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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. 00–070–3]

Mycogen c/o Dow and Pioneer; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc., corn line designated as line 1507, which has been genetically engineered for insect resistance and tolerance to the herbicide glufosinate, 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 Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc., in their petition for a determination of nonregulated status and our analysis of other scientific data. This notice also announces the availability of our written determination document and a finding of no significant impact.

EFFECTIVE DATE: June 14, 2001.

ADDRESSES: You may read the determination, an environmental assessment and finding of no significant impact, and the petition in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there 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. Susan Koehler, Biotechnology Assessments Section, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–4886. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734–4885; e-mail: kay.peterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On May 15, 2000, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 00–136–01p) from Mycogen Seeds c/o Dow AgroSciences LLC (Mycogen c/o Dow), of Indianapolis, IN, and Pioneer Hi-Bred International, Inc. (Pioneer), of Johnston, IA, seeking a determination that a corn line designated as *Zea mays* L. cultivar line 1507 (line 1507), which has been genetically engineered for resistance to certain lepidopteran insect species and tolerance to the herbicide glufosinate, does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On September 6, 2000, APHIS published a notice in the **Federal Register** (65 FR 53976–53977, Docket No. 00–070–1) announcing that the Mycogen c/o Dow and Pioneer petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn line and food products derived from it. In the notice, APHIS solicited written comments from the public as to whether corn line 1507 posed a plant pest risk. The comments were to have been received by APHIS on or before November 6, 2000. APHIS received no comments on the subject petition during the designated 60-day comment period.

APHIS then published a notice in the **Federal Register** on April 18, 2001 (66 FR 19915–19916, Docket No. 00–070–2), announcing the availability for public comment of an environmental assessment (EA) for a proposed determination that corn line 1507 would no longer be considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Comments were to have been received by APHIS on or before May 18, 2001. We received no comments on the EA during the designated 30-day comment period.

Analysis

Corn line 1507 has been genetically engineered to express a Cry1F insecticidal protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *aizawai (Bt aizawai).* The Cry1F protein is said to be effective in controlling the larvae of common pests of corn such as European corn borer, southwestern corn borer, black cutworm, fall armyworm, and corn ear worm. The subject corn line also contains the *pat* gene derived from the bacterium *Streptomyces viridochromogenes.* The *pat* gene encodes a phosphinothricin acetyltransferase (PAT) protein, which confers tolerance to the herbicide glufosinate. Expression of the added genes is controlled in part by gene sequences from the plant pathogens cauliflower mosaic virus and *Agrobacterium tumefaciens.* The microprojectile bombardment method was used to transfer the added genes into the recipient inbred corn line Hi-II.

Corn line 1507 has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogens. However, evaluation of data from field tests conducted under APHIS notifications since 1997 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of the subject corn line.

Determination

Based on its analysis of the data submitted by Mycogen c/o Dow and Pioneer and a review of other scientific data and field tests of the subject corn line, APHIS has determined that corn line 1507: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than insect-resistant and herbicide-tolerant corn varieties developed by traditional plant breeding; (3) is unlikely to increase the weediness potential for any sexually compatible cultivated or wild species; (4) will not cause damage to raw or processed agricultural commodities; (5) will not harm nontarget organisms, including threatened or endangered species or organisms that are recognized as beneficial to the agricultural ecosystem; and (6) should not reduce the ability to control insects or weeds in corn or other crops. Therefore, APHIS has concluded that the subject corn line and any progeny derived from hybrid crosses with other corn varieties will be as safe to grow as corn in traditional breeding programs that is not subject to regulation under 7 CFR part 340.

The effect of this determination is that the Mycogen c/o Dow and Pioneer corn line 1507 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 corn line or its progeny. However, importation of corn line 1507 or 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 has been prepared to examine the potential environmental impacts associated with this determination. 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 finding of no significant impact (FONSI) with regard to its determination that the Mycogen c/o Dow and Pioneer corn line 1507 and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Done in Washington, DC, this 2nd day of August 2001.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–20307 Filed 8–13–01; 8:45 am]
BILLING CODE 3410–34–P

Approval of Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc. Request (00-136-01p) Seeking a Determination of Non-regulated Status For *Bt* Cry1F Insect Resistant, Glufosinate Tolerant Corn Line 1507

Environmental Assessment and Finding of No Significant Impact

June 2001

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 00-136-01p) for a determination of nonregulated status received from Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc. under APHIS regulations at 7 CFR Part 340. The subject of this petition, corn line 1507, is genetically engineered to express two foreign proteins, a truncated Cry1F insecticidal protein and a phosphinothricin-N-acetyltransferase enzyme, which confer resistance to certain lepidopteran insect pests and tolerance to glufosinate herbicide, respectively. On April 18, 2001, APHIS published a notice in the ***Federal Register*** (66 FR 19915-19916, Docket no. 00-070-2) announcing the availability of the EA for public review and comment. No comments were received during the designated 30 day comment period; however the EA was revised to reflect the current status of recent conclusions by the U.S. Environmental Protection Agency and the Food and Drug Administration regarding the use of this corn line as a pesticide and as food or feed. Based on the analysis carried out in the EA, APHIS has reached a finding of no significant impact (FONSI) to the environment from its determination that corn line 1507 and progeny derived from it shall no longer be considered regulated articles.

M. J. Firko

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U.S. Department of Agriculture
Date: 6/14/01

USDA/APHIS Decision on Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc. Petition 00-136-01P Seeking a Determination of Nonregulated Status for *Bt* Cry1F Insect Resistant, Glufosinate Tolerant Corn Line 1507

Environmental Assessment

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APPENDICES

I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) prior to making its determination on the regulated status of corn (*Zea mays*) line 1507 that has been genetically engineered (transformed) for lepidopteran insect resistance and glufosinate herbicide tolerance. APHIS has received a petition (designated 00-136-01P) from Mycogen Seeds c/o Dow AgroSciences LLC (Indianapolis, Indiana) and Pioneer Hi-Bred International, Inc. (Johnston, Iowa) for a determination that corn line 1507 does not present a plant pest risk, and therefore should no longer be treated as a regulated article under APHIS regulations found at 7 CFR Part 340. The petition contains information to support this determination.

The corn line 1507 has been developed to provide farmers an alternative option for the control of certain lepidopteran insect larvae (including European corn borer, southwestern corn borer, fall armyworm, and black cutworm) that are pests of corn. This lepidopteran resistance has been achieved through the insertion and expression of a truncated *cry1F* gene derived from the bacterium *Bacillus thuringiensis* subsp. *aizawai*. This gene encodes a Cry1F insecticidal protein that is efficacious in controlling these lepidopteran larvae. Corn line 1507 also expresses the *pat* gene, which is derived from the bacterium *Streptomyces viridochromogenes.* This gene encodes a phosphinothricin-N-acetyltransferase (PAT) enzyme. PAT detoxifies glufosinate and thereby confers tolerance to herbicides based on this active ingredient. The herbicide tolerance provides an alternative weed management tool for farmers and a method of selecting for corn which contains the transgenes. Corn line 1507 is a regulated article under APHIS regulations at 7 CFR Part 340 because some DNA sequences used to regulate the expression of these foreign genes in corn were derived from plant pests. The genes, along with these regulatory sequences, were introduced into the corn genome via the particle bombardment technique.

As a regulated article, the importation, interstate movement, or cultivation in the environment in the United States of corn line 1507 has been conducted under authorizations from APHIS that require 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 addresses the potential for impacts to the human environment that might be incurred from an APHIS determination of nonregulated status for corn line 1507 as requested. After a review of the available evidence, including that provided in the petition as well as other scientific literature, APHIS believes that corn line 1507 will be just as safe to grow as corn varieties that are traditionally bred or that have been deregulated under 7 CFR Part 340.

II. BACKGROUND

A. Development of line 1507 corn.

Corn line 1507 has been developed to provide farmers an alternative option for the control of larvae of certain lepidopteran insects which are significant pests in corn. The petition states that *B.t.* Cry1F corn line 1507 is highly efficacious in the control of European corn borer (ECB), southwestern corn borer (SWCB), fall armyworm (FAW), and black cutworm (BCW), and moderately efficacious in the control of corn earworm (CEW). Larvae of ECB, SWCB, and FAW feed and burrow on corn leaves, stem whorls, stalks and/or ears resulting in stalk lodging, dropped ears, and damaged grain. BCW larvae cut off plants at or slightly below the soil surface, reducing plant stands. CEW feed primarily on the corn silk and ears resulting in yield loss and grain damage. *Bacillus thuringiensis* (*B.t.*) bacteria produce a group of related toxins (delta-endotoxins) that when ingested by susceptible lepidopteran insects result in their death. Preparations of *B. thuringiensis* containing delta-endotoxins are used as foliarly applied biopesticides. However, they are not routinely effective against ECB and the other stalk boring larvae because at certain stages these larvae primarily feed inside the plants where the foliar applied biopesticide cannot reach. The same problem is encountered with other nonsystemic, foliarly applied chemical insecticides. The recent development and approval of transgenic corn plants expressing *B.t.* delta-endotoxins has provided growers with another safe and efficacious option for the control of ECB which growers have widely embraced. Pioneer Hi-Bred International, Inc. (Pioneer) has modified the corn line 1507 to express a gene developed by Mycogen that produces a shorter version of a different delta-endotoxin protein, Cry1F, which has a slightly broader spectrum of activity against lepidopteran pests of corn than currently available corn varieties expressing *B.t.* Cry1A delta-endotoxins.

Corn line 1507 is also genetically modified to express the phosphinothricin-N-acetyltransferase (PAT) enzyme encoded by the *pat* gene derived from the bacterium *Streptomyces viridochromogenes.* PAT detoxifies glufosinate and thereby confers tolerance to herbicides based on this active ingredient (e.g. the herbicides Basta®, Rely®, Finale®, and Liberty®). The herbicide tolerance provides an alternative weed management tool for farmers and a method of selecting for the corn which contains the transgenes.

The truncated *cry1F* gene and the *pat* gene coding sequences were fused to regulatory sequences which enable the Cry1F and PAT proteins to be expressed constitutively throughout most of the plant. These regulatory regions were derived from genes from corn and from the plant pathogens cauliflower mosaic virus (CaMV) and *Agrobacterium tumefaciens.* No proteins are produced from the regulatory regions themselves.

Particle bombardment, a technique that is commonly used to introduce new genetic material into plants, was used to introduce these new gene constructs into corn to create the transgenic line 1507. Because line 1507 corn is engineered to contain genetic material from plant pathogens, it is considered to be a regulated article under APHIS regulations at 7 CFR Part 340.

Corn line 1507 has been field tested in a wide variety of locations, in at least 20 States and in Puerto Rico since 1997 under notifications or permits from APHIS that are listed in Appendix A, and in Chile as well. This field testing was conducted, in part, to confirm that line 1507 corn exhibits the desired agronomic characteristics and does not pose a plant pest risk. Although these field tests were conducted in agricultural settings, APHIS acknowledgment of notifications for the tests have stipulated that the regulated article and its offspring must not persist in the environment after completion of the test. Therefore, measures were employed to ensure physical and reproductive confinement from other sexually compatible plants and to manage volunteers. Reports for those field tests completed under APHIS authorization and other information contained in the petition have been submitted to APHIS upon which to base a determination that line 1507 corn does not pose a plant pest risk.

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. Line 1507 corn 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.

Line 1507 corn 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, including herbicides, be registered before distribution or sale, unless exempt by EPA regulation. On May 5, 2000, the EPA announced receipt of an application from Mycogen Seeds, c/o Dow Agrosciences LLC [EPA File Symbol 68467-E] and Pioneer Hi-Bred International, Inc. [EPA File Symbol 29964-G] to register the pesticide product *Bt* Cry1F protein and the genetic material necessary for its production in corn plants (65 *FR* 26199). This application had previously been reported as a seed increase registration application on November 26, 1999 (64 FR 66474), but it was modified to request full commercial use. This active ingredient is not included in any previously registered product. 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. On May 18, 2001, the EPA granted a conditional, time-limited registration for this pesticide product in field corn that will automatically expire on midnight September 30, 2001. Prior to this date, EPA will determine whether to extend the expiration date, convert the registration to a non-expiring registration, or let the registration expire.

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. On June 15, 2000, the EPA announced receipt of the initial filing of a pesticide petition (PP 0G6112), submitted by Mycogen Seeds c/o Dow AgroSciences LLC, proposing an exemption from the requirement of a tolerance for residues of plant-pesticides *B.t.* Cry1F protein and the genetic material necessary for the production of this protein in or on all food commodities (65 *FR* 37545-37547). On May 18, 2001 the EPA granted the proposed exemption, but it is limited to field corn, sweet corn, and popcorn.

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. Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc. submitted a summary of their safety assessment to the FDA on June 28, 2000. On May 18, 2001 the FDA acknowledged the companies' conclusions that maize line 1507 is not materially different in composition, safety, or other relevant parameters from maize currently on the market, and that it does not raise issues that would require premarket review or approval of FDA, and they indicated that they had no further questions concerning line 1507.

