASS (2010). "The Census of Agriculture." Retrieved January 11, 2010, from <http://www.agcensus.usda.gov/>.

Attachment
Finding of No Significant Impact
Response to Comments
Petition 07-108-01p

On May 11, 2011, APHIS published a notice in the Federal Register (76 FR 27301-27303, Docket no. APHIS-2007-0130) announcing the availability of the Syngenta 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 July 11, 2011. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 7 comment responses were received from various groups and individuals during the comment period. An additional 4,045 names were submitted as an attachment to one of the comment documents. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. The 7 comments expressed opposition to a determination of nonregulated status of COT67B 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 COT67B cotton detailed in the EA or the PPRA; 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. In addition, a single public comment generally claimed that the draft EA was inadequate. However, no explanation was provided for this reasoning. The following are responses to substantive comments received by APHIS.

1. Comment: A commenter expressed concern regarding gene flow from COT67B cotton to organic cotton.

Response: As discussed in Chapter IV of the EA, it is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic seed, will be substantially impacted by the expected commercial use of COT67B cotton. Transgenic cotton lines including those that are resistant to lepidopteran insects are already in widespread use by farmers. COT67B cotton should not present any new and different issues and impacts for organic and other specialty cotton producers and consumers. According to the petition, agronomic trials conducted in 2005 and 2006 in a variety of locations in the U.S. demonstrated that COT67B cotton is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Syngenta, 2007). No differences were observed in pollen diameter, weight, and viability. Therefore, COT67B cotton is not expected to have an increased ability to cross pollinate other cotton varieties.

Organic farming operations as described by the USDA National Organic Program (NOP) requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will

be carried between the fields (Baier, 2008; Bradford, 2006; NCAT, 2003; Sundstrom et al., 2002). Commonly used production practices for cotton and the practical methods typically used by cotton farmers using organic methods to protect their crop under organic production (NCAT, 2003) provide many measures that greatly reduce the likelihood of accidental gene flow between COT67B cotton and non-GE cotton fields.

The US-EPA (2001) acknowledges the potential for gene transfer of the Bt endotoxin from Bt cotton to other cultivated cotton varieties in close proximity. However, commercially available cotton cultivars are generally considered to be self-pollinated (Hartman et al., 1981). Wind pollination is considered unimportant because cotton pollen is heavy and sticky and is not transported easily by the wind. Some insect cross-pollination can occur if suitable insects are present and in large enough numbers (Fryxell, 1979; McGregor, 1976). However, pollen movement by insects is considered to be low (McGregor 1976). A majority of field-based research with cotton shows an outcrossing rate of 10% or less within 1 meter of the pollen source (Andersson and Carmen de Vicente, 2010). Cross pollination percentages between cotton plots remain very low and exponentially decrease with distance, regardless of potential insect pollinator activity (Llewellyn and Fitt, 1996; Van Deynze et al., 2005). These results demonstrated and reinforced the efficacy of separation distance as a tool in mitigating gene flow between neighboring cotton fields (Umbec et al., 1991; USDA-APHIS, 2011), where cross pollination was found to average 0.01 percent at a distance of 5331 feet (Van Deynze et al., 2005).

Based on these factors and organic cotton growers continued adherence to NOP approved production standards, such as the maintenance of adequate isolation distances between GE and non-GE cotton fields, the planting of border or barrier rows to intercept pollen, employing natural barriers to pollen movement such as tree lines, and staggering planting dates, a determination of nonregulated status of COT67B cotton would not increase the likelihood of gene flow from COT67B cotton to organic cotton.

References

- Andersson, M. S. and M. Carmen de Vicente (2010). *Gene Flow between Crops and Their Wild Relatives*. Baltimore, The Johns Hopkins University Press.
- Hartman, H. T., W. J. Flocker, et al. (1981). *Plant Science: Growth, Development and Utilization of Cultivated Plants*. Englewood Cliffs, NJ, Prentice-Hall, Inc.
- Andersson MS and Carmen de Vicente M. (2010) *Gene Flow between Crops and Their Wild Relatives*. Baltimore: The Johns Hopkins University Press.
- Baier A (2008). Organic standards for crop production ATTRA. Retrieved December, 2010 from http://attra.ncat.org/attra-pub/PDF/nopstandard_crops.pdf
- Bradford KJ (2006). *Methods to Maintain Genetic Purity of Seed Stock* Publication 8189. University of California, Division of Agriculture and Natural Resources. Retrieved from <http://ucanr.org/freepubs/docs/8189.pdf>
- Fryxell PA. (1979) *The Natural History of the Cotton Tribe (Malvaceae, tribe Gossypieae)*. College Station and London: Texas A&M University Press
- Hartman HT, Flocker WJ, and Kofranck AM. (1981) *Plant Science: Growth, Development and Utilization of Cultivated Plants*. Englewood Cliffs, NJ: Prentice-Hall, Inc.

