

# Notices

Federal Register

Vol. 67, No. 226

Friday, November 22, 2002

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. 01-025-2]

#### Monsanto Co.; Availability of Determination of Nonregulated Status for Cotton Genetically Engineered for Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

**SUMMARY:** We are advising the public of our determination that the Monsanto Company cotton designated as Event 15985, which has been genetically engineered for insect resistance, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Monsanto Company in its petition for a determination of nonregulated status, our analysis of other scientific data, and comments received from the public in response to a previous notice. This notice also announces the availability of our written determination and our finding of no significant impact.

**EFFECTIVE DATE:** November 5, 2002.

**ADDRESSES:** You may read a copy of the determination, an environmental assessment and finding of no significant impact, the petition for a determination of nonregulated status submitted by Monsanto Company, and all comments received on the petition and the environmental assessment in our reading room. The reading room is located in room 1141, USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure that someone is

available to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.gov/ppd/rad/webrepor.html>. FOR FURTHER INFORMATION CONTACT: Dr. David Heron, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5141. To obtain a copy of the determination or environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: [Kay.Peterson@aphis.usda.gov](mailto:Kay.Peterson@aphis.usda.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

On December 7, 2000, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 00-342-01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for cotton (*Gossypium hirsutum* L.) designated as Bollgard II Cotton Event 15985 (event 15985), which has been genetically engineered for resistance to certain lepidopteran insect pests. The Monsanto petition states that the subject cotton should not be regulated by APHIS because it does not present a plant pest risk.

On March 18, 2002, APHIS published a notice in the **Federal Register** (67 FR 11973-11974, Docket No. 01-025-1) announcing that the Monsanto petition and an environmental assessment (EA) were available for public review. That notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject cotton and food products developed from it. APHIS received seven comments on the petition and the EA during the 60-day comment period, which ended May 17, 2002. The comments were received from university entomologists and extension specialists, an agricultural services company, and a consumer advocacy group. Six comments were in support of the subject petition, and one comment was critical of the EA prepared for the proposed determination of nonregulated status. The commenters supporting nonregulated status for the subject

cotton emphasized its effectiveness in insect control and the related reductions in insecticide applications, the importance of the two *Bacillus thuringiensis* (Bt) toxins in high dose insect resistance management strategies, its usefulness in integrated pest management, the absence of the risk of development of a new plant pest, and the similarities in the environmental effects of event 15985 cotton to traditionally-bred varieties. One commenter stated that the EA prepared for the petition was inadequate and the preparation of an environmental impact statement was necessary because allowing large-scale commercialization of this cotton constituted a major Federal action that would significantly impact the environment. The alleged inadequacies in the EA included failures to address the cumulative effects of gene stacking, the concerns of organic farmers, and the environmental impacts of the approval of a so-called illegal grant of the genetic resource of insect susceptibility to Bt from the public trust into the possession of commercial entities. We have provided a response to these comments as an attachment to our finding of no significant impact (FONSI), which is available from the person listed under FOR FURTHER INFORMATION CONTACT.

Cotton event 15985 has been genetically engineered to express a Cry2Ab insecticidal protein derived from the common soil bacterium *B. thuringiensis* subsp. *kurstaki* (Btk). The petitioner states that the Cry2Ab protein is effective in providing protection from the feeding of lepidopteran insect pests such as tobacco budworm, pink bollworm, and cotton bollworm. The subject cotton event also expresses the  $\beta$ -D-glucuronidase (GUS) protein used as a selectable marker. Expression of the added genes is controlled in part by gene sequences from the plant pathogens cauliflower mosaic virus and *Agrobacterium tumefaciens*. Particle acceleration technology was used to transfer the added genes into the recipient Delta and Pine Land Company variety 50B (DP50B). Cotton cultivar DP50B expresses a Btk Cry1Ac insecticidal protein and a NPTII selectable marker protein, and was developed from cotton event 531, which was deregulated by APHIS in 1995 (APHIS No. 94-308-01p).

Cotton event 15985 has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. This cotton has been field tested since 1998 in the United States under APHIS notifications. In the process of reviewing the notifications for field trials of the subject cotton, APHIS determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive and physical containment or isolation, would not present a risk of plant pest introduction or dissemination.

#### Determination

Based on its analysis of the data submitted by Monsanto, a review of other scientific data, field tests of the subject cotton, and comments submitted by the public, APHIS has determined that cotton event 15985: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than cotton developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or organisms, such as bees, that are beneficial to agriculture. Therefore, APHIS has concluded that the subject cotton and any progeny derived from hybrid crosses with other nontransformed cotton varieties will be as safe to grow as cotton in traditional breeding programs that is not subject to regulation under 7 CFR part 340.

The effect of this determination is that Monsanto's cotton event 15985 is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the subject cotton or its progeny. However, importation of cotton event 15985 and seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

#### National Environmental Policy Act

An EA was prepared to examine the potential environmental impacts associated with a determination of nonregulated status for Monsanto's cotton event 15985. The EA was prepared in accordance with (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions

of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on that EA, APHIS has reached a FONSI with regard to its determination that cotton event 15985 and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and FONSI are available from the individual listed under FOR FURTHER INFORMATION CONTACT.

Done in Washington, DC, this 19th day of November 2002.

Peter Fernandez,

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 02-29752 Filed 11-21-02; 8:45 am]

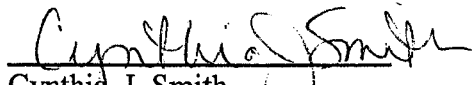
BILLING CODE 3410-34-P

Approval of Monsanto Company Petition (00-342-01P) Seeking a Determination of Nonregulated Status for Bollgard II Cotton Event 15985 Producing the Cry2Ab Insect Control Protein derived from *Bacillus thuringiensis* subsp. *kurstaki*

**Environmental Assessment and Finding of No Significant Impact**

October 2002

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA) has prepared an environmental assessment (EA) prior to approving a petition (APHIS number 00-342-01P) received from Monsanto Company for a determination of nonregulated status under APHIS regulations at 7 CFR Part 340. The subject of this petition, Cotton Event 15985, is genetically engineered for resistance to feeding damage by certain lepidopteran insect pests of cotton by the insertion of gene which encodes production of the Cry2Ab protein. Cotton event 15985 is also genetically engineered to express a selectable marker, the enzyme neomycin phosphotransferase which confers resistance to the antibiotic kanamycin. On March 18, 2002, APHIS published a notice in the Federal Register (67 FR 11973-74, Docket no. 01-025-1) announcing the availability of the petition and EA for public review and comment. During the designated 60-day comment period, APHIS received seven comments. APHIS' analysis of and response to these comments is included as an attachment to this finding. Based on the analysis carried on in the EA and our response to the comments, APHIS has reached a finding of no significant impact (FONSI) to the environment from its determination that Cotton Event 15985, and progeny derived from it, shall no longer be considered regulated articles. This determination is attached to the EA as Appendix D.

  
Cynthia J. Smith,  
Acting Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture  
Date: NOV 05 2002

## **APHIS' Analysis and Response to Comments Received on Petition 00-342-01P and the EA.**

APHIS received seven (7) comments on the petition and the EA during the 60-day comment period. The written comments were received from university entomologists and extension specialists, an agricultural services company, and a consumer advocacy group. The comment letters in favor of a determination of nonregulated status for Cotton Event 15985 totaled six (6) , whereas one (1) comment letter opposed deregulation.

The comments supporting nonregulated status for the subject cotton emphasized its effectiveness in insect control and the related reductions in insecticide applications, the importance of the two BT proteins as part of high-dose insect resistance management strategies, its usefulness in integrated pest management, the absence of the risk of development of a new plant pest, and the similarities in the environmental effects of event 15985 cotton to traditionally-bred cotton varieties.

One commenter found the EA prepared for the petition inadequate and the preparation of an environmental impact statement necessary because allowing large scale commercialization of this cotton constituted a major federal action that will significantly impact the environment. The commenter alleged inadequacies in the EA which included failures to address the cumulative effects of gene stacking and the concerns of organic farmers, and the illegal grant of the genetic resource of insect susceptibility to BT from the public trust into the possession of commercial entities. Further characterization of and response to those comments in opposition are given below. APHIS has confined the response to the points made by the commenter to those which relate to plant pest or environmental risks posed by the subject determination of nonregulated status under the regulations in 7 CFR part 340.

### **Allowing large scale commercialization of Cotton Event 15985 requires an Environmental Impact Statement.**

APHIS believes that the commenter has mis-characterized the scope of the agency's determination of nonregulated status. The APHIS determination of nonregulated status does not dictate the extent to which this cotton or subsequent progeny will be used in agricultural production. The regulations at 7 CFR Part 340 are not marketing regulations. Nonregulated status would merely remove the requirement for APHIS authorizations for interstate movements, importations, and cultivation.

In response to the commenter's claim that APHIS must prepare a complete environmental impact statement (EIS), APHIS notes that the agency's NEPA Implementing Procedures (7 CFR 372) do not indicate that this type of action is of the class of actions normally requiring the preparation of an EIS. A determination of nonregulated status is characteristic of the class of actions normally requiring an EA, but not necessarily an EIS. The APHIS analysis documented in the EA (and in the response to comments) does not indicate that a significant impact to the human environment is likely; therefore the preparation of an EIS is not appropriate. APHIS does not believe a decision to deregulate Cotton Event 15985, when combined with previous decisions

to deregulate other genetically engineered crops with totally different traits, uses, and markets, will influence or cause a significant cumulative impact to the human environment which would warrant the preparation of an EIS.

**Failure to address the cumulative effects of gene stacking.**

APHIS understands the phrase "gene stacking" to mean the combination of certain genes with other genes present in the organism. For example, in the case of cotton it is common for plant breeders to stack or combine desirable traits such as lint strength with resistance to insects by selecting the individual plants that perform well even when insect infestations are severe.

In conducting its assessment, APHIS has considered that Cotton Event 15985 and its progeny will be crossed with other cotton lines to produce new varieties. With each cross comes the possibility of recombining the thousands of genes which are responsible for the characteristics of the resultant cotton plants. The cumulative effects of gene stacking are part of all variety development programs, regardless of whether recombinant DNA techniques are used to introduce certain genes. APHIS has considered the long history of plant breeding as part of its evaluation, and the fact that plant breeders and growers are constantly selecting those plants which exhibit desired traits.

**Failure to address the concerns of organic farmers.**

In the commenter's section on concerns of organic farmers, the commenter makes several references to the impact on non-GMO corn, the corn seed market, and genetically engineered corn in the crops and commodities of organic farmers. APHIS believes that it is unlikely that Cotton Event 15985 will impact the non-GMO corn. Cotton and corn do not interbreed and APHIS believes that it is very easy to distinguish the seeds and plants of cotton from corn.

Even if the commenter had meant to raise this issue with organic cotton seed, APHIS does not agree that the EA is inadequate in the analysis of the impacts of the issues related to organic farmers. The determination of nonregulated status under 7 CFR Part 340 does not affect the provisions of the the National Organic Program (NOP) which is administered by USDA's Agricultural Marketing Service. The NOP considers that the presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards. (Please refer to the preamble of the NOP final rule at residue testing, changes requested but not made, (3) Threshold for Genetic Contamination for a discussion of "adventitious presence" in relation to organic production; available on-line at website: <http://www.ams.usda.gov/nop/nop2000/Final%20Rule/preamble/pre-residues.htm>.) Further, the NOP requires that organic production operations have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances from adjoining land that is not under organic management. The organic system plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods.

**Failure to address the illegal grant of the genetic resource of insect susceptibility to BT from the public trust into the possession of commercial entities.**

The APHIS determination of nonregulated status does not address intellectual property rights in any way. The issue of whether such organisms could be patented was decided by the U.S. Supreme Court on June 16, 1980 (Diamond v. Chakrabarty, No. 79-136) when the court ruled that forms of life carrying a manmade genetically engineered component can be patented. APHIS is not involved in decisions on granting of resources to commercial entities, but rather regulates under authority of the Plant Protection Act (Title IV, Pub. L. 106-224, 114 Stat. 438, 7 U.S.C. 7701-7772) certain genetically engineered plants to assure that such plants do not pose a plant pest risk to agriculture or the environment. APHIS considers a range of environmental impacts in making our determination, but these considerations are independent of patent issues of which this agency has no control.