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 line 1507 corn as a regulated article under APHIS regulations. Mycogen Seeds c/o Dow AgroSciences LLC (Indianapolis, Indiana) and Pioneer Hi-Bred International, Inc.(Johnston, Iowa), the developers of line 1507 corn, submitted a petition requesting a determination from APHIS that corn transformation event TC1507 and the resulting maize line 1507 derived from it or any progeny derived from crosses with maize line 1507 and any other nonregulated corn varieties, no longer be considered regulated articles under 7 CFR Part 340.

IV. ALTERNATIVES

A. No Action

Under the "no action" alternative, APHIS would come to a determination that line 1507 corn and its progeny should continue to be regulated under 7 CFR Part 340. Permits or acknowledgment of notifications from APHIS would still be required for their introduction. APHIS would choose this alternative if there were insufficient evidence to demonstrate lack of plant pest risk from the uncontained cultivation of line 1507 corn and its progeny.

B. Proposed Action: Determination of Nonregulated Status

Under this alternative, line 1507 corn and its progeny would no longer be considered regulated articles under 7 CFR Part 340. Permits from or notifications to APHIS would no longer be required for introductions in the United States and its territories of line 1507 corn or its progeny. A basis for this determination would be established, which would result in a "Finding of No Significant Impact (FONSI) under NEPA. Unrestricted cultivation of the lines would be permitted by APHIS. Such a determination, however, does not preclude any restriction which might be placed on cultivation of this corn by other regulatory agencies also having authority over the use of this corn. The current conditional pesticide registrations for line 1507 corn recently granted by the EPA include restrictions on the sale and cultivation of this corn in certain counties in Indiana, Illinois, Michigan, Minnesota, Wisconsin, New Hampshire, and New York where the endangered Karner blue butterfly exists.

V. POTENTIAL ENVIRONMENTAL IMPACTS

The potential environmental impact of each of the alternatives cited in IV. A. and B. will be presented.

Alternative A.
In a decision to choose alternative A., no action, these plants would still require APHIS authorization to be planted. In this case measures would need to continue to be implemented to ensure physical and reproductive confinement of corn line 1507 and any progeny derived from it.

If growers do not have improved varieties of corn seed derived from line 1507, they may choose to plant another cultivar with similar properties as an alternative, or they may use other chemical or biological control mechanisms or management practices if they feel that their lepidopteran pest pressure and weed pressure is high enough to warrant it.

Other deregulated transgenic lepidopteran resistant corn expressing other Bt delta-endotoxins and other herbicide tolerant corn varieties are available by seed companies, and have been widely adopted by farmers in the United States (Fernandes-Cornejo and McBride, 2000; Carpenter and Gianessi, 1999). Herbicide tolerant varieties include the transgenic Liberty Link™ varieties resistant to the herbicidal active ingredient glufosinate-ammonium (e.g. as found in the herbicide Liberty® which is registered in the United States for use on seed designated as Liberty Link™), transgenic Roundup Ready™ varieties resistant to the herbicidal active ingredient glyphosate (as found in the herbicide Roundup®), as well as nontransgenic varieties resistant to two other types of herbicides: the acetolactate synthase (ALS) inhibiting herbicide imidazolinone (IMI) and sethoxydim (Knake, 1998; Fernandez-Cornejo and McBride, 2000). Other nontransgenic, corn borer-tolerant, hybrid varieties of corn are also available (Davidson and Lyons, 1987). Several chemical insecticides and biological or cultural control measures can be used to control the pests targeted by Bt Cry1F in line 1507 corn, and several herbicides and cultural practices can be used to manage weeds in corn. Details regarding the extent to which different control methods are currently employed, and the impacts from these are discussed in Section V. F. of this document.

No significant adverse impacts are envisioned if APHIS chooses alternative A.

Alternative B.
A decision to choose alternative B, deregulation of corn line 1507, is addressed below. The environmental impacts of unrestricted cultivation of corn line 1507 are compared to any impacts posed by the cultivation and distribution of corn not subject to APHIS regulation under 7 CFR Part 340.

A. Plant pathogenic properties

APHIS considered the potential for the transformation process, the introduced DNA sequences, or their expression products to cause or aggravate disease symptoms in corn line 1507 or other plants or to cause the production of plant pathogens. We also considered whether data indicate that unanticipated plant pest effects would arise from cultivation of line 1507 corn.

For the transformation process, cultured embryos from a public corn line designated Hi-II were used as the recipient material. Hi-II is a cross between A188 and B73 inbred lines of maize. The embryos were bombarded with microprojectiles coated with a linear portion of DNA (designated PHI8999A) containing the genetic constructs for both the *cry1F* and *pat* genes that had been cut out of a circular plasmid designated PHP8999, which is described in more detail in Table 1 of the petition.

APHIS analyzed data that demonstrates that a line 1507 corn plant regenerated from the embryo callus culture transformation event designated TC1507 contains one copy of the following genetic constructs derived from PHI8999A: (1) the truncated *cry1F* gene originally derived from *B.t.* var. *aizawai* strain PS811 whose transcription is directed by the promoter and a 5' untranslated region from the corn ubiquitin gene including the first exon and intron and whose termination/polyadenylation sequences were derived from the *Agrobacterium tumefaciens* open reading frame 25 (ORF25 PolyA); and (2) the *pat* gene derived from *Streptomyces viridochromogenes* that encodes the enzyme phosphinothricin acetyltransferase (PAT) whose transcription and termination/polyadenylation sequences were derived from the cauliflower mosaic virus (CaMV) 35S RNA promoter and terminator, respectively. Data also demonstrate that both the truncated Cry1F protein and the PAT protein are expressed. Line 1507 corn also contains a second, presumably unexpressed, copy of the truncated *cry1F* gene which lacks the full ubiquitin promoter.

The donor organisms for the *cry1F* and *pat* genes (*B.t.* var. *aizawai* strain PS811 and *Streptomyces viridochromogenes*, respectively) are soil-inhabiting bacteria. Neither of these bacteria are plant or human pathogens, and the Cry1F and PAT proteins encoded by these genes do not cause disease symptoms or the production of infectious agents in plants. The truncated *cry1F* gene and the *pat* gene coding sequences were modified for optimal expression in the plant, in part, by changing their codon bias to that favored by plants. The protein encoded by the truncated *cry1F* gene is nearly identical to the first 605 amino acids of the Cry1F protein protoxin produced by the *B.t.* var. *aizawai* strain PS811. The only exception is a single amino acid substitution, leucine for phenylalanine at position 604. This truncated Cry1F protein corresponds to the insecticidally active portion of the delta endotoxin that remains following cleavage of the 569 amino acids from the end of the 1174 amino acid full length protoxin in the gut of susceptible lepidopteran larvae. The PAT protein catalyzes an acetylation reaction which converts L-phosphinothricin, the active ingredient in glufosinate ammonium herbicides, to an inactive form (OECD, 1999).

Some of the noncoding regulatory sequences that were fused to the truncated *cry1F* gene and the *pat* gene to allow constitutive expression and processing of their messenger RNA (mRNA) in plants were derived from plant pathogens. *A. tumefaciens* is the bacterium that causes a crown gall disease in plants, and CaMV is a plant virus which causes disease primarily in cruciferous plants. None of these sequences cause disease symptoms in plants, nor do they encode the production of an infectious agent.

The line 1507 corn plant was crossed with an elite inbred corn line to produce seed used for further breeding and analysis. APHIS analyzed data and information submitted in the petition that characterize the nature, stability, inheritance, and expression of the inserted genetic constructs and their encoded proteins in different generations of plants derived from line 1507. DNA analysis of seeds from two different generations (see Petition, Section V.A. and B., Table 4 and Figs. 5-9) supports the conclusion that (1) line 1507 contains within its genomic DNA (nuclear chromosomes) a single copy of an intact fragment containing both the *cry1F* and *pat* gene constructs with their associated noncoding regulatory regions and a second copy of the *cry1F* coding region lacking the majority of the associated ubiquitin regulatory sequences; and (2) these genetic constructs were stably inherited and cosegregated over four generations of backcrossing. As expected, data also show that a bacterial antibiotic resistance selectable marker gene located on PHP8999 is not present in line 1507. Inheritance data provided for two different generations (see Petition Section V.C. Table 5, amended July 19, 2000) supports the conclusion that both the *pat* gene and at least one of the *cry1F* genes are stably inherited and expressed as genetically linked, Mendelian dominant genes. Data characterizing the expression of the encoded Cry1F and PAT proteins in hybrids derived from a third backcross generation of line 1507 (see Petition Section V.D. Table 6 and Section V.E. Figs. 11-13) support the conclusion that, as expected, the proteins are constitutively expressed and are of the correct molecular weight, with some minor proteolytic degradation of Cry1F. No apparent fusion or truncated proteins were detected. Cry1F protein was detectable in whole plants (minus the roots) collected at four weeks prior to pollination and following senescence and in leaves, pollen, silk, stalk, and mature grain; whereas PAT was only detectable in leaf tissue. Efficacy data submitted with the petition support the conclusion that hybrids derived from line 1507 exhibit the expected traits conferred by the expression of the introduced genes, i.e., resistance to lepidopteran insects and tolerance to glufosinate-ammonium herbicide (see Petition appendix Volume 17 and Response to Deficiency #3 dated July 19, 2000, respectively).

Reports evaluated by APHIS for field tests conducted since 1997 in 14 States (North Dakota, South Dakota, Nebraska, Missouri, Minnesota, Wisconsin, Iowa, Illinois, Indiana, Michigan, Delaware, Tennessee, Texas, Hawaii) and in Puerto Rico indicate that no differences were observed between line 1507 hybrid corn and the nontransgenic hybrid counterparts for disease and pest susceptibility, other than resistance to the targeted lepidopteran pests. These tests included the major corn growing areas of the United States. In the field trial report for permit 99-028-01r, a physiological phenomenon known as firing, whereby progressive death and drying of leaf tissue occurs from the lower leaves to the upper leaves over of period of days, was reported for plants derived from a cross between line 1507 corn and another regulated transformation event. In all cases, this effect was associated with the second transformation event, and has otherwise not been associated with line 1507 (letter from Pioneer to APHIS dated November 21, 2000 and supporting data submitted January 8, 2001). APHIS analysis of this data along with data submitted on agronomic performance and grain and forage composition of hybrids derived from line 1507 corn (described in more detail below in sections B. and G., respectively) support the conclusion that except for the intended traits conferred by the introduced genes, these plants exhibit traits similar to other corn hybrids. Therefore, no unanticipated plant pest effects are expected to result from their cultivation. Corn derived from line 1507 is not expected, nor has it been observed, to exhibit new disease symptoms or cause such symptoms to occur in other plants.

B. Potential impacts based on the relative weediness of line 1507 corn compared to currently cultivated corn varieties.

APHIS evaluated whether line 1507 corn is any more likely to become a weed than the nontransgenic recipient corn line, or other corn currently cultivated, by considering the characteristics of line 1507 corn, the new traits conferred upon it due to expression of the transgenes, and the characteristics associated with previously deregulated corn engineered to express similar traits. APHIS also evaluated whether line 1507 corn was any more likely to transmit weedy characteristics to other cultivated corn.

In the United States, corn is not listed as a weed in the major weed references (Crockett, 1977; Holm *et al.*, 1979; Muenscher, 1980), nor is it present on the lists of noxious weed species distributed by the Federal Government (7 CFR Part 360). Furthermore, corn has been grown throughout the world without any report that it is a serious weed. Cultivated corn is unlikely to become a weed. It is not generally persistent in undisturbed environments without human intervention. Although corn volunteers are not uncommon, they are easily controlled by herbicides or mechanical means. Corn also possesses few of the characteristics of plants that are notably successful weeds (Baker, 1965; Keeler, 1989).

Corn line 1507 exhibits no characteristics that would cause it to be more weedy than the parent corn line or other corn hybrids. As noted above, reports from field trials in the United States indicate that no differences were observed between line 1507 hybrid corn and the nontransgenic hybrid counterparts for disease and pest susceptibility, other than resistance to the targeted lepidopteran pests. APHIS evaluated data submitted in the petition that show that no significant differences were observed in agronomic performance traits between a line 1507 hybrid and an appropriate hybrid control grown without insecticides in various field trials across the United States in 1999 (see Petition Section V.G., Table 8). Traits evaluated include yield, percent seed moisture, grain density, accumulated growing degree units to reach reproductive maturity (both 50 percent pollen shed or silking), plant and ear height, seedling emergence and establishment, vigor measured from emergence to the one-leaf stage and from the three- to five-leaf stage, stalk and root lodging, dropped ears, and top integrity. Data was also provided that indicate that hybrids of line 1507 are comparable to other corn hybrids in seed germination characteristics under optimal conditions and under cold stress (see Petition SectionV.G.Table 9). Therefore, data do not indicate that hybrids derived from line 1507 would be any more competitive or vigorous in their ability to germinate or establish in different environments or reproduce or have other characteristics that would increase their capacity to compete or persist as a weed.