- Llewellyn D and Fitt G. (1996) Pollen dispersal from two field trials of transgenic cotton in the Namoi Valley, Australia. *Molecular Breeding*, 2(2), 157-166.
- McGregor SE. (1976) *Insect Pollination of Cultivated Crop Plants*. Washington: U.S. Government Printing Office.
- NCAT (2003). NCAT's organic crops workbook: a guide to sustainable and allowed practices National Center for Appropriate Technology. Retrieved March 30, 2010 from <http://attra.ncat.org/attra-pub/PDF/cropsworkbook.pdf>
- Sundstrom F, Williams J, Van Deynze A, and Bradford K (2002). Identity Preservation of Agricultural Commodities Seed Biotechnology Center, UC Davis. Retrieved June, 2011 from <http://ucanr.org/freepubs/docs/8077.pdf>
- Syngenta (2007). Petition for the Determination of Nonregulated Status for Event COT67B. Submitted by J. N. Reed, Regulatory Affairs Manager. Syngenta Biotechnology, Inc. (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).
- Umbeck P, Barton K, Nordheim E, McCarty J, Parrott W, and Jenkins J. (1991) Degree of Pollen Dispersal by Insects from a Field Test of Genetically Engineered Cotton. *Journal of Economic Entomology*, 84, 1943-1950.
- USDA-APHIS (2011). Syngenta Biotechnology, Inc. Petition (07-108-01p) for Determination of Nonregulated Status of Lepidopteran-Resistant Event COT67B Cotton Draft Environmental Assessment United States Department of Agriculture - Animal and Plant Health Inspection Service. Retrieved June, 2011 from http://www.aphis.usda.gov/brs/aphisdocs/07_10801p_dea.pdf
- Van Deynze AE, Sundstrom FJ, and Bradford KJ. (2005) Pollen-Mediated Gene Flow in California Cotton Depends on Pollinator Activity. *Crop Sci.*, 45(4), 1565-1570.

2. Comment: A commenter expressed concern regarding the safety of COT67B fiber on human skin.

Response: As discussed in Chapter IV of the EA, based on the analysis of field and laboratory data and scientific literature provided by Syngenta (Syngenta, 2007), and safety data available on earlier insect-resistant GE cotton, along with the completion of the consultation process with FDA, APHIS has concluded that a determination of nonregulated status of COT67B cotton would have no significant impacts on human health.

The EPA concluded that human exposure to Cry proteins as the result of skin contact with plants is not likely, due to the containment of Cry proteins within individual plant cells that limits this exposure route (EPA, 2010). Following a voluntary consultation between Syngenta Biotechnology and the FDA regarding COT67B, FDA concluded that COT67B does not present a human health risk (FDA, 2011). Additionally, the Cry1Ab protein, like several other similar Cry proteins, was granted a permanent exemption from the requirement of tolerance by the EPA through its statutory authority under the Federal Food Drug and Cosmetics Act (40 CFR 180.1173).

Dermal contact with Cry1Ab in processed COT67B fiber is unlikely to pose a human health risk due to several factors. These factors include: a) a lack of similarity between Cry1Ab and any known toxin (beyond other Cry proteins) or allergen following a bioinformatics query; b) the recognition by FDA and EPA that Cry1Ab is unlikely to pose a significant human health risk; c)

the absence of Cry1Ab in COT67B fiber separated from seed; and d) the fact that the processing of cotton fiber prior to incorporation into various products results in little or no plant protein persistence of any kind (Davies et al., 2001; ICAC, 2000; Syngenta, 2007). Thus, direct dermal exposure to COT67B fiber is unlikely to result in a human health risk because Cry1Ab is not regarded as a risk to human health and it is unlikely to be found in processed cotton fibers used in clothing.

References

- Davies H, Williams D, and Hardy A (2001) Opinion on Genetically Modified Cotton and Medical Devices. European Commission Health and Consumer Protection Directorate-General. Retrieved June, 2011 from http://ec.europa.eu/food/fs/sc/ssc/out216_en.pdf
- EPA (2010) Biopesticide Registration Action Document: Cry1Ab and Cry1F Bacillus thuringiensis (Bt) Corn Plant-Incorporated Protectants. Washington DC: Environmental Protection Agency. Retrieved June, 2011 from <http://www.epa.gov/oppbppd1/biopesticides/pips/cry1f-cry1ab-brad.pdf>
- FDA (2011). Completed Consultation on Bioengineered Foods Food and Drug Administration. Retrieved June, 2011 from <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing>
- ICAC (2000) Report of an Expert Opinion on Biotechnology in Cotton. Washington DC: International Cotton Advisory Committee. Retrieved June, 2011 from http://www.icac.org/cotton_info/tis/biotech/documents/expert_panel/Reportexpert.pdf
- Syngenta (2007). Petition for the Determination of Nonregulated Status for Event COT67B. Submitted by J. N. Reed, Regulatory Affairs Manager. Syngenta Biotechnology, Inc. (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).