**USDA-APHIS Decision on Monsanto Company Petition 00-342-01P**  
**Seeking a Determination of Nonregulated Status**  
**for Bollgard II Cotton Event 15985 Producing the Cry2Ab**  
**Insect Control Protein derived from *Bacillus thuringiensis* subsp. *kurstaki***

## **Environmental Assessment**

### **TABLE OF CONTENTS**

I.	SUMMARY	1
II.	BACKGROUND	1
III.	PURPOSE AND NEED	3
IV.	ALTERNATIVES	3
V.	POTENTIAL ENVIRONMENTAL IMPACTS	4
VI.	LITERATURE CITED	17
VII.	PREPARERS AND REVIEWERS	21
VIII.	AGENCY CONTACT	21

### **APPENDICES**

Appendix A: Biology of cotton and potential for introgression into related species.

Appendix B: List of APHIS authorizations for field tests of Cotton Event 15985

Appendix C: Summary table of data submitted with the petition in support of nonregulated status for Monsanto's Bollgard II Cotton Event 15985.

Appendix D: Table comparing environmental impacts of Cry2Ab with other insecticides used to control lepidopteran pests of cotton in the United States.

Appendix E: Determination of nonregulated status for Cotton Event 15985.

---

Trade and company names are used in this publication solely to provide specific information. Mention of a trade or company name does not constitute a warranty or an endorsement by the U.S. Department of Agriculture to the exclusion of other products or organizations not mentioned.

Registrations of pesticides are under constant review by the U.S. Environmental Protection Agency (EPA). Use only pesticides that bear the EPA registration number and carry the appropriate directions.

## **I. SUMMARY**

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has prepared an Environmental Assessment (EA) prior to making its determination on the regulated status of cotton (*Gossypium hirsutum* L.) line designated as Bollgard II Cotton Event 15985 (hereafter referred to as Cotton Event 15985). Like its predecessor, Bollgard I, Cotton Event 15985 has been genetically engineered to express a bacterial gene from *Bacillus thuringiensis* (BT) which enables the plant to resist feeding damage from lepidopteran insects.

APHIS is making this determination in response to a petition (designated 00-342-01P) received from Monsanto Company for a determination that Cotton Event 15985 does not present a plant pest risk, and therefore should no longer be considered as a regulated article under APHIS regulations found at 7 CFR Part 340. The petition submitted by Monsanto contains extensive information relevant to this determination. Cotton Event 15985 has been considered a regulated article under APHIS regulations at 7 CFR Part 340 because some DNA regulatory sequences used to control the expression of these foreign genes in cotton were derived from plant pests.

As a regulated article under the provisions of 7 CFR Part 340, the importation, interstate movement, or cultivation in the environment of Cotton Event 15985 has been conducted under authorizations from APHIS. These authorizations stipulate conditions of physical and reproductive confinement that preclude the regulated article from becoming mixed with nonregulated articles or persisting in the environment outside the test site.

This EA summarizes the APHIS review of potential environmental impacts that might occur from an APHIS determination that Cotton Event 15985 should no longer be considered a regulated article under the regulations found at 7 CFR Part 340.

## **II BACKGROUND**

### **A. Development of Cotton Event 15985.**

Monsanto developed Cotton Event 15985 to serve as a replacement and/or an improvement to the first generation of BT-cotton varieties they designate as Bollgard I. The primary lepidopteran pests to be controlled are cotton bollworm (*Helicoverpa zea*), tobacco budworm (*Heliothis virescens*), and pink bollworm (*Pectinophora gossypiella*). The petition describes field tests in which Cotton Event 15985 appeared to be more effective than Bollgard I varieties in the control of cotton bollworm, tobacco budworm and pink bollworm. In one test, Fall armyworm control was also shown to be improved.



## **B. APHIS Regulatory Authority.**

APHIS regulations under 7 CFR Part 340, which are promulgated pursuant to authority granted by the Plant Protection Act (Title IV, Pub. L. 106-224, 114 Stat. 438, 7 U.S.C. 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. A genetically engineered 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 and is also a plant pest, or if there is reason to believe that it is a plant pest. Cotton Event 15985 has been considered a regulated article because some noncoding DNA regulatory sequences were derived from plant pathogens.

Section 340.6 of the regulations, entitled "Petition for Determination of Nonregulated Status", provides that a person may petition the Agency to evaluate submitted data and determine that a particular regulated article does not present a plant pest risk and should no longer be regulated. If APHIS determines that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it is derived, the Agency can grant the petition in whole or in part. Therefore, APHIS permits or notifications would no longer be required for field testing, importation, or interstate movement of that article or its progeny.

## **C. U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Regulatory Authority.**

Cotton Event 15985 is also subject to regulation by other agencies. The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides be registered before distribution or sale, unless exempt by EPA regulation. On March 21, 2001, the EPA announced receipt of an application from Monsanto Company [EPA File Symbol 524-LEE] to register the pesticide product *Bt* Cry2Ab protein and the genetic material necessary for its production in cotton plants (<http://www.epa.gov/EPA-PEST/2001/March/Day-21/p6761.htm>). This active ingredient is not included in any previously registered product. The EPA has not announced its final decision on this application. Before a product may be registered as a pesticide under FIFRA, it must be shown that when used in accordance with widespread and commonly recognized practices, it will not cause unreasonable adverse effects on the environment.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA; and the FDA enforces the tolerances set by the EPA. In the Federal Register of October 10, 1997 (62 FR 52998) (FRL-5748-5), EPA issued a notice pursuant to Section 408 of the FFDCA announcing the filing of a pesticide tolerance petition, petition number 7F4888, by Monsanto regarding the Cry2Ab protein. EPA received no comments in response to this filing and subsequently published in the Federal Register on May 11, 2001, its regulation establishing a time-limited exemption from the requirement of a tolerance for residues of the

plant-pesticide Cry2Ab2 protein (synonym for the Cry2Ab protein). This regulation will expire May 1, 2004.

FDA's 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, and appears at 57 *FR* 22984-23005. Monsanto Company submitted a summary of their safety assessment to the FDA on June 30, 2000, and FDA sent a letter to Monsanto indicating that the agency had completed its food safety and nutritional consultation on Cotton Event 15985 on July 18, 2002.

### **III. PURPOSE AND NEED**

In compliance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*) and the pursuant implementing regulations (40 CFR 1500-1508, 7 CFR Part 1b; 7 CFR Part 372), APHIS has prepared this EA before making a determination on the status of Cotton Event 15985 as a regulated article under APHIS regulations found at 7 CFR Part 340.

### **IV. ALTERNATIVES**

#### **A. No Action: Continuation as a Regulated Article**

Under the "no action" alternative, APHIS would not come to a determination that Cotton Event 15985 should no longer be considered as a regulated article under 7 CFR Part 340. As such, APHIS authorizations would still be required for introductions, thereby effectively precluding the possible use of this cotton and its progeny from typical commercial farming production. APHIS can choose this alternative if there is insufficient evidence to demonstrate lack of plant pest risk from the unconfined cultivation of Cotton Event 15985 cotton and its progeny.

#### **B. Proposed Action: Determination of Nonregulated Status, in Whole**

Under this alternative, APHIS would determine that Cotton Event 15985 cotton and its progeny would no longer be considered regulated articles under 7 CFR Part 340, because they do not meet the definition described in the regulation. With such a determination of nonregulated status, APHIS authorizations would not be required for not be necessary for introductions of this cotton in the United States or its territories. A determination of nonregulated status under 7CFR Part 340 does not preclude any other requirements which might be placed on the use of these plants by other regulations (e.g., registration with EPA).

#### **C. Proposed Action: Determination of Nonregulated Status, in Part**

The regulations at 7 CFR Part 340.6 (d) (3) (I) state that APHIS may "approve the petition in whole or in part." There are two ways in which a petition might be approved in part:

1. Approval of some but not all of lines requested in the petition. In some petitions, applicants request de-regulation of lines derived from more than one independent transformation event. In these cases, supporting data must be supplied for each line. APHIS could approve certain lines requested in the petition, but not others.

2. Approval of the petition with geographic restrictions. APHIS could determine that the regulated article poses no significant risk in certain geographic areas, but may pose a significant risk in others. In such a case, APHIS might choose to approve the petition with a geographic limitation stipulating that the approved lines could only be grown without APHIS authorization in certain geographic areas.

## **V. POTENTIAL ENVIRONMENTAL IMPACTS**

APHIS considered potential environmental impacts of each of the three alternatives described in Section IV above.

### **A. Alternative A: No Action**

If APHIS takes no action (i.e., does not grant nonregulated status), commercial scale production of Cotton Event 15985 and its progeny is effectively precluded. These plants could still be grown, although still under the requirements of APHIS authorizations (permits or notifications). The plants could be evaluated in field trials for variety development as they have been grown for the past several years. APHIS is unaware of any significant environmental impacts associated with field testing of these plants, and the Agency expects that future field tests under APHIS authorizations would be similar.

With respect to commercial production, APHIS believes that without the option of cultivating Cotton Event 15985 or its progeny, cotton producers would still have the same options available to them for the control of insect pests of cotton. It appears likely that the potential environmental impact from continued regulated status of Cotton Event 15985 would not be significant. Cotton farmers would continue to use existing technologies for the control of these target lepidopteran pests. Appendix A lists the chemical insecticides that can be used for the control of these pests. Although the chemical insecticides are commonly considered to have a negative effect on nontarget organisms, including humans, cotton farmers might also choose the first generation BT-cotton varieties which utilize the Cry1Ac protein to deter feeding of lepidopteran insects. The EPA has recently re-registered the use of these varieties for use in the United States. It is estimated that approximately one-third of US cotton acreage is planted with BT-cotton varieties which express the *cry1Ac* gene (National Cotton Council, 1999).

The development and registration of varieties based on Event 15985 and its progeny could increase the control options to growers and extend the usefulness of the first generation BT-cotton varieties by slowing the development of insect populations that would develop resistance to the Cry1Ac

protein produced in these varieties. However, granting nonregulated status does not guarantee the extent to which a new plant line, such as Cotton Event 15985, would be adopted by growers.

As regulated articles, the field testing of Cotton Event 15985 plants could continue under APHIS authorizations (permits or notifications), but commercial scale production would not be feasible. APHIS does not foresee significant impacts to the environment if Alternative A is chosen.

## **B. Alternative B: Approval of the Petition in Whole**

APHIS may grant a petition for nonregulated status in whole or in part. By granting the petition in whole, APHIS would grant the petition as requested, i.e., that Cotton Event 15985 would no longer be considered a regulated article. The APHIS assessment of the environmental impacts of such a determination are discussed in the following sections. Environmental impacts of unrestricted cultivation of cotton line 15985 are compared to impacts of current practices in the cultivation or distribution of cotton not regulated under 7 CFR part 340.

### **1. Plant pathogenic properties**

APHIS has considered whether the regulated article exhibits plant pathogenic attributes that would pose a plant pest risk. APHIS has focused first on the DNA sequences introduced and the transformation protocol used to introduce the sequences. APHIS considered information from the scientific literature as well as primary observations made by the developer when the plants were grown in the environment.

#### ***Recipient organism***

The starting plant material for the transformation was cotton derived from Delta and Pine Land Company variety 50B (also known as DP50B and event 531), a variety which expresses the *cry 1Ac* gene. As stated above, this line was deregulated in 1995 by APHIS and received the appropriate registration from EPA so that it could be commercially released to growers beginning in 1996. Since that time, traditional plant breeding was used to introduce the insect protection of *cry1Ac* into numerous cotton varieties which have been known commercially as Bollgard and NuGard cotton. As expected from commercially successful varieties, these varieties have not exhibited any plant pathogenic characteristics.