The introduced genetic constructs and new traits, lepidopteran insect resistance and tolerance to glufosinate herbicides, are not expected to cause line 1507 corn to become a weed. None of the characteristics of weeds described by Baker involve resistance or susceptibility to insects, and there is no reason to expect that the protection against the target insects provided by this new corn line would release it from any constraint that would result in increased weediness. Genetically engineered corn varieties with these traits have been widely grown in the United States since at least 1996. Estimates of the percentage of corn acreage in 1998 planted to Bt corn and Liberty Link™ corn are 18% and 7.5%, respectively (Carpenter and Gianessi, 1999). APHIS could find no reports of increased weediness in these corn varieties.

In the United States, when corn fields are rotated to another crop, usually soybeans, corn plants may volunteer and pose a minor weed problem. Glufosinate-based herbicides are used for post-emergent control of many broadleaf and grassy weeds. Volunteers of line 1507 corn or offspring of crosses between line 1507 corn and other non-herbicide tolerant corn lines could be controlled using physical methods or with the use of other herbicides that are not based on glufosinate and which are registered for use on the crop, as appropriate. If crop varieties resistant to different herbicides are planted within pollination distance of each other (e.g. in adjacent fields), volunteers with multiple herbicide tolerance could emerge in the subsequent growing season. However, several factors make the probability of such occurrences rare in corn: (1) temporal differences in pollination dates and/or planting dates of different varieties will reduce the likelihood of concurrent periods of pollen shed or silking; (2) the pollen load within a given field will tend to swamp out the effect of pollen drift from adjacent fields; (3) corn pollen is only viable for about 30 minutes under optimal conditions (Canadian Food Inspection Agency, 1994); (4) corn pollen concentration drops off rapidly from the source to less than 1% within 60 meters (Raynor *et al.*, 1972); and (5) strict measures are taken to ensure genetic purity during production of hybrid corn seed. By making appropriate choices in varieties, planting locations, crop rotations, and herbicides, growers can avoid such occurrences. Despite the fact that corn varieties tolerant to the herbicides glufosinate-ammonium, glyphosate, imidazolinone, or sethoxydim have been planted over at least the last five years (at about three percent of U.S. corn acreage in 1996 to about 19 percent in 1998) (Fernandez-Cornejo and McBride, 2000), APHIS could find no reports of multiple herbicide tolerant corn volunteers posing a weed problem. Should such multiple herbicide tolerant volunteers occur with varieties developed from corn line 1507 and corn that is tolerant to another herbicide active ingredient with a different mode of action, an alternative herbicide with a mode of action different from those to which resistance has developed or other measures such as mechanical cultivation can be used to control the volunteer if it poses a weed problem in a subsequent crop.

APHIS concludes that, with the exception of increased resistance to certain lepidopteran insects and tolerance to glufosinate herbicides, line 1507 corn has agronomic traits similar to those of traditionally bred corn, and it does not exhibit traits that would cause increased weediness. Its cultivation should not lead to increased weediness of other cultivated corn.

C. Potential impacts from gene introgression from line 1507 corn into its sexually-compatible relatives.

APHIS evaluated the potential for gene introgression to occur from line 1507 corn to sexually compatible wild relatives and considered whether such introgression would result in increased weediness. Cultivated corn, or maize, *Zea mays* L. subsp. *mays*, is sexually compatible to varying degrees with other members of the genus *Zea* collectively referred to as teosinte and to a much lesser extent with members of the genus *Tripsacum* (see Appendix B for a more detailed discussion).

The genus *Tripsacum* contains several species, most of which are native to Mexico, Central and South America and three of which exist as wild and/or cultivated in the United States. (Hitchcock, 1971). Though many of these species occur where corn might be cultivated, successful gene introgression from corn under natural conditions is highly unlikely.

Teosinte populations are normally confined to the tropical and subtropical regions of Mexico, Guatemala, and Nicaragua. They primarily exist within and around cultivated maize fields and are partially dependent on agricultural or open habitats. In some cases they are grazed upon by cattle which distribute the seed. While some teosinte may be considered to be weeds in certain instances, they are also used by some farmers for maize breeding (Sánchez and Ruiz, 1997, and references therein). In Mexico, conservation measures are already in place to collect germplasm and protect some of the wild populations of *Zea* species *in situ*.

Gene introgression from line 1507 corn into teosinte or *Tripsacum* species would require that varieties be developed, and approved for cultivation in locations where these relatives are located. Mexico as well as other countries in South America (e.g. Brazil, Argentina, and Uruguay) have regulatory procedures in place that require a full evaluation of transgenic plants before they can be introduced into their environment.

Since line 1507 corn does not exhibit characteristics that cause it to be any more competitive or weedy than other cultivated corn, its potential impact due to the limited potential for gene introgression into teosinte and extremely limited potential for gene introgression into *Tripsacum* species is not expected to be greatly different from that of other varieties of cultivated corn bred for increased resistance to lepidopteran pests or for herbicide tolerance. Researchers at CIMMYT (an internationally funded, nonprofit scientific research and training organization headquartered in Mexico) collaborating with scientists from other countries have developed maize genotypes with multigene resistance to several major lepidopteran pests of maize in Latin America (Smith, 1997, and references therein). Teosinte is described to be susceptible to many of the same pests and diseases which attack cultivated corn (Sánchez and Ruiz, 1997, see discussion), while at the same time resistance to the lepidopteran pests sugarcane borer and FAW have been identified in Caribbean and/or Mexican maize populations (Smith, 1997, and references therein). It is unlikely that potential introgression of ECB resistance or glufosinate tolerance traits from line 1507 corn would cause teosinte to become more weedy in the absence of glufosinate herbicide selection. Because the *Tripsacum* species are not considered to be weeds in the United States (Holm et al., 1979), the unlikely introgression of the glufosinate herbicide tolerance trait from line 1507 corn would not be expected to provide a selective advantage to these populations since they would not be routinely subject to herbicide treatments.

D. Potential impact on nontarget organisms, including beneficial organisms and threatened or endangered species.

APHIS evaluated the potential for line 1507 corn plants and their products to have damaging or toxic effects directly or indirectly on nontarget organisms. Nontarget organisms considered were those representative of the exposed agricultural environment, including those that are recognized as beneficial to agriculture or as threatened or endangered in the United States. APHIS also considered potential impacts on other "nontarget" pests, since such impacts could potentially change agricultural practices.

The expression of PAT in corn plants is not expected to have deleterious effects or significant impacts on nontarget organisms, including beneficial organisms, based on data provided in the petition and APHIS analyses of previously deregulated transgenic corn lines that express PAT. The DNA encoding the PAT protein is not toxic and the PAT protein shares no homology with proteins known to be toxic or allergenic (OECD, 1999).

The Cry1F protein expressed in line 1507 corn is similar to the well known Cry1A class of lepidopteran-specific toxins produced by *B.t.* strains. The specificity of the insecticidal activity of these Cry proteins appears to be dependent upon their binding to specific receptors present in the mid-gut of lepidopteran insects (Lambert, *et al.*, 1996; Van Rie *et al.*, 1990; Van Rie *et al.*, 1989; Hofmann *et al.*, 1988a and 1988b; and Wolfersberger *et al.*, 1986). These insecticidal proteins are not expected to adversely effect other invertebrates and all vertebrate organisms, including non-target birds, mammals and humans, because these organisms would not be expected to contain the receptor protein found in the insect's midgut.

Potential impacts on nontarget, non-lepidopteran pests.
Target pests of the modified Cry1F protein expressed in line 1507 corn are larvae of certain lepidopteran pests of corn. Field test reports for APHIS permits and notifications and efficacy studies submitted indicate that, as expected, corn line 1507 hybrids are protected to varying degrees against feeding damage from certain lepidopteran pests including ECB, SWCB, FAW, BCW, CEW (Petition, Vol. 17). The petition notes that breeders visually monitored the *B.t.* Cry1F corn line 1507 hybrids and non-modified maize lines during field tests conducted under APHIS notifications for pest resistance, and they reported no differences in insect damage caused by non-lepidopteran pests such as aphids, rose beetles, corn flea beetles, and red spider mites.

Potential impacts on nontarget organisms, including beneficial organisms.
APHIS evaluated the results of several studies submitted that were designed to evaluate the sensitivity of representative nontarget organisms to Cry1F as expressed in different test substrates: i.e., line 1507 corn grain or pollen expressing modified Cry1F protein; or Cry1F purified from a Cry-minus bacterial strain engineered to express the protein toxin. The results of these studies are included in Appendix C of this Environmental Assessment. Data supporting these studies was submitted to the EPA in support of the registration of the plant-pesticide. APHIS concluded that the petitioner adequately demonstrated that the bacterially-produced

Cry1F, as purified and prepared for these studies, was similar enough in its biochemical properties (molecular weight, amino acid sequence, and lack of glycosylation) and in its biological activity against lepidopteran larvae to warrant its use as a test substance comparable to Cry1F as produced in line 1507 corn. In both cases, the predominant active protein purified from these sources was a protease-resistant core protein with a molecular weight of approximately 65 kDa. Tests included acute dietary toxicity studies with beneficial arthropods such as honeybee larvae, predatory ladybird beetle (*Hippodamia convergens*) and green lace wing (*Chrysopa carnea*), and parasitic hymenoptera (*Nasonia vitripennis*); a 28 day chronic effects study on survival and reproduction of the soil-dwelling arthropod Collembola (springtails) (*Folsomia candida*); and acute toxicity studies with other nontarget organisms including earthworms, the freshwater invertebrate *Daphnia magna*, Northern bobwhite, and mice. Results of these studies indicate that no deleterious effects on these organisms would be expected due to incidental exposure or feeding on line 1507 corn. This takes into consideration the levels of the Cry1F protein measured in different tissues of line 1507 corn, the environmental fate and likely routes and levels of exposure to line 1507 corn plant tissue or residues of this tissue that contain the active toxin, and dietary preferences.

In addition to the laboratory studies, results of a small scale field study conducted in 1999 in Johnston, Iowa (Petition, Vol. 16) demonstrated that there was no consistent pattern of differences in abundance of several categories of beneficial arthropod predators observed in plots planted to two transgenic corn lines expressing the Bt. Cry1F (one of which was line 1507 corn) or the non-transformed genetically similar corn[1].

Potential impacts on monarch butterflies

Laboratory studies have suggested that monarch butterfly larvae may be adversely effected by feeding on their host plant (milkweed) when it is exposed to pollen from transgenic corn plants expressing other *B.t.* Cry proteins (Losey *et al.*, 1999; Hansen and Obrycki, 2000). Several different *Bt* toxins, Cry1Ab, Cry1Ac, and Cry9C, have been conditionally registered as plant-pesticides as expressed in different Bt corn transformation events, but the status of some of these registrations has recently changed. Transformation events containing Cry1Ac and Cry9C will no longer be available due to voluntary cancellations (U.S. EPA, 2000a). In December of 1999, the EPA subsequently issued a monarch butterfly adverse effects data call in for all registrants of *Bt* corn products and presented current and possible new data requirements to evaluate ecological effects, including the risk to monarch butterflies (U.S. EPA, 2000b). An analysis of recent data, literature, and information on the monarch butterflies, milkweed, pollen movement, and the toxicity of purified Cry proteins against monarch larvae, is presented by the EPA in their preliminary risk and benefit assessment of transgenic plants (U.S. EPA, 2000a). Their preliminary conclusion is that there is a low probability of adverse effects of *Bt* corn on monarch larvae. Milkweeds located within 1 meter of cornfields are unlikely to be dusted with toxic levels of *Bt* pollen from the two most widely planted *Bt* corn varieties whose registrations are not

[1]The categories observed included lady beetle adults and larvae, predacious beetles, brown lacewings, green lacewings, insidious flower bugs, assassin bugs, damsel bugs, dragonflies, and spiders. Parasitic wasps were also observed, but most likely moved freely between maize lines in the plots.

being withdrawn or canceled, Monsanto's MON 810 and Novartis Seeds, Inc. Bt11 (both of which express Cry1Ab).

The toxicity to monarch larvae of Cry1F as expressed in line 1507 is even lower than the currently registered *Bt* corn plant-pesticides. Data provided in the petition (Vol. 5) indicate that the estimated environmental concentration (EEC) of Cry1F due to line 1507 pollen exposure does not exceed the no effect level (10 micrograms/g) for monarch larvae at any point inside or outside of maize fields. In addition, the EEC of Cry1F on milkweed leaves due to surface deposits of pollen from hybrids of Bt Cry1F line 1507 is estimated to be less than the LC_{50} (that concentration at which 50% mortality is observed) for greater than 90% of Lepidoptera species at distances greater than 0.2 m from the field edge. This estimate is probably representative of what one would expect for pollen disposition on other weeds or plants growing in and around corn fields. Therefore, cultivation of line 1507 corn is not expected to harm monarch butterfly larvae, nor is it expected to significantly affect the majority of other nontarget lepidopteran larvae beyond the field margins.