#### ***Transformation system***

The transformation system for Cotton Event 15985 employed a particle acceleration technology technique that shoots DNA into plant cells without the use of an intermediary organism to accomplish transfer of the DNA sequences described below. This is a well characterized technique that has been used for the transformation of plant cells for over a decade. Monsanto researchers introduced a fragment of the plasmid PV-GHBK11 (see below) by cutting the plasmid to obtain the fragment with the *cry2Ab* and *uidA* genes. Sequences on the remainder of the plasmid (the so-called plasmid backbone) were not introduced.

### ***DNA sequences introduced to make Cotton Event 15985***

The Monsanto petition provided data to support the conclusion that Cotton Event 15985 contains one new DNA insert (petition, page 53). The inserted DNA consists of the following sequences: the 35S promoter of cauliflower mosaic virus (CaMV) with a duplicated enhancer region, a synthetic polylinker sequence of 30 bases, the coding region for the *uidA* gene from *E. coli*, a polylinker of 46 bases, the 3'-nontranslated terminating sequences of the nopaline synthase (*nos*) gene of *Agrobacterium tumefaciens*, a synthetic polylinker sequence of 64 bases, the 35S promoter of CaMV with a duplicated enhancer region, the leader sequences from the petunia heat-shock protein HSP70, and the N-terminal chloroplast transit peptide from the EPSPS gene of the *Arabidopsis thaliana*, a synthetic polylinker of 6 bases, the *cry2Ab* gene of *B. thuringiensis* subsp. *kurstaki*, a synthetic polylinker sequence of 22 bases and the 3'-terminator sequences of the *nos* gene of *A. tumefaciens*. Molecular genetic analyses of the genetic elements indicated that all were intact with the exception of a deletion of approximately 260 bases of the 5'-terminus of the 35S promoter of the *uidA* gene.

Monsanto presented data to confirm that sequences of the plasmid backbone were not introduced when Cotton Event 15985 was made (see petition text page 49 and Figure 16).

Of all of the DNA sequences inserted in the construction of Cotton Event 15985, only the 35S promoter and the *nos* termination sequences were derived from organisms known to be plant pests (CaMV and *A. tumefaciens*, respectively). These noncoding sequences are well characterized, both in their native organisms and as part of recombinant DNA constructs used in plant engineering so that introduced genes can be expressed. There are no data to suggest that the 35S promoter or *nos* terminator sequences cause plant disease or pose a plant pest risk in transgenic plants. Multiple generations of Cotton Event 15985 plants have been observed closely, and the developer has confirmed the expectation that these noncoding DNA sequences do not cause disease in the plants (see sections below for discussion of additional evaluations of the attributes of Cotton Event 15985 plants).

None of the other donor organisms used as sources for the DNA sequences engineered into the cotton to make Cotton Event 15985 are organisms with demonstrated plant pest characteristics. Both *Escherichia coli* and *Bacillus thuringiensis* subsp. *kurstaki* are bacteria commonly found in soils around the world. *E. coli* is also a common constituent of the microbial flora which live in the intestinal tracts of mammals, including humans. *B. thuringiensis* strains have been used for decades in agriculture as the basis for microbial pesticide formulations (bacteria are grown in laboratories to prepare suspensions that can be applied to plant surfaces to deter plant eating insects).

### ***Evaluation of intended effects in Cotton Event 15985: expression of cry2Ab and uidA***

As intended, Cotton Event 15985 expresses the proteins encoded by the *cry2Ab* and *uidA* genes. The petition summarized data which demonstrated the expression of these two proteins and that the gene expression traits also were inherited in a predictable manner when Cotton Event 15985 plants were crossed with other cotton plants (see petition pages 53-61 for Mendelian inheritance data and expression of *cry2Ab* and *uidA* genes). Expression of the Cry2Ab protein was detectable in leaf, seed, and whole plant samples but not in pollen (see petition, pages 55-61). Expression of the beta-

D-glucuronidase protein was detected in leaf and seed samples, but the researchers did not assay whole plant and pollen samples.

Expression of the Cry2Ab protein is designed to confer resistance to certain lepidopteran pests of cotton, and the Monsanto petition provided data on field tests of Cotton Event 15985 in which the plants exhibited some resistance to the lepidopteran insect pests. In 81 field trials conducted during 1998 and 1999 to evaluate insect control efficacy, increased control of the main target insects was detectable in 36 trials, but the other trials had insufficient insect populations feeding on the plants to allow the researchers to distinguish differences. As intended, Cotton Event 15985 plants exhibited some resistance to the lepidopteran insect pests not targeted by the Cry1Ac protein (e.g., loopers and armyworms). However, consistent control was not always demonstrated, because the target pest populations were sometimes too low to provide statistically significant data.

#### ***Evaluation of possible unintended effects in Cotton Event 15985***

Expression of the proteins Cry2Ab and  $\beta$ -D-glucuronidase are not expected to cause plant disease or influence susceptibility of Cotton Event 15985 to plant pathogens or pests. Monsanto evaluated the expression levels of these proteins in Cotton Event 15985 plants growing in the field and confirmed that the plants were no more susceptible to pathogens and pests of cotton other than the expected resistance to certain lepidopteran pests. In field tests, no differences were noted for disease susceptibility or severity in the Cotton Event 15985 plants compared to the control cotton plants that had no BT genes or expressed only the *cry1Ac* gene. These data were reported from field tests in 16 states and Puerto Rico (these represent all states in which cotton is a major crop).

In order to evaluate possible unintended effects of the transformation process, including tissue culture, APHIS considers a wide range of plant attributes in much the same way that traditional plant breeders evaluate the offspring from traditional plant crosses or mutagenesis procedures. These attributes include information on plant morphology, development, chemical composition, and interactions with organisms which that plant species typically interacts. The petition included extensive information on the attributes of Cotton Event 15985. Most of these data were derived from Cotton Event 15985 plants grown in field tests which are designed to simulate conditions that mimic those found in typical cotton cultivation in the United States. Since 1998, Cotton Event 15985 has been evaluated in over 250 field trials conducted in the United States, Puerto Rico, Argentina, South Africa, and Australia. Over the course of 1998 and 1999, Cotton Event 15985 plants were evaluated at a total of 98 field test locations in the United States.

These field observations were made by cotton breeders, agronomists, academics, crop consultants, state variety trials officials, private growers, entomologists, field cooperators, and Monsanto field researchers, all people who are very familiar with cotton agronomic properties and cultivation of the crop. In addition to insect damage ratings, plants were evaluated for disease incidence and severity, plant morphology and maturity parameters, total yield of seed and fiber, and fiber quality (see pages 61-75 in the Petition). Evaluations were made at multiple locations each year in all fifteen major cotton growing states in the United States. Examples of the morphology and maturity characteristics measured include seed germination, plant height, node number, boll size, and boll retention. The

field observations support the conclusion that Cotton Event 15985 is typical of traditional cotton in terms of growth and agronomic performance.

Monsanto also analyzed any potential for changes in the nutrient composition of the seeds and found that the protein, fat, ash, carbohydrate, fatty acids, calories, moisture, and fiber content of Cotton Event 15985 were similar to those of the parental cultivar and within the range of values measured for other commercially grown cotton cultivars. Likewise, amino acid values were similar as were the levels of nine different minerals (Petition, pages 75-77).

Cotton plants naturally produce the compound gossypol, a known toxicant that is believed to protect the plants from being eaten by insects and herbivorous mammals. Levels of the gossypol in Cotton Event 15985 plants were indistinguishable from those measured in the parental cotton cultivar (Petition, pages 77-78).

In evaluating the range of plant attributes, Cotton Event 15985 appears to be similar to the parental cotton line, and differs only in its enhanced ability to resist feeding damage from some lepidopteran pests of cotton. These observations provide further evidence that Cotton Event 15985 has not been modified in unintended ways in the course of transformation, plant generation, and traditional plant breeding. Cotton Event 15985 appears to be similar to its parental line, and other commercial cotton varieties, except for the intended increased resistance to feeding damage from certain lepidopteran pests of cotton. APHIS can not envision any plant pest effects arising from a determination that Cotton Event 15985 should no longer be considered regulated articles under the APHIS regulations found at 7CFR Part 340.

## **2. Potential Impacts based on the relative weediness of Cotton Event 15985 compared to currently cultivated cotton varieties.**

APHIS evaluated whether Cotton Event 15985 would be any more likely to become a weed than the parental line DP50B, or than other cotton varieties currently offered for commercial use. The cultivated cotton from which line 15985 is derived, *Gossypium hirsutum*, is not typically considered a weed species in the United States or other countries (Reed, 1977; Muenscher, 1980; Holm et al., 1977, 1997, USDA, NRCS, 2001) nor is it listed in the Weed Science Society's Composite List of Weeds (1989). However, the Southern Weed Science Society lists *G. hirsutum* as a potential weed in southern Florida (Southern Weed Science Society, 1998). Without human intervention, such as the typical agricultural practices, the cotton plant is a perennial, surviving many years if conditions allow. Cotton does not tolerate cold conditions, and only Hawaii, southern Florida, and Puerto Rico remain warm enough to allow cotton plants to survive the winter. Cotton has some characteristics as a weed, and it has been identified as one in southern Florida.

The Monsanto petition contained data which describe the agronomic properties and pest susceptibility of Cotton Event 15985 in order to further substantiate that these transgenic plants are similar in growth and development to the parental cotton line. Cotton Event 15985 plants have been grown in more than 250 field trials in the United States, Puerto Rico, Argentina, South Africa, Costa

Rica, and Australia since 1998. Quantitative and qualitative field observations of the plants indicate that Cotton Event 15985 plants are similar to other cotton plants.

In addition to the results summarized above, APHIS notes that there have been no reports of increased weediness associated with the plant that is most similar to Cotton Event 15985, namely its parent DP50B, a BT-cotton which has been engineered to express the Cry1Ac protein (see above). Cotton cultivars derived from DP50B have been grown commercially for five years in the United States with no reports of weediness problems. On the basis of all the submitted data and field observations to date, Cotton Event 15985 appears to pose no greater plant pest risk of weediness than that posed by traditional cotton cultivars.

### **3. Potential impacts from gene introgression from Cotton Event 15985 to its sexually compatible relatives.**

Cotton Event 15985, like other cotton, can pass its traits to offspring by transmitting pollen to other plants which are sexually compatible, in this case, some species of the genus *Gossypium* (see Appendix A for a brief technical discussion of the biology and reproductive capability of cotton). Recently, EPA has provided an even more detailed overview of the genus *Gossypium* in its (see especially pages IIC7-IIC13 in US EPA, 2001).

APHIS considered whether such crosses are likely to occur when Cotton Event 15985 is grown, and whether the offspring from such crosses are more likely to pose any greater risk of weediness than crosses of other cotton cultivars with these sexually compatible species.

The genus *Gossypium* contains 39 species, of which generally four species are cultivated for the cotton fibers that are attached to the seeds. Cotton Event 15985 is *Gossypium hirsutum*, the cotton species referred to as upland cotton. Most of the cotton grown in the United States is *G. hirsutum*, but Pima cotton (*G. barbadense* L.) is also grown. In addition to these cultivated species, there are two wild *Gossypium* species in the United States, *G. thurberi* and *G. tomentosum*, which are found in parts of Arizona and Hawaii, respectively. Neither *G. thurberi* nor *G. tomentosum* are listed as weeds, either on the Federal or State lists of noxious weeds (see [http://plants.usda.gov/cgi\\_bin/noxious.cgi?earl=noxious.cgi](http://plants.usda.gov/cgi_bin/noxious.cgi?earl=noxious.cgi)). An older literature citation lists *G. tomentosum* as a weed of unknown importance in its range (Holm et al., 1979).

Genetic incompatibility precludes successful crosses of *G. hirsutum* with *G. thurberi*, but the compatibility of crosses between *G. hirsutum* and *G. tomentosum* is more unknown. Some researchers have speculated that crosses may have occurred in the evolution of *G. tomentosum*, but genetic exchange appears to be rare. Part of the rarity may be due to the fact that *G. hirsutum* is largely self-pollinating rather than cross-pollinating. In addition, the pollinators of *G. hirsutum* tend to be bumblebees, whereas moths pollinate *G. tomentosum*. Also, *G. hirsutum* flowers are sexually receptive for pollination during the day, *G. tomentosum* compatibility is at night.



Even in cases of complete genetic compatibility (*G. hirsutum* crossed with another *G. hirsutum*), successful outcrossing is severely limited when the plants are separated by more than 660 feet. In experiments designed to detect gene flow, detectable gene flow was very low (less than 1%) when *G. hirsutum* plants were 25 meters apart (Umbeck, 1991). Cotton breeders and seed producers routinely use field data to decide on the isolation distances for the production of certified and foundation cotton seeds (660 and 1320 feet, respectively).

In sum, APHIS believes that it is very unlikely that Cotton Event 15985 will successfully cross with wild sexually compatible relatives when grown in the United States. In the unlikely event that such crosses do occur, however, the lack of increased weediness of Cotton Event 15985 (described in the section above) suggests that any offspring would be unlikely to pose an increased risk of weediness.

Because it is unlikely that *G. hirsutum* will readily cross *G. thurberi* and *G. tomentosum*, it is unlikely that the *cry2Ab* gene will introgress from Cotton Event 15985 into *G. thurberi* and *G. tomentosum*. In the registration requirements for the first generation of BT-cotton varieties, the EPA stipulated geographic restrictions in parts of the United States where *G. thurberi* and *G. tomentosum* are found, imposing conditions based on reproductive compatibility in crosses of *G. hirsutum* to other *G. hirsutum*. As summarized above, however, such crosses between the cultivated and wild cottons do not appear to occur in nature. There are no reports of intermediate cotton types that one would expect in the areas where *G. hirsutum* has been grown in proximity to *G. thurberi* and *G. tomentosum*.

On July 2001, EPA published its final FIFRA regulations regarding plant incorporated protectants (of which the BT Cry proteins are an example). It states the following: "The potential for most plants containing plant-incorporated protectants to pose weediness concerns is directly considered by USDA/APHIS under PPA."

Outcrossing considerations may be different in other parts of the world. For example, other species which might potentially intercross with *G. hirsutum* cultivars include *G. mustelinum* in northeastern Brazil, and *G. lanceolatum* in mid-Mexico (Fryxell 1979). Other Old World *Gossypium* cottons are diploid, as are the other five genera of cotton relatives among the *Gossypieae* Tribe (Fryxell, 1979). The likelihood of successful intercrossing with these species may be quite low because of the production of triploids that are likely to be sterile. This is consistent with the fact that such intergeneric crosses have not been observed (Fryxell, 1979).

APHIS believes that gene flow from Cotton Event 15985 to wild cotton relatives is not likely, and if it occurs, would not lead to increased weediness. APHIS agrees with the EPA statement in its final rule on plant-incorporated protectants that "weediness is generally thought to be due to a multiplicity of factors" (EPA, 2001). The National Research Council came to the same conclusion that "genetically modified crops are not known to have become weedy through the addition of traits such as herbicide and pest resistance" (National Research Council, 1989).

#### **4. Potential impacts on nontarget organisms, including beneficial organisms and threatened and endangered species**

APHIS evaluated the potential that Cotton Event 15985 might have an adverse impact on populations of nontarget organisms, i.e., organisms other than the lepidopteran pests of cotton. Such nontarget organisms might be impacted by direct exposure to Cotton Event 15985 plants or their offspring. As discussed in the previous section, APHIS considers it highly unlikely that Cotton Event 15985 will naturally cross with its wild relative, so nontarget organisms would have to be exposed to the tissues of Cotton Event 15985 which express the Cry2Ab protein. To evaluate these potential effects, a standard battery of nontarget organisms are evaluated for their sensitivity by forcing them to ingest controlled amounts of the test substance, in this case, the Cry2Ab protein. Nontarget test organisms also included organisms that are found in or near to the agricultural environment in which Cotton Event 15985 will be grown. In the course of its review for its pesticide registration review, the EPA evaluates potential nontarget effects, also. Based on the data presented, and information in the scientific literature, mitigation measures can be developed if effects on nontarget organisms are anticipated. In the case of pesticide registrations, EPA can mandate mitigation measures as part of the conditions for registration.

##### ***Potential impacts on monarch butterflies***

A 1999 study by Losey et al. reported results from a laboratory study in which monarch butterflies died after eating corn pollen which expressed a BT Cry1Ac protein. These results led to considerable controversy about the potential effects that might arise when nontarget insects ingest plant pollen in which the BT insecticidal protein is expressed. A series of studies over the past two years have concluded that monarch butterflies are unlikely to be significantly affected under the conditions found in the agricultural and nonagricultural environments which they inhabit. This conclusion is consistent with the findings of several scientists which were published as several reports in the Proceedings of the National Academy of Sciences (PNAS) and summarized in an accompanying risk assessment by Sears et al. (2001). In the case of Cotton Event 15985 and other BT-cotton plants, it appears that exposure of monarch butterflies to Cry2Ab protein is even less likely than in the case of corn. Whereas corn plants are wind pollinated and pollen can land on surrounding vegetation that might be ingested by nontarget organisms such as the monarch butterfly, cotton plants are insect-pollinated which largely restricts pollen to the cotton flower. Monarch butterflies are also not likely to be exposed to the Cry2Ab protein expressed by Cotton Event 15985 plants, because the primary geographic range and habitats for monarch butterflies and cotton cultivation do not coincide. Also, in the specific case of Cotton Event 15985, the expression of the Cry2Ab protein in the pollen is extremely low (below the threshold of experimental detection, see petition pages 56-57). Therefore, it appears that the risk of a significant impact on monarch populations from Cotton Event 15985 is very low.

##### ***Potential Impact on Other Non-target Species***

Like the Cry1 class of insecticidal proteins, the specificity of the Cry2Ab protein's insecticidal activity is dependent upon binding to specific receptors present in the insect mid-gut (Lambert, et al., 1996; Van Rie et al., 1990; Van Rie et al., 1989; Hoffmann et al., 1988a and 1988b; and

Wolfersberger et al., 1986). The Cry2Ab protein has activity only against species within the Order Lepidoptera. Likewise, the Cry2Ab protein is not expected to adversely affect most other invertebrates and all vertebrate organisms, including non-target birds, mammals and humans, because these would not be expected to contain the receptor protein found in the midgut of target insects. To evaluate the potential of Cotton Event 15985 to have damaging or toxic effects on representative terrestrial and an aquatic species, APHIS evaluated data from a series of ecological toxicology experiments. The test organisms were bobwhite quail, channel catfish, and several invertebrate beneficial organisms including: collembola, ladybeetles, adult and larval honeybees, green lacewing larvae, parasitic wasps, and earthworms. Data were presented in the petition in which these non-target organisms were exposed to high doses of leaf tissue, grain, or pollen containing purified Cry2Ab protein. No adverse effects were observed at the maximum concentrations to which the various test organisms would be exposed from cotton.

Appendix C of this environmental assessment is a summary table in which Cotton Event 15985 is compared to conventional chemical insecticides used to control lepidopteran pests of cotton. The comparison encompasses environmental fate and potential nontarget effects. In general, Cotton Event 15985, and the Cry2Ab protein expressed by these plants compares favorably to these products with respect to the potential for harm in the environment.

Further evidence of the safety of the Cry2Ab protein was provided in data that Monsanto submitted to EPA in support of an exemption for a tolerance for the Cry2Ab protein. On May 11, 2001, EPA published their conclusion in the Federal Register that the potential for the Cry2Ab2 protein to be food allergen is minimal. Regarding toxicity to the immune system, the acute oral toxicity data submitted support the prediction that the Cry2Ab protein would be non-toxic to humans (<http://www.epa.gov/EPA-PEST/2001/May/Day-11/p11917.htm>). Monsanto also provided copies of these data in an appendix of their petition to APHIS.

The other protein product engineered to be expressed in Cotton Event 15985 is the enzyme  $\beta$ -D-glucuronidase, encoded by the *uidA* gene. The *uidA* gene and  $\beta$ -D-glucuronidase have a history of safe use and have no known toxicity to non-target organisms. The enzyme activity is known in many human tissues (Jefferson et al., 1986), as well as in the fruit, seed coat, and endosperm of various plants (Hodal, et al., 1992). The safety of  $\beta$ -D-glucuronidase was further acknowledged August 16, 2001, when EPA published in the Federal Register the agency's regulation establishing an exemption from the requirement of a tolerance for residues of  $\beta$ -D-glucuronidase from *Escherichia coli* and the genetic material necessary for its production in or on all food commodities when applied/used as a plant pesticide inert ingredient (<http://www.epa.gov/fedrgstr/EPA-PEST/2001/August/Day-16/p20665.htm>).

***Potential impact on threatened and endangered species.***

APHIS also considered the likely impact that nonregulated status of Cotton Event 15985 might have on species which are on the Federal List of Threatened and Endangered Species. The incorporation of another type of BT-cotton (Cotton Event 15985 and its progeny) into cotton production may further the reduction of chemical pesticide use and the concomitant potential for negative impact to

nontarget species via spray drift, bioaccumulation in food chains, and the contamination of surface and groundwater sources. APHIS did not focus its analysis extensively on such potential benefits, but examined the potential harm that might result from threatened and endangered species which are similar to the target insect pests and therefore likely to be sensitive to Cry2Ab when ingested.

The threatened and endangered species which are most likely to be negatively affected by the Cry2Ab protein expressed in Cotton Event 15985 would be lepidopteran insects. Since it is not possible to use such species to quantify sensitivity to the Cry2Ab protein, the APHIS evaluation started with the assumption of some toxicity and focused instead on whether it is likely that these species would be exposed to the Cry2Ab protein expressed by Cotton Event 15985. APHIS believes that exposure of these species is only likely if the species occur in the areas where cotton is grown, because cotton plant parts (seeds, pollen, crop debris) are not readily transported long distances without the intervention of humans.

In the states which grow cotton, only California, Florida, and North Carolina have lepidopteran species that are on the Federal endangered species list. APHIS considered the likely impacts on the relevant species of each state.

Of the 15 California species, 13 are found in coastal counties or in montane areas just inland from the Pacific Coast, habitats which are far from the cotton growing areas in the Central Valley of California. Only one species, the Quino Checkerspot (*Euphydryas editha quino*) has populations in a cotton producing county. This Nymphalid butterfly is found in both upland sage scrub or chaparral communities and in meadows. Its host plants, the dotseed plaintain and the exerted Indian paintbrush both are adequate hosts for the larvae only in late winter and spring, and in the summer, the vegetation mostly dies back. The adults emerge in early or midspring, and lay eggs which continue to grow until the summer dries the vegetation. A larval diapause occurs until the late winter and the hostplants again flourish, until pupation occurs. It is likely that the insects would not commonly overlap with cotton cultivation, although in some years this might occur (Fish and Wildlife Service, 2001). Meadows in the vicinity of cotton and other agricultural production are likely to have been used for growing crops, and that is one reason why this insect has become endangered. Thus, geographic isolation is likely to prevent Cotton Event 15985 from impacting this butterfly. The Fish and Wildlife Service has not described any agricultural impact on the populations of the Quino Checkerspot butterfly except the impact of livestock which trample the insect's host plants (Fish & Wildlife Service, 1997).

A second endangered lepidopteran species in California, the Kern Primrose Sphinx (*Euproserpinus euterpe*), may occupy habitat near cotton cultivation sites in Kern County. This moth has not been detected since 1982, but was formerly collected within southern Kern County. Its host plant is evening primrose, *Camissonia* spp., which are distributed throughout Southern California and beyond. APHIS does not believe that Cotton Event 15985 would have an impact on the Kern Primrose Sphinx.