Potential impacts on threatened and endangered arthropods.
Because of the lack of toxicity of the PAT protein and the demonstrated toxicity of Cry1F to only certain species of lepidopteran larvae, APHIS focused its analysis of impacts on threatened and endangered lepidopteran species. A Biological Opinion from the Department of Interior Fish and Wildlife Service was issued on December 18, 1986, concerning possible effects of foliar spray of *B. t.* subsp. *kurstaki* on threatened and endangered species. Based on difference in exposure routes between foliar spray and expression in plants, APHIS believes that the Biological Opinion is inapplicable. The majority of endangered lepidopterans have very restrictive habitat ranges; and their larvae typically feed on specific host plants, none of which include corn or its sexually compatible relatives. An examination of county distribution of endangered lepidopterans shows that, for the most part, they do not occur in agricultural settings where corn is grown (Petition, Figure 14). The only possible exceptions are Karner blue butterfly and Mitchell's satyr butterfly. APHIS examined the potential for impact on these two species due to exposure to corn pollen expressing Cry1F landing on their host plants. The assessment of risk to monarch butterfly associated with non-target exposure to maize pollen containing Cry1F on their milkweed host plant indicates rapid fall-off in exposure with distance, and consequently there is limited potential for non-target effects beyond the immediate field extremity (Petition Vol. 5).

Mitchell's satyr butterfly occur in northern wetlands fed by seeps and springs known as fens, and their larvae, which are present throughout the summer, feed primarily on sedges (USFWS, 1999). Some of the populations have been observed within 800 meters of corn fields (Wayne Wheling, APHIS Entomologist, personal communication to Susan Koehler). This distance should be sufficient to preclude exposure to toxic concentrations of pollen containing Cry1F. Pollen drift onto sedges in these fens will be further inhibited by the pines and oaks that typically surround these habitats.

The Karner blue requires wild lupine *(Lupinus perennis)* as an oviposition substrate and larval food source, while the adults feed on wild flowers. As of 1992, Karner blue is known to exist along the northern extent of the range of wild lupine, where there are prolonged periods of winter snowpack, in parts of Wisconsin, Michigan, Minnesota, Indiana, New Hampshire, New York, and Illinois (Haack, 1993). Karner blue is associated with wild lupine growing on dry, sandy soils in pine barrens, oak savannah, forest trails and previously disturbed habitats such as utility rights-of-way, military installations, airports, highway corridors, sand roads and sand pits, and abandoned farm fields (Haack, 1993). Wild lupine thrives in full sun to partial shade, and does not survive long in full shade (Haack, 1993), and thus would not survive long in a mature corn field. Likewise, the Karner blue is associated with areas of low to semi-closed canopy cover (Haack, 1993). Therefore, Karner blue larvae are not expected to be found in a mature corn field. In an addendum to their Environmental Assessment for the pesticide registration for line 1507 corn dated April 27, 2001, the EPA indicated that "there are anecdotal reports of wild lupine growing 'within a couple of hundred meters of corn fields'" and that "there are recent reports that wild lupine may, in rare instances, grow in the vicinity of corn fields, especially in cases where the field may have been fallow in the previous season". They noted however, that "there are no reports of Karner blue larvae or wild lupine within one meter of corn fields".

The overlap of Karner blue larval feeding with the period of corn pollen shed is minimal. Karner blue has two brood per year; larvae from overwintering eggs emerge from mid to late April and feed for three to four weeks, and the next generation of larvae emerge and feed from early June through mid July (USFWS, 2000a, b) or late July (Haack, 1993) (USFWS, 2000a,b). Only the second generation larvae have some potential for overlap with pollen shed. Data available from the National Agricultural Statistics Service and information obtained from personal communication with representatives from Crop (or Seed) Improvement Associations in Wisconsin (Mark Martin 5/24/01), Michigan (Randy Judd, 5/18/01), Minnesota (Ben Lang, 5/17/01), and New York (Don Shardlow, 5/16/01), and Cornell (field corn breeder, Margaret Smith, 5/21/01) indicates that in states where Karner blue exists, field and seed corn pollination typically begins either the last week of June or the first two weeks of July and proceeds through mid to late August, however, most of the pollination occurs after July 20 . Sweet corn is grown in some of these states, and their pollination dates are more variable.

Because Cry1F protein is active against Lepidoptera, some activity against the Karner blue at high dose levels would not be surprising, particularly for the younger instars. While the NOEL (no observable effect level) for Karner blue larvae has not been determined, it is unlikely, based on data from other lepidopteran larvae that effects would be observed at distances greater than 1 meter from the field margin. However, due to a lack of a NOEL for Cry1F specifically for Karner blue, and a lack of knowledge about the precise proximity of corn to Karner blue habitats, the EPA has restricted the sale of this corn in 2001 in specific counties where the Karner blue butterfly is known to exist. The pesticide registrations (EPA Reg. Numbers 29964-3 and 68467-2) indicate that it must be stated in the Product Use Guide that Cry1F corn will not be sold in these counties or distributed to anyone who will plant in these counties. The registrations also require the registrants to provide annual sales data for each state and a listing of an estimate of the acreage planted within such states and counties with sales limitations. Furthermore, the registrations are for field corn only, and do not include use of Cry1F in sweet corn. The EPA and APHIS will be initiating joint discussions with the Fish and Wildlife Service prior to the expiration of the pesticide registrations for corn line 1507 on September 30, 2001 to determine whether these restrictions are necessary to protect Karner blue.

Based on this analysis, APHIS concludes that cultivation of line 1507 corn should not have a significant potential to harm nontarget and beneficial organisms common to agricultural ecosystems, nor will it effect species recognized as threatened or endangered by the U.S. Fish and Wildlife Service.

E. Potential impacts on biodiversity

Our analysis concludes that line 1507 corn exhibits no traits that would cause increased weediness, that its cultivation should not lead to increased weediness of other cultivated corn or other sexually compatible relatives, and it 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 concludes that there is no potential for significant impact to biodiversity from a determination of nonregulated status as requested in the petition.

F. Potential impacts on agricultural and cultivation practices

APHIS considered potential impacts associated with the cultivation of lepidopteran-resistant and glufosinate-ammonium tolerant corn line 1507 on current agricultural practices, in particular, those used to control lepidopteran insect pests and weeds in corn and other crops. The potential impacts on organic farming and on minorities and children were also considered.

Impacts of previously deregulated lepidopteran-resistant corn on insect control
To examine the potential impacts of cultivation of *B.t.* Cry1F line 1507 corn, APHIS considered the impacts that other lepidopteran resistant *Bt* corn varieties have had on agricultural practices in the U.S. The major pest controlled by these *Bt* corn varieties is the ECB, but other important pests controlled to varying degrees are CEW, SWCB, and other stalk boring lepidoperan larvae. A risk and benefits assessment for reregistration of *Bt* corn and cotton plant-pesticides has been prepared by the EPA (U.S. EPA, 2000a) and is posted at the following EPA internet site: *http://www.epa.gov/scipoly/sap*. Issues being considered by the EPA pertaining to this assessment were the subject of a meeting convened on October 18-20, 2000 by the EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Food Quality Protection Act (FQPA) Scientific Advisory Panel (SAP). Before these new *Bt* corn varieties were available, farmers were willing to accept lower corn yields rather than incur the expense, trouble, and uncertain results of chemical insecticide applications to control the target pests. Following the registration of *Bt* corn varieties in 1995, growers were quick to embrace this new technology. Estimates of *Bt* corn acreage as a percent of total corn acreage planted are 1% (0.4 million acres) in 1996 to 26% (19.7 million acres) in 1999. EPA's analysis of pesticide usage in corn for the major corn-producing states for which data were available shows that for insecticides recommended for ECB control, acre treatments with respect to acres planted have declined from 8% in the 3 years prior to the introduction of *Bt* corn (1992 to 1995) to 5% in 1999. The four states with highest percentage of Bt corn (25 to 36%) saw a reduction from 6 million to slightly over 4 million (about one-third) in the number of acre treatments of insecticides recommended for ECB control. Most of the reduction has been with the organophosphate insecticides chlorpyrifos and methyl parathion, which are also registered for control of corn rootworm (CRW) larvae and/or adults. Total corn insecticide usage did not show a decline, perhaps because the 4

high adopter states are also high CRW states. Most of the insecticide used in corn in the major corn producing states in the midwestern cornbelt in 1996 was targeted at CRW control (Fernandez-Cornejo and Jans, 1999, Appendix 1, Table 1.1). The same is true for 1998, as compiled statistics on corn insecticide use across 16 major corn producing states indicate that chemical insecticides registered for CRW control were applied on over 33% of this corn acreage (USDA, 1999).

In order to delay the potential evolution of resistance in the target pests to *B.t.* Cry proteins expressed in plants, growers have been required by the EPA and/or the developers to implement insect resistance management (IRM) strategies. The IRM plan that is currently being used for commercial *Bt* corn lines was developed by the National Corn Growers Association in cooperation with biotechnology providers and university entomologists, and it can be viewed at *http://www.ncga.com/02profits/insectMgmtPlan/main.htm*. The plan includes monitoring for compliance with the IRM plan, monitoring for the development of resistant ECB, SWCB, and CEW populations, and mitigation measures in the event that resistant populations are confirmed. *Bt* Cry1Ab corn, as well as *Bt* Cry3A potatoes and *Bt* Cry1Ac cotton, have been in commercial production for five years, and according to EPA's preliminary assessment, no reported insect resistance has occurred to the *B.t.* toxins expressed in these products (U.S. EPA, 2000a). For corn, this includes ECB, CEW, and SWCB.

Potential impacts of line 1507 corn on insect control practices

Efficacy data from field evaluations conducted in 1999 provided by the petitioner (Petition, Volume 17) indicate that line 1507 tested in multiple hybrid backgrounds is statistically more efficacious than the comparable non-Bt corn in the control of ECB, SWCB, FAW, and BCW and moderately efficacious in the control of CEW, and it can provide significantly superior control of FAW and BCW and equal or slighter greater control of ECB, SWCB, and CEW than currently marketed *Bt* Cry1A transgenic events. Therefore, growers may choose to adopt *Bt* Cry1F corn line 1507 instead of nontransgenic corn or the current transgenic lepidopteran-resistant *Bt* corn lines, particularly if they experience heavy pest pressure from FAW and BCW. Data from 1996 for 16 states surveyed indicate that of the total acre-treatments of insecticides, 62% were targeted at CRW, 11% were targeted at cutworms and armyworms, and 19% were targeted at other moths and caterpillars (including cornborers) (Fernandes-Cornejo and Jans, 1999, Appendix 1, Table 1.1). At least 6 of the 16 states used a higher percentage of pesticides on cutworms and armyworms than on other caterpillars and moths. These include Indiana, Kentucky, Missouri, Ohio, Pennsylvania, and South Carolina. Since none of these states are among the highest adopters of Bt corn (U.S. EPA, 2000a), there may be new markets for this product in those states. Based on this analysis, APHIS believes that cultivation of *Bt* Cry1F corn line has the potential to further reduce insecticide applications targeted not only for ECB and the other cornborers, but for cutworms and armyworms as well, provided these insecticides are not also being applied to control other pests such as CRW. Chemical control options for cutworms and armyworms include planting-time soil insecticide applications (primarily organophosphates, carbamates, or phenylpyrazoles or rescue insecticide applications (primarily pyrethroids). Some of the chemical insecticides recommended for the control of ECB and SWCB include carbamates (carbofuran and carbaryl), organophosphates (e.g.,chlorpyrifos, methyl parathion) and synthetic pyrethroids (e.g., permethrin, lambda-cyhalothrin, and esfenvalerate) (Mississippi State University Extension Service, 1999; Gray and Steffey, 1999). Because many of these insecticides also kill predators or parasites that help to keep minor pests under control, additional pesticides are sometimes applied to kill mites and/or sucking insects (e.g. dimethoate). Many of these insecticides are more toxic to humans and nontarget organisms (including some of the natural parasites or predators used to control them) than are *B.t.* delta endotoxins (for example, see Appendix C, and Gray and Steffey, 1999); therefore, a reduction in their use should provide benefits to the environment as well as to humans, particularly farm workers and their children who are at higher risk from exposure.

APHIS does not anticipate that cultivation of line 1507 corn would affect the use of other biological or cultural control methods for the target pests since these methods are used on less than about 3% of the total corn acreage, particularly by organic farmers. 1996 survey data on pest management practices in corn indicate that *B.t.* foliar insecticides were used on only 2.4% of insecticide-treated acres, and beneficial insects were released on less than 0.5 % of acres planted (Fernandez-Cornejo and Jans, 1999, Table 8). This is despite the fact that several *B.t.* foliar insecticides (based on *B.t. kurstaki* and *B.t. aizawai*) and beneficial insects such as the tachina fly *Lydella thompsoni*, *Trichogamma* parasites and Spined Soldier Bug (*Podisus maculiventis*), as well as other biologicals, such as the fungus *Beauveria bassiana,* are available for control of the same pests targeted for control in corn line 1507 (see *http:www.agrobiologicals.com*).