In North Carolina, another endangered butterfly, the St. Francis Satyr (*Neonympha mitchellii francisci*) is known, although cotton cultivation near its known habitat is unlikely. This butterfly lives in the boggy areas and wide wet meadows of the Ft. Bragg military base (Fish & Wildlife Service, 1994), an area where cotton cultivation is unlikely.

In Florida, the Schaus swallowtail (*Heraclides aristodemus ponceanus*) is a subtropical species which lives in the far southern portion of the state. It is most commonly found on Elliot Key and North Key Largo. Cotton is not grown in this region, so exposure is very unlikely.

APHIS also considered threatened and endangered species other than lepidopterans. The petition provided data which support the conclusion that the Cry2Ab protein is not toxic to invertebrates other than lepidopterans. Data also corroborated that the Cry2Ab is relatively nontoxic to vertebrates (includes fish, birds, reptiles, amphibians, and mammals). These analyses are part of the EPA's registration review that would be required before Cotton Event 15985 or its progeny could be sold as insect resistant cotton varieties.

APHIS considered potential effects of the exudation of Cry2Ab protein from the roots of on soil organisms, and noted that recent studies in the scientific literature reported essentially no effects (Sims and Ream, 1997). These findings are consistent with studies of the exudates from BT-corn varieties; the exudates did not appear to effect the soil organisms that were evaluated (Saxena and Stotsky, 2000, 2001a, 2001b).

In total, these analyses, the data submitted by Monsanto, and the information in the scientific literature suggest that Cotton Event 15985 should not pose a significant risk of harm to nontarget organisms.

## **5. Potential Impacts on Biodiversity**

After careful evaluation, APHIS believes that Cotton Event 15985 exhibits no traits that would cause increased weediness, that its cultivation should not lead to increased weediness of other cultivated cotton or other sexually compatible relatives, and is unlikely to harm non-target organisms common to the agricultural ecosystem or threatened or endangered species recognized by the U.S. Fish and Wildlife Service. Based on this analysis, APHIS believes that it appears unlikely that Cotton Event 15985 will pose a significant impact on biodiversity.

## **6. Potential Impacts on Agricultural and Cultivation Practices**

APHIS considered the potential impacts of Cotton Event 15985 on current agricultural practices in the United States, including potential impacts on organic farming. APHIS also considered any potential cumulative effects that might arise from the use of Cotton Event 15985 or its progeny in agricultural production.

### ***Impacts on current agricultural practices***

The Economic Research Service of the USDA reports that in the year 2000 an estimated 35% of cotton acreage in the United States was planted with approved genetically engineered varieties which utilize the Cry1Ac protein to deter feeding damage from lepidopteran insect pests (<http://www.ers.usda.gov/Briefing/AgChemicals/Questions/bioqa1.htm>). As described above, Cotton Event 15985 was developed to provide another option for better control of these pests and prolong the useful lifetime of Cry1Ac-protected varieties already in commercial use. The possible commercial use of varieties based upon Cotton Event 15985 may enable a continued reduction in the use of insecticides to control lepidopteran pests of cotton. The Economic Research Service of the USDA has reported a reduction in pesticide use by cotton growers using the first generation of Cry1Ac-protected cotton varieties. Growers have still had to use chemical and other strategies to control cotton pests that are not affected by the Cry1Ac protein. However, it is believed by both growers and researchers that reduced reliance on chemical pesticides in cotton cultivation allows populations of beneficial organisms (insects, mites, wasps, etc) to increase to levels that can exert effective control of some of the cotton pests.

### ***Potential impacts on organic farming***

It is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic grain, will be significantly impacted by the expected commercial use of this product since: (a) nontransgenic cotton will likely still be sold and will be readily available to those who wish to plant it; (b) farmers purchasing seed will know this product is transgenic because it will be marketed and labeled as *Bt Cry2Ab* lepidopteran resistant, and, based on the IRM plan, farmers will be educated about recommended management practices.

Several transgenic cotton varieties resistant to lepidopteran insects are already in widespread use by farmers. Varieties derived from Cotton Event 15985 should not present new and different issues than those with respect to impacts on organic farmers. APHIS has considered that cotton is open-pollinating and it is possible that the genes from Cotton Event 15985 could move to cotton in an adjacent field. All cotton, whether genetically engineered or not, can transmit pollen to nearby fields, and a very small influx of pollen originating from a given cotton variety does not appreciably change the characteristics of cotton in adjacent fields. As described previously in this assessment, the rate of cross-pollination from one field to another is expected to be quite low, even if flowering times coincide. The frequency of such an occurrence decreases with increasing distance from the pollen source such that it is sufficiently low at 1320 feet away to be considered adequate for production of even the most restrictive standard for foundation cotton seeds (see footnote 19 for the table found at <http://www.aphis.usda.gov/biotech/isolate.html>).

### ***Potential cumulative effects***

If Cotton Event 15985 or its progeny were used on a commercial scale, impacts are not likely to be significant. It is possible that the use of this cotton could result in some decreased use of chemical insecticides which are currently used to protect the plants from lepidopteran pests. The pesticidal use of Cotton Event 15985 and traditional chemical pesticides in cotton cultivation are regulated by the EPA. EPA reviews the use of Insect Resistance Management (IRM) strategies to extend the

useful life of transgenic plants with plant-incorporated protectants used in plants such as BT-cotton. It is expected that EPA and Economic Research Service of the USDA would monitor the use of this product to determine impacts on agricultural practices as they have done previously for Bt-cotton varieties.

#### **7. Potential impacts on raw or processed agricultural commodities.**

Our analysis of data on agronomic performance, disease and insect susceptibility, and compositional profiles of the seeds and fiber indicate no significant differences between Cotton Event 15985 and its parent and other cultivars of *G. hirsutum* grown in the United States. APHIS does not foresee either a direct or indirect plant pest effect on any raw or processed plant commodity.

#### **8. Potential environmental impacts outside the United States.**

APHIS has also considered potential environmental impacts outside the United States and its territories associated with a determination of nonregulated status for Cotton Event 15985. Any international traffic in cotton subsequent to this determination would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC). The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (105 countries as of October, 1996). In addition, issues that may relate to commercialization of particular agricultural commodities produced through biotechnology are being addressed in international forums. APHIS continues to play a role in working toward harmonization of biosafety and biotechnology guidelines and regulations included within the RPPO for our region, the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States. NAPPO's Biotechnology Panel advises NAPPO on biotechnology issues as they relate to plant protection. APHIS also participates regularly in biotechnology policy discussions at forums sponsored by the European Union and the Organization for Economic Cooperation and Development. APHIS periodically holds bilateral or quadrilateral discussions on biotechnology regulatory issues with other countries, most often Canada and Mexico and have participated in numerous conferences intended to enhance international cooperation on safety in biotechnology, and sponsored several workshops on safeguards for planned introductions of transgenic crops (crucifers, maize, wheat, potatoes, rice, tomatoes) most of which have included consideration of international biosafety issues.

In the course of these wide ranging studies and interactions, APHIS has not identified any impacts from the cultivation of Cotton Event 15985 on the environment that can not reasonably be mitigated through normal agricultural practices. It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new cotton cultivars internationally, apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR Part 340.

### **C. Alternative C, Approval of the Petition in Part**

**1. Approval of some, but not all, of the lines requested in the petition.** Under this alternative, APHIS may consider approval of some, but not all, of the lines requested in the petition. The petition requested a determination of nonregulated status only for Cotton Event 15985 and any progeny lines derived from it by traditional breeding practices. Therefore, APHIS can consider only Cotton Event 15985 for approval.

**2. Approval of the petition with geographic restrictions.** EPA is currently reviewing the application to register the use of Cotton Event 15985 under its regulations for plant-incorporated protectants. EPA has the authority to impose geographic limitations on the use of specific pesticides and routinely does so to protect threatened and endangered species, as well as other non-target organisms. EPA and APHIS agree that the threatened and endangered lepidopteran species do not typically feed on cotton, so they are not likely to be exposed to the Cry2Ab protein expressed by Cotton Event 15985. Cotton plants are not considered to be wind pollinated, so it is not likely that the relatively heavy pollen grains will move from the cotton plants to rest on the surface of other substrates that will be ingested by these threatened and endangered lepidopteran species. On the basis of these considerations, APHIS can find no reason for placing geographic restrictions on planting of Cotton Event 15985 by granting the petition in part.

### **VI. LITERATURE CITED**

Baker, H.G. 1974. The evolution of weeds. *Annual Review of Ecology and Systematics* 5: 1-24.

Fish and Wildlife Service. 2001. Endangered and Threatened Wildlife and Plants; Proposed Determination of Critical Habitat for the Quino Checkerspot Butterfly; Proposed Rule. *Federal Register*. 66 (26) 9475-9507.

Fish and Wildlife Service. 1994. Endangered and Threatened Wildlife and Plants; Proposed Rule to List the Saint Francis' Satyr as Endangered. *Federal Register* 59, 443 18350 (04/18/94) 443

Fish and Wildlife Service. 1997. Endangered and Threatened Wildlife and Plants; Determination of Endangered Status of the Laguna Mountains Skipper and Quino Checkerspot Butterfly. Final rule. *Federal Register*. 62 (11) 2313-2322.

Fryxell, P.A. 1984. Cotton. Pp. 27-57. In, Kohel, R.J. and Lewis, C.F., Ed., *Taxonomy and Germplasm Resources*. American Soc. Agron., Crop Sci. Soc. Amer., Soil Sci. Soc. Of Amer., Madison, Wi.

Fryxell, P.A. 1979. *The Natural History of the Cotton Tribe (Malvaceae, Tribe Gossypieae)*. Texas A&M University Press, College Station, TX.



Godfrey, L, Goodell, P. Grafton-Cardwell, E., Toscano, N. Natwick, E.T. Brazzel, J. 2000. UC IPM Pest Management Guidelines: Cotton. The Regents of the University of California. (<http://www.ipm.ucdavis.edu/PMG/r114303511.html>)

Hardee, D.D., van Duyn, J.W., Layton, M.B. and Bagwell, R.D. 2001. Bt Cotton and management of the tobacco budworm-bollworm complex. USDA ARS. Agricultural Research Service Publication ARS-154. 40 p.

Hodal, L.A. Bocharadt, J.E. Nielsen, O, Mattsson, and Oak, F.T. 1992. Detection, expression, and specific elimination of endogenous beta-glucuronidase activity in transgenic and non-transgenic plants. *Plant Science* 87, 117-122.

Holm, L.G., Plucknett, D.L., Pancho J.V., and Herberger, J.P. 1977. *The World's Worst Weeds: Distribution and Biology*. University Press of Hawaii, Honolulu.

Holm, L.G., Pancho J.V., Herberger, J.P., and Plucknett, D.L. 1979. *Geographical Atlas of World Weeds*. John Wiley and Sons, NY.

Holm, L.G., Doll, J., Holm, E., Pancho J.V., and Herberger, J.P. 1997. *World Weeds; Natural Histories and Distribution*. John Wiley and Sons, NY.

Jefferson, R.A. Kavanagh, T.A. and Bevan, M.W. 1986. Beta-glucuronidase for *Escherichia coli* as a gene-fusion marker. *Proc. Nat. Acad. Sci. USA* 83, 8447-8451.

Jesse, L.C.H. and Obyycki, J.J. 2000. Field deposition of Bt transgenic corn pollen: lethal effects on monarch butterfly. *Oecologia* 125, 241-248.

Jiang, C-X., Chee, P.W. Draye, X., Morrell, P.L. Smiths, C.W. and Paterson, A.H. 2000. Multilocus interactions restrict gene introgression in interspecific populations of polyploid *Gossypium* (Cotton). *Evolution* 54, 798-814.

Layton, M.B., Stewart, S.D., Williams, M.R. and Long, J.L. 1999. Performance of Bt cotton in Mississippi, 1998. *Proc. Beltwide Cotton Conf.* 942-945. National Cotton Council, Memphis, Tennessee.

Losey, J.E., Rayor, L.S., Carter, M.E. and Smith, M.E. 1999. Transgenic pollen harms monarch larvae. *Nature* 399, 214.

Muenscher, W. C. 1980. *Weeds*. Second Edition. Cornell University Press, Ithaca and London. 586 pp.

National Research Council. 1989. *Field Testing Genetically Modified Organisms: Framework for Decisions*. National Academy Press, Washington, D.C.

Saxena, D. and Stotzky, G. 2000. Insecticidal toxin from *Bacillus thuringiensis* is released from roots of transgenic Bt corn *in vitro* and *in situ*. *FEMS Microbiology Ecol.* 33, 35-39.

Saxena, D. and Stotzky, G. 2001a. Fate and effects of the insecticidal toxins from *Bacillus thuringiensis* in soil. (<http://gophisb.biochem.vt.edu/>). Information Systems for Biotechnology, May, 2001.

Saxena, D. and Stotzky, G. 2001b. *Bacillus thuringiensis* (bt) toxin released from root exudates and biomass of Bt corn has no apparent effect on earthworms, nematodes, protozoa, bacteria and fungi in soil. *Soil Biology and Biochemistry* (in press).

Sims, S.R. and Ream, J.E. 1997. Soil inactivation of the *Bacillus thuringiensis* subsp. *kurstaki* cryIIA insecticidal protein within transgenic cotton tissue: laboratory microcosm and field studies. *J. Agric. Food Chem.* 45, 1502-1505.

Southern Weed Science Society. 1998. Weeds of the United States and Canada. CD-ROM. Southern Weed Science Society. Champaign, Illinois.

US EPA. 2001. *Bt* Plant-Incorporated Protectants September 29, 2001 Biopesticides Registration Action Document. [http://www.epa.gov/pesticides/biopesticides/otherdocs/bt\\_brad2/6%20cotton.pdf](http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2/6%20cotton.pdf)

US EPA. 2001b. 40 CFR Parts 152 and 174 - Plant-Incorporated Protectants; Final Rules and Proposed Rule. Federal Register July 19, 2001.  
[http://www.epa.gov/pesticides/biopesticides/pip/pip\\_rule.pdf](http://www.epa.gov/pesticides/biopesticides/pip/pip_rule.pdf)

US EPA. 2000a Biopesticide Fact Sheet *Bacillus thuringiensis* subsp. *kurstaki* Cry1Ac Delta-Endotoxin and Its Controlling Sequences as Expressed in Cotton (006445) Issued: 4/00. Office of Biopesticide Programs.

US EPA. 2000b. *Bacillus thuringiensis* subspecies *kurstaki* Cry1Ac Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn [Dekalb DBT-418] (006463) Issued: 4/00 Office of Biopesticide Programs.

US EPA. 2000c. *Bacillus thuringiensis* Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for Its Production in Corn [MON 810] (006430) Office of Biopesticide Programs.

US EPA. 2001. Biopesticides Registration Action Document on *Bacillus thuringiensis* (Bt) Plant-Incorporated Pesticides ([http://www.epa.gov/pesticides/biopesticides/reds/brad\\_bt\\_pip2.htm](http://www.epa.gov/pesticides/biopesticides/reds/brad_bt_pip2.htm)).

US EPA. 2000. Biopesticide Fact Sheet. *Bacillus thuringiensis* subsp. *kurstaki* Cry1Ac Delta-Endotoxin and Its Controlling Sequences as Expressed in Cotton Issued: 4/00. US EPA, Office of Pesticide Programs.  
(<http://www.epa.gov/opbppd1/biopesticides/factsheets/fs006445t.htm>)

US EPA. 2000d. *Bacillus thuringiensis* Plant-pesticides. Biopesticides registration action document. Preliminary risks and benefits section. US Environmental Protection Agency. Biopesticides and Pollution prevention Division. <http://www.epa.gov/scipoly/sap/2000/october>

US EPA. 2000e. Bt cotton refuge requirements for the 2001 growing season. US Environmental Protection Agency. Biopesticides and Pollution prevention Division. ([http://www.epa.gov/oppbppd1/biopesticides/otherdocs/bt\\_cotton\\_refuge\\_2001](http://www.epa.gov/oppbppd1/biopesticides/otherdocs/bt_cotton_refuge_2001))

USDA, NRCS. 2001. The PLANTS Database, Version 3.1 (<http://plants.usda.gov>). National Plant Data Center, Baton Rouge, LA 70874-4490 USA.

USDA, NRCS. 2001. The PLANTS Database, Version 3.1 (<http://plants.usda.gov>). National Plant Data Center, Baton Rouge, LA 70874-4490 USA.

Weed Science Society of America. 1989. Composite List of Weeds. WSSA. Champaign, Illinois.

## **VII. PREPARERS AND REVIEWERS**

John Cordts, M.S., Biotechnologist  
David Heron, Ph.D., Biotechnologist (Preparer)  
Margaret Jones, Ph.D., Biotechnologist  
Susan Koehler, Ph.D., Biotechnologist  
Bruce Macbryde, Ph.D., Biotechnologist  
Virgil Meier, Ph.D., Biotechnologist  
Hanu Pappu, Ph.D., Biotechnologist  
L. Carmen Soileau, Ph.D., Biotechnologist  
John Turner Ph. D., Biotechnologist  
James L. White, Ph.D., Senior Operations Officer (Reviewer)  
Shirley P. Ingebritsen, M.A., Regulatory Analyst (Reviewer)

## **VIII. AGENCY CONTACT**

Ms. Kay Peterson, Regulatory Analyst  
USDA, APHIS, Biotechnology Regulatory Services  
4700 River Road, Unit 147  
Riverdale, MD 20737-1237

Phone: (301) 734-4885  
Fax: (301) 734-8669  
kay.peterson@usda.gov

## Appendix A: Biology of cotton and potential for introgression into related species.

### Cotton as a Crop

Four species of the genus *Gossypium* are known as cotton, which is grown primarily for the seed hairs that are made into textiles. Cotton is predominant as a textile fiber because the mature dry hairs twist in such a way that fine, strong threads can be spun from them. Other products, such as cottonseed oil, cake, and cotton linters are byproducts of fiber production.

Cotton, a perennial plant cultivated as an annual, is grown in the United States mostly in areas from Virginia southward and westward to California, in an area often referred to as the Cotton Belt (McGregor, 1976).

### Taxonomy of Cotton

The genus *Gossypium*, a member of the Malvaceae, consists of 39 species, four of which are generally cultivated (Fryxell, 1984). The most commonly cultivated species, *G. hirsutum* L., is the subject of this Environmental Assessment. Other cultivated species are *G. arboreum* L., *G. barbadense* L., and *G. herbaceum* L.

Four species of *Gossypium* occur in the United States (Fryxell, 1979; Kartesz and Kartesz, 1980). *Gossypium hirsutum* is the primary cultivated cotton. *Gossypium barbadense* is also cultivated. The other two species, *G. thurberi* Todaro and *G. tomentosum* Nuttall ex Seemann, are wild plants of Arizona and Hawaii, respectively. *Gossypium tomentosum* is known from a few strand locations very close to the ocean.

### Genetics of Cotton

At least seven genomes, designated A, B, C, D, E, F, and G, are found in the genus (Endrizzi, 1984). Diploid species ( $2n=26$ ) are found on all continents, and a few are of some agricultural importance. The A genome is restricted in diploids to two species (*G. arboreum*, and *G. herbaceum*) of the Old World. The D genome is restricted in diploids to some species of the New World, such as *G. thurberi*.

By far, the most important agricultural cottons are *G. hirsutum* and *G. barbadense*. These are both allotetraploids of New World origin, and presumably of ancient cross between Old World A genomes and New World D genomes. How and when the original crosses occurred have been subject to much speculation. Euploids of these plants have 52 somatic chromosomes, and are frequently designated as AADD. Four additional New World allotetraploids occur in the genus, including *G. tomentosum*, the native of Hawaii. *Gossypium tomentosum* has been crossed with *G. hirsutum* in breeding programs.

The New World allotetraploids are peculiar in the genus, because the species, at least in their wild forms, grow near the ocean, as invaders in the constantly disturbed habitats of strand and associated environs. It is from these "weedy" or invader species that the cultivated cottons developed (Fryxell, 1979).

### **Pollination of Cotton**

*Gossypium hirsutum* is generally self-pollinating, but in the presence of suitable insect pollinators can exhibit cross pollination. Bumble bees (*Bombus* spp.), Melissodes bees, and honey bees (*Apis mellifera*) are the primary pollinators (McGregor, 1976). Concentration of suitable pollinators varies from location to location and by season, and is considerably suppressed by insecticide use. If suitable bee pollinators are present, distribution of pollen decreases considerably with increasing distance. McGregor (1976) reported results from an experiment in which a cotton field was surrounded by a large number of honey bee colonies, and movement of pollen was traced by means of fluorescent particles. At 150 to 200 feet, 1.6 percent of the flowers showed the presence of the particles. The isolation distance for Foundation, Registered, and Certified seed in 7 CFR Part 201 is 1320 feet, 1320 feet, and 660 feet, respectively.

Research in Mississippi shows that pollen movement decreases rapidly after 40 feet (12 meters). Umbeck et al. (1991) studied pollen and successful gene movement of cotton in Mississippi test plots. Around a central transgenic test plot of 98,800 plants with rows running north-south, they planted 23 one-meter border rows of nontransgenic cotton to the east and to the west, and 25 meters of non transgenic cotton border rows to the north and to the south, each divided into two 12.5 meter long plots. The border rows to the north and south were continuous with the transgenic rows. They took 32,187 seed samples from all border rows at bottom, middle, and top plant position (representing seasonal variation) and used a kanamycin resistance marker gene to test for seeds resulting from pollen movement out of the central transgenic plot. To the east and west, gene movement at the first row was 0.057 and 0.050, and dropped rapidly to row 8, and was not detected in subsequent rows to the east, and detected occasionally at <0.01 in rows to the west. Combined data for east and west border rows beyond row 9 gave total outcrossing of 0.0012. To the north and south, detections were totaled for each 12.5 meter block and gave figures of 0.0053 and 0.0047 for north and south inner block and 0.0015 and 0.0021 for north and south outer block.

*Gossypium tomentosum* seems to be pollinated by lepidopterans, presumably moths (Fryxell, 1979). The stigma in *G. tomentosum* is elongated, and the plant seems incapable of self-pollination until acted upon by an insect pollinator. The flowers are unusual too, because they stay open at night; most *Gossypium* flowers are ephemeral: they open in the morning and wither at the end of the same day.

## Weediness of Cotton

Although the New World allotetraploids show some tendencies to "weediness" (Fryxell, 1979), the genus shows no particular weedy aggressive tendencies.

## Modes of Gene Escape in Cotton

Genetic material of *G. hirsutum* may escape from a test area by vegetative material, by seed, or by pollen.

Propagation by vegetative material is not a common method of reproduction of cotton. Physical safeguards that inhibit the movement of vegetative material from the area should be adequate to prevent gene movement by this means.

Movement of seed from the test area can likewise be inhibited by adequate physical safeguards.

Movement of genetic material by pollen is possible only to those plants with the proper chromosomal type, in this instance only to those allotetraploids with AADD genomes. In the United States, this would only include *G. hirsutum*, *G. barbadense*, and *G. tomentosum*. *Gossypium thurberi*, the native diploid from Arizona with a DD genome, is not a suitable recipient. Movement to *G. hirsutum* and *G. barbadense* is possible if suitable insect pollinators are present, and if there is a short distance from transgenic plants to recipient plants. Physical barriers, intermediate pollinator-attractive plants, and other temporal or biological impediments would reduce the potential for pollen movement.

Movement of genetic material to *G. tomentosum* is more unknown. The plants are chromosomally compatible with *G. hirsutum*, but there is some doubt as to the possibility for pollination. The flowers of *G. tomentosum* seem to be pollinated by moths, not bees. And they are receptive at night, not in the day. Both these factors would seem to minimize the possibility of cross-pollination. However, Fryxell (1984) reports that *G. tomentosum* may be losing its genetic identity from introgression hybridization of cultivated cottons by unknown means.