Line 1507 corn could also provide a new tool for managing target insects that might become resistant to other insecticides currently used, including potentially other *Bt*-based insecticides. The IRM plan submitted for *Bt* Cry1F corn line 1507 is the same IRM plan that is currently being used for the other commercial *Bt* corn lines. The pesticide registration for line 1507 corn specifies that growers will be required to sign a Stewardship Agreement affirming their intention to comply with this requirement. Therefore, APHIS does not believe this will result in a significant change in agricultural practices. With the intensive monitoring programs in place for all *Bt* plant-pesticides, *Bt* toxin resistant insect populations, should they develop, are likely to be detected and mitigation actions put in place as called for in the IRM plans and/or the registration conditions.

APHIS concludes that cultivation of line 1507 corn should pose no greater impediments on the control of insects in corn and other crops than the currently practiced methods of control of the target pests, ECB, SWCB, FAW, and BCW; i.e., the use of ECB-tolerant corn cultivars, including other previously deregulated *Bt* transgenic corn transformation events, and the application of chemical and biologically-based insecticides.

Impacts of previously deregulated herbicide tolerant corn on weed control

Several herbicide tolerant corn varieties are commercially available. These were described under Alternative A. The first glufosinate-ammonium tolerant corn varieties were deregulated by APHIS in June 1995. In 1996, prior to the introduction of Roundup Ready™ (glyphosate herbicide tolerant) corn, pest management data for corn indicate that 1) 3% of acres planted were to herbicide resistant varieties, 2) 83% of pesticide treatments were for weed control, and of those, 20% were post emergence, 39% preemergence, and 41% both, 3) mechanical cultivation was used for weed control on 51% of acres planted (Fernandez-Cornejo and Jans, 1999). It is estimated that the adoption of other herbicide tolerant corn varieties (including Liberty Link™ varieties) was associated has been related with a overall decrease in herbicide use in 1996 (especially for the chloroacetamide herbicide family) (Fernandez-Cornejo and Klotz-Ingram, 1998). Nonetheless, in 1997, 96% of the corn acreage in the 10 major corn-producing states were treated with herbicides. At least 18 different herbicide active ingredients are used, many in combination. Atrazine (which performs well for control of broadleaf weeds) and the chloroacetamides metolachlor and acetochlor (which perform well for control of annual grass weeds) together account for 72% of the total applied in 1997 (Knake, 1998; Fernandez-Cornejo and McBride, 2000). In 1998, it is estimated that 18.4% of corn acreage planted was to herbicide-resistant varieties (some of which are stacked with Bt Cry genes) (Fernandes-Cornejo and McBride, 2000) and 7.5% of corn acreage was planted to Liberty Link™ corn (Carpenter and Gianessi, 1999).

Potential impacts of line 1507 corn on weed control

APHIS evaluated data submitted by the petitioners that show that hybrids derived from line 1507 corn exhibit tolerance to glufosinate ammonium herbicides at concentrations that provide effective weed control and excellent crop safety (see Petitioners response to deficiency number 3 dated July 19, 2000). Liberty® glufosinate-ammonium herbicide is currently registered by the EPA for use only on Liberty Link™ (glufosinate-ammonium tolerant) crops - field corn, soybeans, sugarbeet, canola, and on potatoes for desiccation only. Line 1507 corn, along with glufosinate-ammonium herbicides, is expected to positively impact current agricultural practices used for weed control in a manner similar to other previously deregulated glufosinate-tolerant corn, that is by 1) offering growers a broad spectrum, post-emergent weed control system for both broadleaf and grass weeds; 2) providing the opportunity to continue to move away from pre-emergent herbicides and residually active herbicides such as atrazine; 3) providing an alternative herbicidal mode of action in corn that allows for improved management of weeds in corn which have developed resistance to herbicides with different modes of action, e.g. triazines and acetolactate synthase (ALS) inhibitors (see *http://www.weedscience.org/Resistance/situation.asp*); and 4) decreasing cultivation needs and increasing the amount of no-till acres.

Volunteers of line 1507 corn can be easily controlled by selective mechanical or manual weed removal or by the use of certain herbicides with active ingredients other than glufosinate ammonium. For example, in soybean, which is the crop most commonly rotated with corn, herbicides based on sulfonylurea, lipid biosynthesis inhibitors, or Fluazifop/fomesafen could be used to control maize volunteers. The commercial introduction and wide adoption in the United States of Roundup Ready™ soybeans has been associated with an increase in the use of glyphosate to control weeds in soybean, while the use of other herbicides has decreased (Fernandez-Cornejo and McBride, 2000; Heimlich *et al.*, 2000). Glyphosate could also be used to control glufosinate tolerant volunteers of line 1507 corn in Roundup Ready™ soybeans. It is estimated that in 1998, 26% of the total soybean acreage was planted to Roundup Ready™ soybeans (Carpenter and Gianessi, 1999). Both glyphosate and glufosinate have relatively low toxicity to humans and wildlife, and do not persist in the environment (Pike, 1999; McGlamery *et al.*, 1999).

APHIS considered the possibility that availability and use of glufosinate-tolerant corn lines such as line 1507 corn could lead to greater use of glufosinate-ammonium herbicide and result in selection and establishment of weeds tolerant to this herbicide. This would have herbicide use implications both for use of glufosinate tolerant crops previously deregulated by APHIS and possibly for other crops grown in rotation. The occurrence of weeds tolerant to other herbicides is well documented, and technical assistance is available to help identify, prevent, and mitigate this risk (Heap, 2000). The risk of glufosinate tolerant weeds developing appears to be quite low. While all herbicides have varying degrees of effectiveness against different weeds, a worldwide survey of herbicide resistant weeds contains no record of weeds that have developed resistance to glufosinate herbicides (Heap, 1997, updated Feb. 1999; Ian Heap personal communication to Susan Koehler, Oct. 20, 2000). Current practices involving rotation of herbicides with different modes of action and cultivation or mowing to eliminate weeds should be effective in reducing or managing the risk. APHIS and the EPA Herbicide Division have initiated a working group to ensure thorough ongoing considerations of issues surrounding herbicide resistant plants, including the potential for the development of glufosinate tolerant weeds.

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 corn 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* Cry1F lepidopteran resistant, and based on the IRM plan, farmers will be educated about recommended management practices. Glufosinate tolerant and lepidopteran resistant Bt corn is already being used by farmers. This particular product will in some cases be used by some farmers instead of the existing lines, and should not present new and different issues. APHIS has considered that corn is open-pollinating and it is possible that the engineered genes could move via wind-blown pollen to an adjacent field. All corn, whether genetically engineered or not, can transmit pollen to nearby fields, and a very small influx of pollen originating from a given corn variety does not appreciably change the characteristics of corn 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 negligible by 660 feet away, the isolation distance considered safe for certified corn seeds. Methods are currently available to prevent or minimize and test for cross-contamination and the National Corn Growers Association has provided information on their website regarding the marketing of both transgenic and nontransgenic corn (see *http://www.ncga.com/11biotechnology/main/index.html*).

Potential impacts on humans, including minorities, low income populations, and children

In the spirit of the directive specified in Executive Order 13045, we attempted to identify and assess environmental health or safety risks that might disproportionately affect children. We also considered any possible adverse impacts on minorities and low income populations as specified under Executive Order 12898. We report that collectively, the available mammalian toxicity and the potential allergenicity profile on Cry1F protein (see Appendix A), along with the history of safe use of microbial *Bt* products and other corn varieties expressing *Bt* proteins and PAT, establishes the safety of corn line 1507 and its products to humans, including minorities, low income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken. None of the impacts on agricultural practices described above are expected to have a disproportionate adverse effect on minorities, low income populations, or children, and may in fact provide benefits. As noted above, the cultivation of previously deregulated corn varieties with similar insect resistance and herbicide tolerance traits has been associated with a decrease and/or shift in pesticide applications for those who adopt these varieties that is either favorable or neutral with respect to environmental and human toxicity.

From the above analysis APHIS is reasonably certain that no significant impacts on agricultural practices with adverse environmental or human health effects are expected from the cultivation of line 1507 corn.

G. Potential impacts on raw or processed agricultural commodities.

APHIS analysis of information and data provided in the petition regarding the disease and insect susceptibility of line 1507 corn hybrids and the nutrient composition profiles of grain and whole plant forage produced from a line 1507 hybrid corn reveal no differences between hybrids derived from corn line 1507 and their nontransgenic hybrid counterparts and other standard hybrids that could have a direct or indirect plant pest effect on any raw or processed plant commodity. Whole plant forage data included proximate analysis (for protein, fat, fiber, and ash). Grain data included proximate analysis, mineral analysis, fatty acid composition, amino acid analysis, vitamin content, and antinutrient content (phytic acid and trypsin inhibitor). Available data show that corn hybrids expressing *Bt* Cry toxins have reduced vulnerability to mycotoxin-producing fungi, thereby enhancing the safety of the *Bt* corn grain for livestock feed and for human food (Munkvold and Hellmich, 1999). In the southern United States where aflatoxin problems are chronic, cultivation of corn line 1507 could potentially further reduce vulnerability to mycotoxin-producing fungi because it provides moderate control of CEW and good control of SWCB as well as FAW, and these are the primary lepidopteran pests feeding on corn ears.

H. Cumulative Impacts

APHIS considered whether the proposed action could lead to cumulatively significant impacts, when considered in light of other past, present, and reasonably foreseeable futures actions, regardless of what agency or person undertakes such actions. In the preceding analysis we have considered the potential for stacking of multiple herbicide tolerance genes, from corn line 1507 and other herbicide tolerance genes in previously deregulated transgenic corn lines or in corn developed by other methods, to pose a weed management problem. We have also considered the cumulative impacts of nontransgenic and previously deregulated transgenic herbicide tolerant corn, and other herbicide tolerant crops typically grown in rotation with corn, on the type and toxicity of herbicides and other management practices that can be used to manage weeds in these crops, including the development and management of herbicide tolerant weeds. We have reviewed and considered studies and reports (e.g. U.S. EPA, 2000a; Fernandez-Cornejo and McBride, 2000) to predict the cumulative impacts of deregulation and any subsequent registration and commercialization of line 1507 corn, in light of other transgenic lepidopteran-resistant *Bt* plants currently on the market, and the potential for stacking with different lepidopteran resistance genes in hybrids. Considerations included impacts on nontarget organisms, changes in pesticides used to control the target pests and other nontarget pests, and the potential for resistance to the *Bt* toxins to develop as a result of exposure to these toxins in *Bt* plant-pesticides or in other *Bt* formulations. Because of the uncertain possibility for target pests to develop cross-resistance to Cry1F and Cry1Ab *Bt* toxins, researchers and the EPA do not recommend, nor do companies intend to develop hybrids with combinations of these genes.

From this analysis, we are reasonably certain that no significant cumulative impact would result if our proposed action, deregulation of corn line 1507, is taken. Given current agricultural, breeding, and regulatory practices or requirements, any potential adverse effects that can reasonably be predicted are likely to be prevented, and if not at least detected and mitigated before a significant impact could occur. As described in Section II, even if a determination of nonregulated status is granted to corn line 1507, cultivation of this line or its progeny would still be limited under regulations by the EPA that require an experimental use permit for pesticides until they are registered conditionally or unconditionally for seed increase or full commercial use, and feed and food use would be regulated by the EPA and FDA. APHIS consulted with EPA personnel on November 14, 2000, and on January 9-12 and 16, 2001 regarding the nontarget effects data, insect resistance management strategy, and toxicity and allergenicity profile of this product which was under review at the EPA, and the EPA raised no concerns about the conclusions we have reached in this Environmental Assessment. APHIS also consulted with the EPA on May 15, 2001 immediately prior to their decision to grant the conditional pesticide registration for corn line 1507.

VI. CONCLUSION

This environmental assessment addresses questions pertinent to the risk to the human environment, including plant pest risks, that could potentially result from an APHIS determination of nonregulated status under 7 CFR Part 340.6 for corn line 1507 and its progeny and their subsequent cultivation in the United States and its territories. It also considers restrictions placed on the cultivation of this line stipulated in the pesticide registration granted by the EPA. APHIS has evaluated information from the scientific literature as well as data submitted in the petition that characterized line 1507 corn and progeny derived from it. After careful analysis, APHIS has come to the following conclusions:

1. Line 1507 corn exhibits no plant pathogenic properties. Although DNA from pathogens were used in its development, these plants are not infected by these organisms, nor can these plants incite disease in other plants.

2. Line 1507 corn is no more likely to become a weed than insect or herbicide tolerant corn that is currently being cultivated. Corn is not a weed, and there is no reason to believe that the introduced genes would enable corn to become a weed pest.

3. Introgression from line 1507 corn into wild plants in the United States and its territories is extremely unlikely. Potential introgression from line 1507 corn into wild relatives is not likely to increase the weediness potential of any resulting progeny nor adversely effect genetic diversity of related plants any more than would introgression from traditional corn hybrids.

4. Line 1507 corn is substantially equivalent in whole plant forage composition and in kernel composition, quality and other characteristics to nontransgenic corn and should have no adverse impact on raw or processed agricultural commodities.

5. Line 1507 corn will not have a significant adverse impact on nontarget organisms, including those beneficial to agriculture; and it will not affect threatened or endangered species.

6. Compared to current agricultural practices, cultivation of line 1507 corn should not reduce the ability to control insects or weeds in corn or other crops.