## LITERATURE CITED

Endrizzi, J. E., Turcotte, E. L., and Kohel, R. J. 1984. Qualitative Genetics, Cytology, and Cytogenetics. pp. 82-129. In Kohel, R. J. and Lewis, C. F., Editors. Cotton. American Society of Agronomy, Crop Science Society of America, and Soil Science Society of America. Madison, Wisconsin. 605 pp.

Fryxell, P. A. 1979. The Natural History of the Cotton Tribe (Malvaceae, Tribe Gossypieae). Texas A&M University Press. College Station and London. 245 pp.

Fryxell, P. A. 1984. Taxonomy and Germplasm Resources. pp. 27-57. In Kohel, R. J. and Lewis, C. F., Editors. Cotton. American Society of Agronomy, Crop Science Society of America, and Soil Science Society of America. Madison, Wisconsin. 605 pp.

Umbeck, P. F., Barton, K. A., Nordheim, E. V., McCarty, J. C., Parrott, W. L., and Jenkins, J. N. 1991. Degree of Pollen Dispersal by Insects from a Field Test of Genetically Engineered Cotton. J. Econ. Entomology 84:1943-1991.

Kartesz, J. T., and Kartesz, R. 1980. A Synonymized Checklist of the Vascular Flora of the United States, Canada, and Greenland. The University of North Carolina Press. Chapel Hill.

McGregor, S. E. 1976. Insect Pollination of Cultivated Crop Plants. Agriculture Handbook No. 496. U.S. Government Printing Office. Washington, DC.

-----

Appendix text prepared by:

*James Lackey, Ph.D.*

*Botanist*

*USDA, APHIS, PPQ*

This document can also be found at <http://www.aphis.usda.gov/biotech/cotton.html>



Appendix B. List of APHIS authorizations to field test Cotton Event 15985.

Total of 115 authorizations under the APHIS notification procedure from 1993-2001.

93-120-55n	99-071-15n	00-357-05n
93-210-01n	99-092-03n	01-005-01n
93-223-01n	99-095-19n	01-005-02n
94-026-03n	99-102-18n	01-005-03n
94-027-03n	99-102-19n	01-005-04n
94-054-02n	99-102-20n	01-005-05n
94-103-01n	99-102-21n	01-005-06n
94-216-04n	99-102-22n	01-005-07n
94-273-02n	99-102-23n	01-005-08n
95-019-02n	99-110-14n	01-005-09n
95-020-10n	99-110-19n	01-009-07n
95-023-01n	99-110-22n	01-039-04n
95-023-02n	99-110-23n	01-039-05n
95-025-05n	99-110-24n	01-039-06n
95-037-01n	99-110-25n	01-040-01n
95-037-02n	99-110-26n	01-046-14n
95-037-03n	99-252-07n	01-046-15n
95-053-03n	99-252-09n	01-046-16n
95-068-03n	00-040-02n	01-058-04n
95-079-06n	00-041-05n	01-058-05n
95-090-02n	00-046-06n	01-058-06n
95-094-12n	00-046-07n	01-086-01n
95-103-03n	00-046-08n	01-094-01n
95-103-05n	00-047-01n	01-102-14n
95-111-02n	00-047-02n	01-241-16n
95-117-01n	00-055-04n	
95-216-01n	00-059-04n	
96-067-01n	00-060-02n	
96-088-01n	00-062-02n	
96-088-02n	00-063-14n	
96-219-03n	00-063-15n	
96-255-01n	00-063-17n	
97-050-14n	00-067-07n	
97-050-15n	00-070-02n	
97-059-09n	00-146-05n	
98-084-22n	00-146-06n	
98-084-23n	00-262-01n	
98-085-19n	00-262-02n	
99-057-05n	00-329-01n	
99-061-11n	00-329-02n	
99-061-12n	00-329-03n	
99-061-13n	00-329-04n	
99-061-14n	00-357-02n	
99-061-15n	00-357-03n	
99-071-14n	00-357-04n	

Environmental fate	Cry2Ab	Bifenthrin (pyrethroid)	Profenofos (Organophosphate)	Methomyl (Carbamate)	Cyhalothrin (pyrethroid)
	<p><i>Bacillus thuringiensis</i> is a spore-forming gram-positive bacterium that has been used commercially for nearly 40 years to control insects. They are found naturally in soils worldwide at significant levels. The Cry2Ab protein has a high degree of sequence similarity (97%) to the Cry2Aa protein produced in commercial <i>B.t.k.</i> products. The proteins produced in these products have an established history of environmental safety, as summarized in the EPA 2001 Registration Eligibility Decision Document.</p>	<p>Breakdown of Chemical in Soil &amp; Groundwater: Bifenthrin does not move in soils with large amounts of organic matter, clay and silt. It also has a low mobility in sandy soils that are low in organic matter. Bifenthrin is relatively insoluble in water, so there are no concerns about groundwater contamination through leaching. It's half-life in soil, the amount of time it takes to degrade to half of its original concentration, is 7 days to 8 months depending on the soil type and the amount of air in the soil.</p> <p>Breakdown of Chemical in Vegetation: Bifenthrin is not absorbed by plant foliage, nor does it translocate in the plant.</p>	<p>Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks.</p> <ul style="list-style-type: none"> <li>Laboratory data indicate that profenofos is not likely to leach into ground water. Profenofos was not detected in the limited groundwater monitoring data available.</li> <li>Surface water sources of drinking water may be contaminated due to runoff or spray drift.</li> </ul>	<p>Methomyl has low persistence in the soil with a reported half-life of approximately 14 days. Because of its high solubility in water and low affinity for soil binding, methomyl may have potential for groundwater contamination. Methomyl is rapidly degraded by soil microbes. Methomyl residues are not expected to be found in treated soil after the growing season in which it is applied. Breakdown in water: Aqueous solutions of methomyl have been reported to decompose more rapidly on aeration, in sunlight, or in alkaline media. The estimated aqueous half-life for the insecticide is 6 days in surface water and over 25 weeks in groundwater. Breakdown in vegetation: Following soil treatment, plants take up methomyl through their roots and translocate throughout the plant. When methomyl is applied to plants, its residues are short-lived. After it is applied to leaves, it has a 3 to 5 day half-life.</p>	<p>Cyhalothrin is moderately persistent in the soil environment. Reported field half-lives range from four to 12 weeks. Its field half-life is probably close to 30 days in most soils. It shows a high affinity for soil and so is not expected to be appreciably mobile in most soils. There is little potential for groundwater contamination. Soils with high sand content or with very low organic matter content may tend to retain the compound to a lesser degree. In field studies of Karate, leaching of λ-cyhalothrin and its degradates from the soil were minimal. Breakdown rates of both the technical product and Karate were similar under aerobic and anaerobic conditions.</p> <p>λ-cyhalothrin has extremely low water solubility and is tightly bound to soil, it is therefore not expected to be prevalent in surface waters. One possible source of infiltration into surface waters would be surface runoff. In this event, the compound would most probably remain bound to the solid particle and settle to the bottom.</p>

	Cry2Ab	Bifenthrin (pyrethroid)	Profenofos (Organophosphate)	Methomyl (Carbamate)	Cyhalothrin (pyrethroid)
Avian Data	<p>Bobwhite quail fed cotton event 15985 cottonseed at 10% of the diet exhibited no mortality and no adverse effects on survival, growth or behavior. These data indicate that birds exposed to Cry2Ab protein from consumption of cottonseed fed cottonseed meal as part of their diet will not be adversely affected.</p>	<p>Bifenthrin is moderately toxic to many species of birds. The dietary concentration (8 day) at which half of the test animals die, the LC50, is 1,280 ppm for mallard ducks and 4,450 ppm for bobwhite quail. The acute oral LD50 is 1,800 mg/kg for bobwhite quail and 2,150 mg/kg for mallard ducks. There is concern about possible bioaccumulation in birds</p>	<p>Risk from profenofos exceeds acute and chronic levels of concern for birds; and triggers risk concerns for endangered species and nontarget birds</p> <ul style="list-style-type: none"> <li>• For birds, the toxicity endpoints are derived from LC50 (acute, 57 ppm) and NOAEC (acute, 10 ppm) data from studies in the bobwhite quail.5 For mammals, the toxicity endpoint is LD50 (300 mg/kg) data from the mouse and rabbit.5 Profenofos significantly affects reproduction</li> </ul>	<p>Methomyl is highly toxic to birds. The acute oral LD50 in bobwhite quail is 24.2 mg/kg. The oral LD50 of methomyl is 28 mg/kg in hens. All deaths occurred within ten minutes of dosing. The clinical signs of toxicity included tearing of the eyes, salivation, occasional convulsions, and respiratory disorders. In Japanese quail, the LD50 is 34 mg/kg.</p> <p>The LD50 of a 90% pure formulation is 15.9 mg/kg in eight-month-old mallards, and 15.4 mg/kg in three- to four-month-old male pheasants. The LD50 for starlings is 42 mg/kg and for redwinged blackbirds is 10 mg/kg.</p>	<p>λ-cyhalothrin's toxicity to birds ranges from slightly toxic to practically non-toxic. In the mallard duck, the reported oral LD50 is greater than 3,950 mg/kg, and the reported dietary LC50 is 3,948 ppm. In bobwhite quail the reported dietary LC50 is greater than 500 ppm.</p> <p>There is evidence that it does not accumulate in the eggs or tissues of birds.</p>

Aquatic Data	Cry2Ab	Bifenthrin (pyrethroid)	Profenofos (Organophosphate)	Methomyl (Carbamate)	Cyhalothrin (pyrethroid)
	<p>Channel catfish fed cotton event 15985 cottonseed at 20% of the diet exhibited no mortality and no adverse effects on survival, growth or behavior</p>	<p>Bifenthrin is very highly toxic to fish, crustaceans and aquatic animals. The LC50 after a 96-hour exposure is 0.00015 mg/l for rainbow trout, 0.00035 mg/l for bluegill, and 0.0016 mg/l for Daphnia. Because of its low water solubility and high affinity for soil, bifenthrin is not likely to be found in aquatic systems.</p>	<p>Risk from profenofos exceeds acute risk levels of concern for freshwater and marine/estuarine fish, and invertebrates. Chronic risk levels of concern are exceeded for aquatic invertebrates. Thirteen fish kill incidents in Louisiana and Mississippi suggest large kills can result when using profenofos under current label conditions. Information provided by USDA indicates that the potential cause for the fish kill incidents may have been attributed to an unusual outbreak of tobacco worms that prompted aggressive pest control. Since these incidents occurred, the availability of several alternatives such as Bt cotton and the implementation of the Stewardship and Careful by Nature educational programs sponsored by the registrant may have reduced the potential for subsequent fish kill incidents.</p> <ul style="list-style-type: none"> <li>• For fish, toxicity end points are derived from LC50 and NOAEC data from studies in rainbow trout, fathead minnow and pinfish. For invertebrates, toxicity end points are derived from LC50 and NOAEC data from studies in <i>Daphnia</i> and mysid.</li> </ul>	<p>Methomyl is moderately to highly toxic to fish and highly toxic to aquatic invertebrates. The 96-hour LC50 in rainbow trout for a liquid formulation of methomyl is 3.4 mg/L and for bluegill sunfish is 0.8 mg/L. The 48-hour LC50 for <i>Daphnia magna</i> (a small, freshwater crustacean) is 0.0287 mg/L. A 28-day fish residue study indicated that methomyl did not accumulate in fish tissue. Methomyl is unlikely to bioconcentrate in aquatic systems.</p>	<p><math>\lambda</math>-cyhalothrin is very highly toxic to many fish and aquatic invertebrate species. Reported LC50s in these species are as follows: bluegill sunfish, 0.21 ug/L; rainbow trout, 0.24 ug/L; <i>Daphnia magna</i>, 0.36 ug/L; mysid shrimp, 4.9 ng/L; sheepshead minnow, 0.807 ng/L. Bioconcentration is possible in aquatic species, but bioaccumulation is not likely. Bioconcentration in channel catfish has been reported as minimal, with rapid depuration (elimination). A bioconcentration factor of 8.58 has been reported in fish (species unspecified), but concentration was confined to non-edible tissues and rapid depuration was observed.</p>