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Appendix A: USDA Approved Field Tests of B.t. Cry1F Corn Line 1507[1]

USDA Notification #	Company Reference #	Planting Dates	Acreage[2]	Field Trial Location	Company
00-088-37n Notification still open. Field data report not yet submitted.[3]	MS132	5/13/00	21.8	Renville County, MN	Mycogen
		5/14/00	19.4	"	
		5/23-27/00	50	Dakota County, MN	
		5/24/00	23.0	"	
		5/11-25/00	19.88	Grundy County, IA	
		5/11/00 - 6/2/00	21.54	"	
		5/11/00 - 6/2/00	15.86	"	
		Pending	1.0	"	
		5/12/00	6.0	Story County, IA	
		5/25 & 31/00	18.3	Fillmore County, NE	
		5/22 & 29/00	13.4	"	
00-068-02n Notification still open. Field data report not yet submitted.	MS123	5/4/00	0.02	Wilkin County, MN	Mycogen
		5/3/00	0.32	"	
		5/6/00	0.018	Renville County, MN	
		5/6/00	0.819	"	
		4/25/00	0.18	Winona County, MN	
		5/3/00	0.344	Jackson County, MN	
		5/2/00	0.5	Brown County, MN	
		5/3/00	0.046	Sac County, IA	
		5/3/00	0.046	"	
		5/2/00	1.38	"	
		4/27/00	0.05	Story County, IA	
		5/25/00	0.023	"	
		5/23/00	0.005	"	
		4/28/00	0.9	"	
		5/5/00	0.1	"	
		5/12/00	1.7	"	
		5/22/00	0.36	"	
		5/4/00	0.5	Plymouth County, IA	
		5/4/00	0.8	Marshall County, IA	
		4/29/00	0.6	Page County, IA	
		5/6/00	0.79	Scott County, IA	
		5/22/00	0.02	Boone County, IA	
		5/3/2000	0.275	Clay County, SD	
		4/28/00	0.1	Cass County, ND	
		5/4/00	0.1	Pierce County, WI	
		4/25/00	0.5	"	
		5/3/00	0.1	Columbia County, WI	
		5/15/00	0.011	"	
		5/15/00	0.011	"	
		5/5/00	1.0	"	
		5/5-11/00	0.8	"	
		4/29/00	0.6	Jefferson County, WI	
		5/23/00	0.18	Dane County, WI	
		4/26/00	.021	York County, NE	
		5/3/00	1.01	"	
		5/5/00	0.11	Dixon County, NE	
		5/1/00	1.1	Butler County, NE	
		5/9/00	0.2	Savoy, IL	
		5/17/00	0.6	Dekalb County, IL	
		6/7/00	0.6	Champaign County, IL	
		6/9/00	0.6	"	
		5/9/00	0.5	"	
		6/7/00	0.1	"	
		6/1/00	0.017	Massac County, IL	
		5/11/00	0.055	Macon County, IL	
		5/2/00	0.95	Logan County, IL	

USDA Notification #	Company Reference #	Planting Dates	Acreage	Field Trial Location	Company
00-068-02n (continued) Notification still open. Field data report not yet submitted.	MS123	5/3/00	1.14	LaSalle County, IL	Mycogen
		5/4/00	1.2	Knox County, IL	
		4/20/00	0.64	Tipton County, IN	
		4/29/00	0.0275	Benton County, IN	
		4/29/00	0.0275	"	
		9/01/00	0.0046	"	
		4/29/00	0.82	"	
		5/25/00	0.006	Tippecanoe County, IN	
		5/25/00	0.01	"	
		5/3/00	1.1	Decatur County, IN	
		5/5/00	0.22	White County, IN	
		5/4/00	0.037	Moore County, TX	
		4/24/00	0.0173	Swisher County, TX	
		pending	30.0	Santa Isabel, PR	
		11/22/00	3.0	Oahu County, HI	
		5/15/00	5.0	Maui County, HI	
		5/31/00		(total for all plantings	
		8/31/00		is 5 acres)	
		9/12/00			
		9/15/00			
		9/25/00			
		4/28/00	0.11	Haskell County, KS	
		4/28/00	0.048	Ford County, KS	
		5/8/00	0.1	Finney County, KS	
		5/25/00	0.022	Riley County, KS	
		5/02/00	0.01	Fayette County, KY	
		5/22/00	0.01	"	
		7/8/00	0.01	"	
		5/31/00	0.01	Caldwell County, KY	
		5/1/00	0.03	Callaway County, MO	
		6/7/00	0.03	Holt County, MO	
		5/10/00	0.06	"	
		pending	0.1	Boone County, MO	
		pending	0.1	Mississippi County, MO	
		4/24/00	0.137	Pike County, MO	
		5/4/00	0.2	Saline County, MO	
		5/30/00	0.027	Ingham County, MI	
		5/5/00	0.78	Lenawee County, MI	
		4/26/00	0.02	Washington County, MS	
		5/16/00	0.02	"	
		5/16/00	0.02	"	
		pending	0.01	Tiff County, GA	
		5/15/00	0.2	Clark County, OH	
		5/15/00	0.02	"	
		5/11/00	0.17	Weld County, CO	
		5/11/00	0.17	"	
00-010-07n	MS121	5/11/00	0.03	Saunders County, NE only, not planted in Lancaster, Dixon, or Clay Counties	Mycogen

USDA Notification #	Company Reference #	Planting Dates	Acreage	Field Trial Location	Company
99-357-08n Still open, report not yet submitted.	MS113	pending pending pending pending	0.5 0.3 0.3 8.9	Huxley, IA; Arlington, WI; Fowler, IN; Santa Isabel, PR	Mycogen
99-110-05n	MS083	5/14/99 5/4/99 5/12/99 5/25/99 5/3/99	0.57 0.8 0.82 0.62 1.1	Wilkin County, MN Renville County, MN Jackson County, MN Brown County, MN Winona County, MN	Mycogen
99-078-10n	MS082	5/2/99 5/4/99 5/13/99 4/30/99 5/8/99 5/3/99 5/8/99 5/11/99 5/7/99 5/1/99 5/3/99 5/4/99 5/12/99 4/30/99 4/28/99 5/12/99 5/12/99 5/19/99 5/10/99 5/27/99 5/14/99 4/22/99 5/14/99 4/26/99	3.0 1.5 1.5 0.58 0.76 0.76 1.4 0.84 1.28 2.6 0.75 0.62 1.0 0.7 0.83 0.28 1.6 0.87 0.75 0.01 0.25 2.15 0.62 0.62	Columbia County, WI Jackson County, WI Jefferson County, WI Richland County, ND Cass County, IL Champaign County, IL Scott County, IA LaSalle County, IL Dawson County, NE Story County IA Madison County, IA Pierce County, WI Sac County, IA Plymouth County, IA Calhoun County, MI Decatur County, IN Benton County, IN York County, NE Butler County, NE Clay County, SD Dixon County, NE Santa Isabel, PR Dane County, WI Cass County, ND	Mycogen
98-267-02n	MS059	12/11/98 2/17/99 4/1/99 4/5/99 4/15/99	5.28	Santa Isabel, PR (total for all plantings is 5.28 acres)	Mycogen
98-127-07n	MS052	6/6/98	0.05, 0.5	Marshalltown, IA Huxley, IA	Mycogen
98-027-02n	MS043	2/26/98 3/13/98 7/3/98 9/18/98 10/9/98 10/27/98	1.7 1.9 2.5 1.2 0.44 0.51	Santa Isabel, PR " " " " "	Mycogen
97-178-02n	MS032a	7/27/97	0.25	Del Mar, DE	Mycogen
97-059-04n	MS028	4/15/97	2.0	Huxley, IA	Mycogen
97-059-02n	MS026	7/1/97	3.0	Santa Isabel, PR	Mycogen

USDA Notification #	Company Reference #	Planting Dates	Acreage	Field Trial Location	Company
98-040-10n	CRN-US-TX-98-49	5/6/98	0.07	Hale County, TX	Pioneer
98-040-12n	CRN-US-HI-98-52	6/18/98	0.45	Kekaha, HI	Pioneer
98-040-13n	CRN-US-PR-98-75	6/1/98	0.12	Salinas, PR	Pioneer
98-072-20n 98-128-19n	CRN-US-IA-98-42 CRN-US-IA-98-	5/4/98 5/19/98	1.08	Polk County, IA "	Pioneer
98-155-01n	CRN-US-HI-98-191	7/8/98 7/27/98	0.38 0.20	Kekaha, HI "	Pioneer
98-296-03n	CRN-US-HI-98-270	3/16/98 4/16/98 6/17/98	0.009 0.001 0.001	Kekaha, HI " "	Pioneer
99-028-01r Comprehensive permit.	CRN-US-CP-99-007	3/31/99 – 4/30/00	1.65 0.08 0.62 0.71 0.67 0.03 0.60 0.06 0.01 0.01 0.06 0.01 0.03 0.23 0.01 0.01 0.01 0.02 0.01	Kauai County, HI Kossuth County, IA Linn County, IA Polk County, IA Bureau County, IL Champaign County, IL McDonough County, IL Tipton County, IN Gratiot County, MI Kandiyohi County, MN Saline County, MO Cass County, ND York County, NE Salinas, PR Beadle County, SD Obion County, TN Hale County, TX Eau Claire, WI Rock County, WI	Pioneer

[1] Includes only those authorizations under which plantings actually took place at the time of petition submission. No plantings of line 1507 corn occurred under the notification 99-274-10n, Mycogen's reference number MS095, in Huxley, IA; Arlington, WI; Fowler, IN; and Santa Isabel, PR.

[2] Acreage reflects the approximate amount planted to corn derived from line 1507.

[3] Field data reports are due six months after termination of all field trials for a given notification or permit. Unless otherwise noted, all field data reports have been submitted.

Appendix B. Potential for introgression from *Zea mays* to its sexually compatible relatives.

Wild diploid and tetraploid members of *Zea* collectively referred to as teosinte are normally confined to the tropical and subtropical regions of Mexico, Guatemala, and Nicaragua. A few isolated populations of annual and perennial teosinte have been reported to exist in Florida and Texas, respectively (USDA-APHIS, 1998b); but local botanists and agronomists familiar with the flora of these regions have not documented any current populations of teosinte there (U.S. EPA, 2000a, see page IIC5). The Mexican and Central America teosinte populations primarily exist within and around cultivated maize fields; they are partially dependent on agricultural niches or open habitats, and in some cases are grazed upon or fed to cattle which distribute the seed. While some teosinte may be considered to be weeds in certain instances, they are also used by some farmers for breeding improved maize (Sánchez and Ruiz, 1997, and references therein).

All teosinte members can be crossed with cultivated corn to produce fertile F_1 hybrids (Doebley, 1990a; Wilkes, 1967; and Jesus Sánchez, personal communication, 1998). In areas of Mexico and Guatemala where teosinte and corn coexist, they have been reported to produce hybrids. Of the annual teosintes, *Z. mays* ssp *mexicana* forms frequent hybrids with maize, *Z. luxurians* hybridizes only rarely with maize, whereas populations of *Z. mays* ssp. *parviglumis* are variable in this regard (Wilkes, 1977; Doebley, 1990a). Fewer fertile hybrids are found between maize and the perennial *Z. perennis* than are found with *Z. diploperennis* (J. Sánchez, personal communication, 1998). Research on sympatric populations of maize and teosinte suggests introgression has occurred in the past, in particular from maize to *Z. mays* ssp. *luxurians* and *Z. mays* ssp. *diploperennis* and from annual Mexican plateau teosinte (*Z. mays* ssp. *mexicana*) to maize (KatoY., 1997 and references therein). Nonetheless, in the wild, introgressive hybridization from maize to teosinte is currently limited, in part, by several factors including distribution, differing degrees of genetic incompatibility, differences in flowering time in some cases, block inheritance, developmental morphology and timing of the reproductive structures, dissemination, and dormancy (Doebley, 1990a; Galinat, 1988). First-generation hybrids are generally less fit for survival and dissemination in the wild, and show substantially reduced reproductive capacity which acts as a significant constraint on introgression. Teosinte has coexisted and co-evolved in close proximity to maize in the Americas over thousands of years, but maize and teosinte maintain distinct genetic constitutions despite sporadic introgression (Doebley, 1990a).

The genus *Tripsacum* contains up to 16 recognized species, most of which are native to Mexico, Central and South America. But three *Tripsacum* species, *T. floridanum*, *T. lanceolatium*, and *T. dactyloides*, exist as wild and/or cultivated in the U.S. (Hitchcock, 1971). Though many of these species occur where corn might be cultivated, gene introgression from line 1507 corn under natural conditions is highly unlikely or impossible. Hybrids of *Tripsacum* species with *Zea* are difficult to obtain outside of a laboratory and are often sterile or have greatly reduced fertility, and none are able to withstand even the mildest winters (Beadle, 1980; Galinat, 1988).

References (see EA, Literature Cited, Section VII.)

Appendix C.

Environmental and human health safety of Cry1F (as expressed in corn Line 1507 or as purified from a microbial source) compared to other common insecticides used on corn to control the target pests European cornborer, southwestern cornborer, fall armyworm, black cutworm, corn earworm, and other nontarget pests.