	Cry2Ab	Bifenthrin (pyrethroid)	Profenofos (Organophosphate)	Methomyl (Carbamate)	Cyhalothrin (pyrethroid)
Nontarget and Beneficial Insects	<p>Studies were conducted to determine whether non-target species of insects and other terrestrial invertebrates are susceptible to Cry2Ab protein. Cry2Ab protein was evaluated in the earthworm, as well as five species of beneficial terrestrial invertebrates representing classes of insects that could be exposed to Cry2Ab protein from event 15985 cotton: adult and larval honey bees (<i>Apis mellifera</i>), collembola (<i>Folsomia candida</i>), green lacewing (<i>Chrysoperla carnea</i>), ladybird beetle (<i>Hippodamia convergens</i>) parasitic wasp (<i>Nasonia vitripennis</i>), and earthworm (<i>Eisenia fetida</i>). Results of the studies indicate that Cry2Ab poses minimal risk to these beneficial nontarget organisms. No adverse effects were observed at the maximum predicted environmental concentration to which the organisms would be exposed.</p>	Data not available from sources consulted.	Based on exposure to aquatic organisms and terrestrial wildlife from cotton usage, adverse effects to non-target organisms and endangered species are unlikely.	Data not available from sources consulted.	Data not available from sources consulted.
Honeybee	<p>Adult and larval honey bees (<i>Apis mellifera</i>) were exposed to Cry2Ab protein from event 15985 cotton. No adverse effects were observed at the maximum predicted environmental concentration to which the organisms would be exposed.</p>	Bifenthrin is toxic to bees	For honeybees, profenofos is highly acutely toxic	Methomyl is highly toxic to bees both by direct contact and through ingestion.	λ-cyhalothrin is highly toxic to bees, with a reported oral LD50 of 38 ng/bee and reported contact LD50 of 909 ng/bee (0.9 ug/bee)

Mammalian toxicity	Cry2Ab	None	Bifenthrin (pyrethroid)	Profenofos (Organophosphate)	Methomyl (Carbamate)	Cyhalothrin (pyrethroid)
	None	Bifenthrin is absorbed through intact skin when applied topically. It undergoes similar modes of breakdown within animal systems as other pyrethroid insecticides. In mammals, bifenthrin is rapidly broken down and promptly excreted. Rats treated with 4 to 5 mg/kg, excreted 70 % in the urine and 20% in the feces within 7 days. After 7 days, the remaining bifenthrin was found accumulated in tissues with high fat content such as the skin and fat in males and females and the ovaries of females. Bifenthrin is less toxic to warm-blooded animals, such as mammals, than to cold-blooded animals. Bifenthrin does not demonstrate any teratogenic effects at the highest levels tested (100 ppm, approximately 5.5 mg/kg/day) in a two-generational study in rats. Mutagenic Effects: Evidence of mutagenic effects from exposure to bifenthrin are inconclusive. Studies of mouse white blood cells were positive for gene mutation. However, other tests of bifenthrinOs mutagenic effects, including the Ames test and studies in live rat bone marrow cells, were negative.	Risk from profenofos exceeds acute and chronic levels of concern for birds; acute levels of concern for small mammals; and triggers risk concerns for endangered species and nontarget birds and small mammals.	Methomyl is highly toxic via the oral route, with reported oral LD50 values of 17 to 24 mg/kg in rats, 10 mg/kg in mice, and 15 mg/kg in guinea pigs. There is no evidence that methomyl is a mutagenic or genotoxic. Methomyl was not carcinogenic in 22- and 24-month studies with rats fed doses of up to 20 mg/kg, nor in a two-year study with mice fed dietary doses of up to 93.4 mg/kg/day. The evidence suggests that methomyl is not carcinogenic. Fate in humans and animals: Methomyl is quickly absorbed through the skin, lungs, and gastrointestinal tract and are broken down in the liver. Breakdown products are readily excreted via respiration and urine	λ-cyhalothrin is moderately toxic in the technical form, but may be highly toxic via some routes in formulation. Cyhalothrin is moderately toxic via the oral route in test animals. Data indicate a moderate to high toxicity via the inhalation route for the formulated product Karate. Chronic Toxicity: It is unlikely that cyhalothrin would cause chronic effects in humans under normal conditions. Reproductive Effects: It is unlikely that cyhalothrin would cause reproductive effects in humans under normal conditions. Teratogenic Effects: No teratogenic or fetotoxic effects were observed in rats and rabbits at the highest doses tested in both species (15 mg/kg/day and 30 mg/kg/day, respectively). Mutagenic Effects: Cyhalothrin produced negative results in Ames mutagenicity assays and other in-vitro cytogenetic assays and chromosomal structural aberration tests indicated no mutagenic or genotoxic effects. Carcinogenic Effects: The evidence regarding the carcinogenicity of lambda cyhalothrin is inconclusive, but suggests that it is probably not carcinogenic	

EPA category	Cry2Ab	Bifenthrin (pyrethroid)	Profenofos (Organophosphate)	Methomyl (Carbamate)	Cyhalothrin (pyrethroid)
		The U.S. EPA has classified bifenthrin as Toxicity Class II-moderately toxic. Products containing bifenthrin must bear the SIGNAL WORD: WARNING	Profenofos is toxicity Class II	Methomyl is a highly toxic compound in EPA toxicity class I. It is classified as Restricted Use Pesticide (RUP) by EPA because of its high acute toxicity to humans. RUPs may be purchased and used only by certified applicators. Reentry periods for farm workers of 1 to 7 days are required, depending on the crop.	$\lambda$ - cyhalothrin is a Restricted Use Pesticide and so may be purchased and used only by certified applicators. It is in EPA Toxicity Class II, and products containing it must bear the signal word WARNING.

Bifenthrin Data: Exttoxnet Extension Toxicology Network Pesticide Information Profiles <http://ace.ace.orst.edu/info/extoxnet/pips/bifenthr.htm>

Methomyl Data: Exttoxnet Extension Toxicology Network Pesticide Information Profiles <http://ace.ace.orst.edu/info/extoxnet/pips/methomyl.htm>

Profenofos Data: US EPA, June 16, 1999 OVERVIEW OF PROFENOFOS REVISED RISK ASSESSMENT [http://www.epa.gov/pesticides/op/profenofos/prof\\_over.pdf](http://www.epa.gov/pesticides/op/profenofos/prof_over.pdf)

Profenofos Mammalian Toxicity Data: CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY DEPARTMENT OF PESTICIDE REGULATION MEDICAL TOXICOLOGY BRANCH SUMMARY OF TOXICOLOGY DATA PROFENOPHOS Farm Chemicals Handbook (2001) v. 87

US EPA Risk Characterization and Recommendations for the Reregistration of Profenofos (August 30, 1996) [http://www.epa.gov/pesticides/op/profenofos/profenofos\\_06.pdf](http://www.epa.gov/pesticides/op/profenofos/profenofos_06.pdf)

Lambda-cyhalothrin data: Pesticide Information Profiles, EXTTOXNET Extension Toxicology Network. [http://www.epa.gov/fedrgstr/EPA-PEST/1997/October/Day-10/p27012.htm](http://ace.orst.edu/cgi-bin/mfms/01/pips/lambdacy.htm?6#mfms) Federal Register Document [Federal Register: October 10, 1997 (Volume 62, Number 197)] [Notices] [Page 52998-53001] ENVIRONMENTAL PROTECTION AGENCY ] Notice of Filing of Pesticide Petitions AGENCY: Environmental Protection Agency (EPA). ACTION: Notice.

Cry2Ab data: Request for Determination of Nonregulated Status for the Related Article: Bollguard II Cotton Event 15985 (*Gossypium hirsutum* L.) Producing the Cry2Ab Insect Control Protein derived from *Bacillus thuringiensis* subsp. *kurstaki*. Submitted to USDA-APHIS December 2000.

Thiodicarb data: Thiodicarb (Larvin) Chemical Fact Sheet 8/84. <http://pmep.cce.cornell.edu/profiles/insect-mite/propetamphos-zetacypem/thiodicarb/insect-prof-thiodicarb.html>

Appendix C. Summary table of data submitted with the petition in support of nonregulated status for Monsanto's Bollgard II Cotton Event 15985.

<b>Molecular Genetic Characterization and Stability</b>
Southern Blot of Cotton Event 15985 for analysis of insert number: Fig. 6, page 30
Southern Blot of Cotton Event 15985 for analysis of copy number: Fig. 7, page 32
Southern Blot of Cotton Event 15985 analysis that cry2Ab coding region is intact: Fig. 8, page 36
Southern Blot of Cotton Event 15985 analysis of lack of plasmid backbone sequences, Figure 16 on page 50
Southern Blot of Cotton Event 15985 for analysis of uidA gene insertion, copy number and intactness, Figures 12, 13, 14, 15
Mendelian inheritance and insert stability, pages 53-55
<b>Phenotypic Characterization and Evidence Supporting Absence of Unintended Effects</b>
Measurement of Cry2Ab protein levels in various plant tissues collected from multiple field sites, Tables 4-8 on pages 55-60
Measurement of Cry2Ab protein levels from multiple time points during the growing season, Table 6, page 58
List of diseases observed in disease susceptibility evaluations of Cotton Event in multiple field trials, pages 61-66
List of insects observed in insect susceptibility evaluations of Cotton Event in multiple field trials, pages 67-71
Agronomic parameters evaluated: mean emergence, flowering and boll development, Table 13
Comparison of seedling vigor and germination characteristics, pages 74-75 and Tables 15 and 16
Compositional analysis of cottonseed cyclopropenoid fatty acids, pages 77-78 and Table 17
Morphological and maturity assessment, pages 73-75
Comparison of gossypol levels, pages 77-78
<b>Data on Environmental consequences of the introduction of Cotton Event 15985</b>
Summary of Cry2Ab toxicity to non-target organisms, Table 18 on page 80
Comparison of insecticide use of conventional cotton compared to Bollgard cotton (Cry1Ac-protected), pages 81-84 and Table 19
Potential impact on agronomic practice, pages 81-83



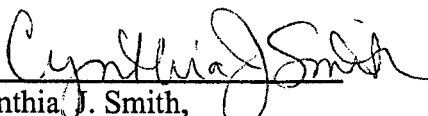
---

---

**Appendix E: Determination of non-regulated status for Bollgard II Cotton Event 15985 Producing the Cry2Ab Insect Control Protein derived from *Bacillus thuringiensis* subsp. *kurstaki***

In response to a petition (designated 00-342-01P) from the Monsanto Company (Monsanto), APHIS has determined that genetically engineered Cotton Event 15985 and progeny derived from it will no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340. Permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for Cotton Event 15985 and its progeny. Importation of seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR Part 319 and the Federal Seed Act regulations at 7 CFR Part 201. This determination is based on APHIS' analysis of field, greenhouse, and laboratory data and references provided in the petition and other relevant information as described in this environmental assessment that indicate that plants derived from Cotton Event 15985 will not pose a plant pest risk for the following reasons: (1) they do not exhibit plant pathogenic properties; (2) they are no more likely to become weeds than their nonengineered parental varieties; (3) they are not likely to increase the weediness potential for any other cultivated plant or native wild species with which the organisms can interbreed; (4) they will not cause damage to processed agricultural commodities; (5) they are not likely to harm other organisms, such as bees and earthworms, that are beneficial to agriculture; and (6) they should not reduce the ability to control insects in cotton or other crops when cultivated.

APHIS acknowledges that there may be new varieties bred from Cotton Event 15985. APHIS believes that such plants are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for cotton descended from Cotton Event 15985, or those observed for other cotton varieties not considered regulated articles under 7 CFR Part 340.

  
Cynthia J. Smith,  
Acting Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture  
Date:

NOV 05 2002