(Dimethoate is used to control nontarget pests including for example, corn leaf aphids, corn rootworm, grasshoppers, and spider mites. The other insecticides control one or more of the target pests; but they also control corn rootworm, and may control additional pests in corn. Insecticides were chosen based on a number of factors including a past history of moderate to high usage based on National Agricultural Statistical Service data for 1996 and 1998 and availability of safety data.)

	Cry1F[1] [Bt protein]	Dimethoate[2] (Cygon®) [organophosphate]	Chlorpyrifos[3] (Lorsban ®) [organophosphate]	Permethrin[4] (Ambush/Pounce®) [pyrethroid]	λ-cyhalothrin[5] (Darate®) [pyrethroid]
Environmental Fate	Cry1F protein is expressed in minute quantities and is retained within the plant. Therefore, common modes of toxicity or routes of exposure are generally not relevant to consideration of the cumulative exposure to *Bacillus thuringiensis* Cry1F insect control protein. The product has demonstrated low toxicity to a large number of organisms listed in this table. In addition, the protein is not likely to be present in drinking water because the protein is deployed in minute quantities within the plant. The time-dependent loss in bioavailability of CryIF protein following incorporation into a typical maize-growing soil was determined under laboratory conditions (Halliday, 1998).The results of this study indicated that soil-applied CryIF protein exhibited a greater than 20-fold decline in biological activity over the 28-day test period. The estimated DT_{50} was 3.13 days. These results are consistent with those for CryIA(b) protein using essentially the same experimental design; a soil DT_{50} of 1.6 days was reported for the CryIA(b) protein.	Dimethoate is of low persistence in the soil environment. Soil half-lives of 4 to 16 days, or as high as 122 days have been reported, but a representative value may be on the order of 20 days. Because it is rapidly broken down by soil microorganisms, it will be broken down faster in moist soils. Dimethoate is highly soluble in water, and it adsorbs only very weakly to soil particles so it may be subject to considerable leaching. However, it is degraded by hydrolysis, especially in alkaline soils, and evaporates from dry soil surfaces. Losses due to evaporation of 23 to 40% of applied dimethoate have been reported. Biodegradation may be significant, with a 77% loss reported in a nonsterile clay loam soil after 2 weeks. In water, dimethoate is not expected to adsorb to sediments or suspended particles, nor to bioaccumulate in aquatic organisms. The half-life for dimethoate in raw river water was 8 days, with disappearance possibly due to microbial action or chemical degradation.	In soils: Chlorpyrifos is moderately persistent with a half-life of usually 60 and 120 days, and a range from 2 wks - > 1 yr., depending on the soil type, climate, and other conditions . It was less persistent in soils with a higher pH (greater than 7.4). Soil half-life was not affected by soil texture or organic matter content. Adsorbed chlorpyrifos is subject to degradation by UV light, chemical hydrolysis and by soil microbes. When applied to moist soils, the volatility half-life was 45 to 163 hours, with 62 to 89% of the applied chlorpyrifos remaining on the soil after 36 hours. In another study, 2.6 and 9.3% of the chlorpyrifos applied to sand or silt loam soil remained after 30 days . Chlorpyrifos adsorbs strongly to soil particles and it is not readily soluble in water. It is therefore immobile in soils and unlikely to leach or to contaminate groundwater. TCP, the principal metabolite of chlorpyrifos, is moderately mobile and persistent in soils. In water: The concentration and persistence of chlorpyrifos will vary depending on the type of formulation. The increase in the concentration of insecticide is slower for granules and controlled release formulations in the water, but the resulting concentration persists longer . Volatilization is probably the primary route of loss of chlorpyrifos from water. Volatility half-lives of 3.5 and 20 days have been estimated for pond water. The photolysis half-life is 3 to 4 weeks during midsummer in the U.S. Research suggests that in water the rate at which it is hydrolyzed decreases by 2.5- to 3-fold with each 10 C drop in temperature. The rate of hydrolysis increases in alkaline waters. In water at pH 7.0 and 25 C, it had a half-life of 35 to 78 days. In vegetation: Chlorpyrifos may be toxic to some plants. Residues remain on plant surfaces for ~ 10 to 14 days. This insecticide and its soil metabolites can accumulate in certain crops.	Permethrin is of low to moderate persistence in the soil environment, with reported half-lives of 30 to 38 days. Permethrin is readily broken down, or degraded, in most soils except organic types. Soil microorganisms play a large role in the degradation of permethrin in the soil. The addition of nutrients to soil may increase the degradation of permethrin. It has been observed that the availability of sodium and phosphorous decreases when permethrin is added to the soil. Permethrin is tightly bound by soils, especially by organic matter. Very little leaching of permethrin has been reported. It is not very mobile in a wide range of soil types. Because permethrin binds very strongly to soil particles and is nearly insoluble in water, it is not expected to leach or to contaminate groundwater. The results of one study near estuarine areas showed that permethrin had a half-life of less than 2.5 days. When exposed to sunlight, the half-life was 4.6 days. Permethrin degrades rapidly in water, although it can persist in sediments. Breakdown in vegetation: Permethrin is not phytotoxic, or poisonous, to most plants when it is used as directed. No incompatibility has been observed with permethrin on cultivated plants.	λ- 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. 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.

	Cry1F [1] [Bt protein]	Dimethoate[2] (Cygon®) [organophosphate]	Chlorpyrifos[3] (Lorsban ®) [organophosphate]	Permethrin[4] (Ambush/Pounce®) [pyrethroid]	λ-cyhalothrin[5] (Darate®) [pyrethroid]
Avian toxicity	A summary value for acute toxicity for bobwhite quail chicks shows an LC_{50}>100,000 mg of grain from Cry1F corn/kg diet (the highest concentration tested). This is equivalent to 10% or 100,000 ppm of the diet being derived from Cry1F corn.	Dimethoate is moderately to very highly toxic to birds. In Japanese quail, a 5-day dietary LC_{50} of 341 ppm is reported. It may be very highly toxic to other birds; reported acute oral LD_{50} values are 41.7 to 63.5 mg/kg in mallards and 20.0 mg/kg in pheasants. Birds are not able to metabolize dimethoate as rapidly as mammals do, which may account for its relatively higher toxicity in these species.	Chlorpyrifos is moderately to very highly toxic to birds. Its oral LD_{50} is 8.41 mg/kg in pheasants, 112 mg/kg in mallard ducks, 21.0 mg/kg in house sparrows, and 32 mg/kg in chickens. The LD_{50} for a granular product (15G) in bobwhite quail is 108 mg/kg. At 125 ppm, mallards laid significantly fewer eggs. There was no evidence of changes in weight gain, or in the number, weight, and quality of eggs produced by hens fed dietary levels of 50 ppm of chlorpyrifos.	Effects on birds: Permethrin is practically non-toxic to birds. The oral LD_{50} for the permethrin formulation, Pramex, is greater than 9900 mg/kg in mallard ducks, greater than 13,500 mg/kg in pheasants, and greater than 15,500 mg/kg in Japanese quail.	λ- cyhalothrin's toxicity to birds ranges from slightly toxic to practically non-toxic. In the mallard duck, the reported oral LD_{50} is greater than 3,950 mg/kg, and the reported dietary LC_{50} is 3,948 ppm. In bobwhite quail the reported dietary LC_{50} is greater than 500 ppm. There is evidence that it does not accumulate in the eggs or tissues of birds.
Aquatic Data	There is no evidence for sensitivity of endangered aquatic species to Cry1F delta endotoxin. Low potential for exposure to Cry1F through drifting Cry1F maize pollen or other tissues derived from Cry1F maizeand toxicity studies with aquatic invertebrates show very limited hazard for fish or invertebrates exposed to Cry1F. The measured effect level (EC_{50}) for the 48 hr. acute dietary toxicity study with *Daphnia magna* was greater than 100 mg Cry1F pollen/liter. This level is several fold higher than the estimated concentration of 1.25 µg Cry1F/liter from pollen drift into fresh water ponds.	Dimethoate is moderately toxic to fish, with reported LC_{50} values of 6.2 mg/L in rainbow trout, and 6.0 mg/L in bluegill sunfish. It is more toxic to aquatic invertebrate species such as stoneflies and scuds.	Chlorpyrifos is very highly toxic to freshwater fish, aquatic invertebrates and estuarine and marine organisms. Cholinesterase inhibition was observed in acute toxicity tests of fish exposed to very low concentrations of this insecticide. Application of concentrations as low as 0.01 pounds of active ingredient per acre may cause fish and aquatic invertebrate deaths. Chlorpyrifos toxicity to fish may be related to water temperature. The 96-hour LC_{50} for chlorpyrifos is 0.009 mg/L in mature rainbow trout, 0.098 mg/L in lake trout, 0.806 mg/L in goldfish, 0.01 mg/L in bluegill, and 0.331 mg/L in fathead minnow]. Chlorpyrifos accumulates in the tissues of aquatic organisms. Studies involving continuous exposure of fish during the embryonic through fry stages have shown bioconcentration values of 58 to 5100. Due to its high acute toxicity and its persistence in sediments, chlorpyrifos may represent a hazard to sea bottom dwellers. Smaller organisms appear to be more sensitive than larger ones .	Effects on aquatic organisms: Aquatic ecosystems are particularly vulnerable to the impact of permethrin. A fragile balance exists between the quality and quantity of insects and other invertebrates that serve as fish food. The 48-hour LC_{50} for rainbow trout is 0.0125 mg/L for 24 hours, and 0.0054 mg/L for 48 hours. As a group, synthetic pyrethroids were toxic to all estuarine species tested. They had a 96-hour LC_{50} of less than or equal to 0.0078 mg/L for these species. The compound has a low to moderate potential to accumulate in these organisms.	λ- cyhalothrin is very highly toxic to many fish and aquatic invertebrate species. Reported LC_5 in these species are as follows: bluegill sunfish, 0.21 µg/L; rainbow trout, 0.24 µg/L; Daphnia magna, 0.36 µg/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 858 has been reported in fish (species unspecified), but concentration was confined to non-edible tissues and rapid depuration was observed.

	Cry1F[1] [Bt protein]	Dimethoate[2] (Cygon®) [organophosphate]	Chlorpyrifos[3] (Lorsban ®) [organophosphate]	Permethrin[4] (Ambush/Pounce®) [pyrethroid]	λ-cyhalothrin[5] (Darate®) [pyrethroid]
Nontarget and beneficial insects	Results indicated that Cry1F delta endotoxin (produced microbially) has an acute LC_{50} greater than 320 µg Cry 1F/g diet for parasitic hymenoptera (*Nasonia vitripennis*), and an acute LC_{50} greater than 480 µg Cry 1F/g diet for green lacewing (*Chrysopa carnea*) and lady bird beetle (*Hippodamia convergens*). These concentrations are several fold higher than the upper bound estimate of 32 µg Cry 1F/g pollen derived from line 1507 corn, and indicate low potential for toxicity due to exposure.	Survival of *Microplitis croceipes* (Cresson) adults, parasitoids of the cotton pests *H.zea* and *H.virescens*, exposed to residues of insecticides applied at recommended rates to cotton was measured in 1989. In unsprayed check treatments, survival was 91.4% after 24 h. The organophosphates profenofos and acephate and the new-generation pyrethroid bifenthrin were highly toxic to *M. croceipes*. All other compounds tested showed some selectivity, including esfenvalerate, cypermethrin, thiodicarb, oxamyl, dicrotophos, dimethoate, and cyhalothrin in order of decreasing survival. The effectiveness of *M. croceipes* as a biocontrol agent of the bollworm and tobacco budworm might be improved through selective use of insecticides to which the parasitoid is tolerant.	Aquatic and general agricultural uses of chlorpyrifos pose a serious hazard to wildlife and honeybees.	Effects on other organisms: Permethrin is toxic to wildlife. It should not be applied, or allowed to drift, to crops or weeds in which active foraging takes place. The International Organization for Biological Control tested the acute toxicity of permethrin to 13 species of beneficial arthropods and found that permethrin caused 99 percent mortality of 12 of the species, and over 80 percent mortality of the other. Effects were persistent, lasting over 30 days. Sublethal doses also impact beneficial arthropods: permethrin inhibited the emergence of a parasitoid wasp from eggs of the rice moth *Corcyra cephalonica* and disrupted the foraging pattern of another parasitoid wasp as it searched for its aphid prey.	Data not available from sources consulted.
Honeybee toxicity	A petition by Dow-Mycogen to deregulate Cry1F maize contains details of this analysis in a CBI appendix, and the petition summary indicates an acute dietary toxicity (honeybees) LD_{50}> 640 ng Cry1F/larvae.	Dimethoate is highly toxic to honeybees. The 24-hour topical LD_{50} for dimethoate in bees is 0.12 µg per bee	Aquatic and general agricultural uses of chlorpyrifos pose a serious hazard to honeybees.	Permethrin is extremely toxic to bees. Severe losses may be expected if bees are present at treatment time, or within a day thereafter.	λ- cyhalothrin is highly toxic to bees, with a reported oral LD_{50} of 38 ng/bee and reported contact LD_{50} of 909 ng/bee (0.9 µg/bee).

	Cry1F [1] [Bt protein]	Dimethoate[2] (Cygon®) [organophosphate]	Chlorpyrifos[3] (Lorsban ®) [organophosphate]	Permethrin[4] (Ambush/Pounce®) [pyrethroid]	λ-cyhalothrin[5] (Darate®) [pyrethroid]
Nontarget soil organisms	A 28-day study to determine the chronic effects of microbially-derived CryIF protein on survival and reproduction of Collembola was conducted with three treatment levels of the CryIF test substance (0.63, 3.1, and 12.5 mg/kg of test diet). At the conclusion of the test, there was less than 10% mortality associated with exposure to either the CryIF protein test substance or the assay control. Reproduction of Collembola was not significantly affected by exposure to the test substance when compared to the assay control. No mortality and no reduction in the number of progeny was observed following exposure to the test materials for 28 days. The results of this study indicate Collembola were not affected by chronic exposure to CryIF at treatment levels exceeding those expected to be found in maize fields based on the calculated worst-case, post-harvest exposure estimates of 0.350 mg Cry1F protein/kg of whole plant material at senescence or 0.063 mg Cry1F protein/kg dry soil. Acute toxicity for earthworm was established by exposure to microbially-produced Cry1F protein in soil. The LC_{50} was > 2.5 mg Cry1F/kg dry soil. This concentration is also considerably higher than the worst-case estimate of Cry1F post-harvest exposure in the soil.	A study of the effects of soil moisture and toxicity of dimethoate was conducted with an enchytraeid worm. Laboratory experiments used dimethoate and small Enchytraeus sp. as the test species. Substrate was natural agricultural field soil cultivated without pesticides for several years. Experimental design consisted of three soil moistures (40, 55, and 70% of water holding capacity) and five pesticide concentrations, plus controls. Measured parameters were survival, size of the parent worms and number and size of juveniles produced. Dimethoate was relatively non-toxic to this species. Dimethoate did not decrease survival, but sublethal effects on adult size and number of juveniles were observed. Adverse conditions in dry soil masked these effects; dimethoate appeared to be less toxic in dry soil than in moist soil.	Data not found in sources consulted.	Data not found in sources consulted.	Data not found in sources consulted

	Cry1F [1] [Bt protein]	Dimethoate[2] (Cygon®) [organophosphate]	Chlorpyrifos[3] (Lorsban ®) [organophosphate]	Permethrin[4] (Ambush/Pounce®) [pyrethroid]	λ-cyhalothrin[5] (Darate®) [pyrethroid]
EPA toxicity class (Class I -highly toxic to Class IV-relatively nontoxic)	Not yet assigned.	Dimethoate is a moderately toxic compound in EPA toxicity class II. Labels for products containing dimethoate must bear the Signal Word WARNING. Dimethoate is a General Use Pesticide (GUP).	Chlorpyrifos is toxicity class II - moderately toxic. Products containing chlorpyrifos bear the Signal Word WARNING or CAUTION, depending on the toxicity of the formulation. It is classified as a General Use Pesticide (GUP). The EPA has established a 24-hour reentry interval for crop areas treated with emulsifiable concentrate or wettable powder formulations of chlorpyrifos unless workers wear protective clothing.	Permethrin is a moderately to practically non-toxic pesticide in EPA toxicity class II or III, depending on the formulation. Formulations are placed in class II due to their potential to cause eye and skin irritation. Products containing permethrin must bear the Signal Word WARNING or CAUTION, depending on the toxicity of the particular formulation. All products for agricultural uses (except livestock and premises uses) are Restricted Use Pesticides (RUPs) because of their possible adverse effects on aquatic organisms.	λ- 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 i must bear the signal word WARNING.
EDF - Integrated Environmental Rankings[6] - Combined human & ecological scores	not ranked	65 to 100% ranked.on the least to most hazardous scale with 100% being the most hazardous	50 to 75%	0 to 25%	not ranked

	Cry1F [1] [Bt protein]	Dimethoate[2] (Cygon®) [organophosphate]	Chlorpyrifos[3] (Lorsban ®) [organophosphate]	Permethrin[4] (Ambush/Pounce®) [pyrethroid]	λ-cyhalothrin[5] (Darate®) [pyrethroid]
Mammalian toxicity	Toxicology studies conducted to determine the toxicity of Cry1F insect control protein demonstrated that the protein has very low toxicity. In an acute oral toxicity study in the mouse, the estimated acute LD_{50} by gavage was determined to be >5,050 mg/kg of the microbially produced test substance. This dose is 12,190 x greater than the estimated 95th percentile for human dietary exposure to Cry1F protein resulting from consumption of foods derived from Cry1F protected corn. In an in vitro study, Cry1F protein was rapidly and extensively degraded in simulated gastric conditions in the presence of pepsin. This indicates that the potential for adverse health effects from chronic exposure is virtually nonexistent. A search of relevant databases indicated that the amino acid sequence of the Cry1F protein exhibits no significant homology to the sequences of known allergens or protein toxins. Thus, Cry1F is highly unlikely to exhibit an allergic response. Collectively, the available data on Cry1F protein along with the safe use history of microbial *Bacillus thuringiensis* products establishes the safety of the plant pesticide *Bacillus thuringiensis* subspecies *aizawai* Cry1F insect control protein and the genetic material necessary for its production in all raw agricultural commodities.	**Acute toxicity:** Dimethoate is moderately toxic by ingestion, inhalation, and dermal absorption. The reported acute oral LD_{50} values for the technical product range from 180 to 330 mg/kg in the rat; although an oral LD_{50} of as low as 28 to 30 mg/kg has been reported. Reported dermal LD_{50} values for dimethoate are 100 to 600 mg/kg in rats, again with a much lower value for an earlier product . Dimethoate is reportedly not irritating to the skin and eyes of lab animals. Severe eye irritation has occurred in workers manufacturing dimethoate, although this may be due to impurities. Via the inhalation route, the reported 4-hour LC_{50} is greater than 2.0 mg/L, indicating slight toxicity. Effects of acute exposure are those typical of organophosphates. **Chronic toxicity**: There was no cholinesterase inhibition in an adult human who ingested dimethoate for 21 days. No toxic effects and no cholinesterase inhibition were observed in individuals who ingested dimethoate for 4 weeks. Repeated or prolonged exposure to organophosphates may result in the same effects as acute exposure, including the delayed symptoms. **Reproductive effects**: When mice were given 9.5 to 10.5 mg/kg/day dimethoate in their drinking water, there was decreased reproduction, pup survival, and growth rates of surviving pups. **Teratogenic effects**: Dimethoate is teratogenic in cats and rats. It is not likely that teratogenic effects will be seen in humans under normal circumstances. **Mutagenic effects**: Mutagenic effects due to dimethoate exposure were seen in mice. Mutagenic effects are unlikely in humans under normal circumstances. **Carcinogenic effects**: An increase in malignant tumors was reported in rats given oral doses of dimethoate for over a year; but the increases were not dose dependent. Thus the evidence of carcinogenicity, even with high-dose, long-term exposure, is inconclusive. This suggests carcinogenic effects in humans are unlikely. **Fate in humans and animals**: Dimethoate is rapidly metabolized by mammals.	**Acute toxicity:** Chlorpyrifos is moderately toxic to humans. Poisoning may affect the central nervous system, the cardiovascular system, and the respiratory system. It is also a skin and eye irritant. Studies in humans suggest that skin absorption of chlorpyrifos is limited. The oral LD_{50} for chlorpyrifos in rats is 95 to 270mg/kg, 60 mg/kg in mice,1000 mg/kg in rabbits, 32 mg/kg in chickens, 500 to 504 mg/kg in guinea pigs, and 800 mg/kg in sheep. The dermal LD_{50} is greater than 2000 mg/kg in rats, and 1000 to 2000 mg/kg in rabbits. The 4-hour inhalation LC_{50} for chlorpyrifos in rats is greater than 0.2 mg/L. **Chronic toxicity:** Repeated or prolonged exposure to organophosphates may result in the same effects as acute exposure including the delayed symptoms. Human volunteers who ingested for 4 weeks 0.1mg/kg/day of chlorpyrifos showed significant plasma cholinesterase inhibition. **Reproductive effects:** Current evidence indicates that chlorpyrifos does not adversely affect reproduction. No effects were seen in 2 studies where animals were tested at doses up to 1.2 mg/kg/day. **Teratogenic effects:** Available evidence suggests that chorpyrifos is not teratogenic. Three studies in pregnant rats or mice indicate that no significant teratogenic effects were seen at doses up to 25 mg/kg/day for 10 days. **Mutagenic effects:** No evidence was found in any of four tests performed that chlorpyrifos is mutagenic. **Carcinogenic effects:** There is no evidence that chlorpyrifos is carcinogenic. There was noincrease in the incidence of tumors when rats were fed 10 mg/kg/day for 104 weeks. **Fate in humans and animals:** Chlorpyrifos is readily absorbed into the bloodstream through the gastro-intestinal tract if it is ingested, through the lungs if it is inhaled, or through the skin if there is dermal exposure. In humans, chlorpyrifos and its principal metabolites are eliminated rapidly. After a single oral dose, the half-life of chlorpyrifos in the blood appears to be about 1 day.	**Acute toxicity**: Permethrin is moderately to practically non-toxic via the oral route. Via the dermal route, it is slightly toxic, with a reported dermal LD_{50} in rats of over 4000 mg/kg, and in rabbits of greater 2000 mg/kg. Permethrin caused mild irritation of both the intact and abraded skin of rabbits. It also caused conjunctivitis when it was applied to the eyes. The 4-hour inhalation LC_{50} for rats was greater than 23.5 mg/L, indicating practically no inhalation toxicity. **Chronic toxicity**: No adverse effects were observed in dogs fed permethrin at doses of 5 mg/kg/day for 90 days. Rats fed 150 mg/kg/day for 6 months showed a slight increase in liver weights. **Reproductive effects**: The fertility of female rats was affected when they received very high oral doses of 250 mg/kg/day of permethrin during the 6th to 15th day of pregnancy. It is not likely that reproductive effects will be seen in humans under normal circumstances. **Teratogenic effects**: Permethrin is reported to show no teratogenic activity. **Mutagenic effects**: Permethrin is reported to show no mutagenic activity. **Carcinogenic effects**: The evidence regarding the carcinogenicity of permethrin is inconclusive. **Organ toxicity**: Permethrin is suspected of causing liver enlargement and nerve damage. **Fate in humans and animals**: Permethrin is efficiently metabolized by mammalian livers. Breakdown products, or "metabolites," of permethrin are quickly excreted and do not persist significantly in body tissues. Permethrin may persist in fatty tissues, with half-lives of 4 to 5 days in brain and body fat.	λ- cyhalothrin is moderately toxic in the technical form, but may be highly toxic via some routes in formulation (e.g., as Karate). 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. It may cause mild eye irritation in rabbits. **Chronic Toxicity**: The principal toxic effects noted in chronic studies with rates were decreased body weight gain and decreased food consumption. It is unlikely that cyhalothrin would cause chronic effects in humans under normal conditions. **Reproductive Effects**: Cyhalothrin caused reduced numbers of viable offspring at doses of 50 mg/kg/day in the second and third generations in the three-generational rat study noted above. It is unlikely that cyhalothrin would cause reproductive effects in humans under normal conditions. **Teratogenic Effects**: No teratogenic or fetotoxic effects were observed in teratology studies of lambda cyhalothrin 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**: Evidence is inconclusive, but suggests that it is probably not carcinogenic. **Organ Toxicity**: No specific target organs or organ systems have been identified in the available studies of chronic toxicity. **Fate in Humans & Animals**: In rat studies, lambda cyhalothrin is rapidly metabolized and excreted via the urine and feces.

1. B.t Cry1F data summary. Petition for Determination of non-regulated status B.t. Cry1F insect -resistant glufosinate-tolerant maize line 1507 (2000) Shanahan, D. and Stauffer, C. Mycogen Seeds, Dow Agrisciences and Pioneer Hi-Bred Intl. Inc. (2000). This petition is assigned APHIS petition number 00-136-01p. The mammalian toxicity profile is derived from the petitioner summary of the pesticide petition to establish an exemption from the requirement of a tolerance for the plant-pesticide *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production in plants in or on all food commodities as it appears in the Federal Register: June 15, 2000 (Volume 65, Number 116), pp 37545-37547.

2. Dimethoate Data: Pesticide Information Profiles, EXTOXNET Extension Toxicology Network. Revised June 1996. *http://ace.orst.edu/cgi-bin/mfs/01/pips/dimethoa.htm?8#mfs* ; H. M. Puurtinen, E. A. T. Martikainen (1997) Effect of Soil Moisture on Pesticide Toxicity to an Enchytraeid Worm, Enchytraeus sp., Arch. Environ. Contam. Toxicol. 33:34-41. *http://link.springer-ny.com/link/service/journals/00244/bibs/33n1p34.html*; Surviv of Microplitis croceipes (Hymenoptera: Braconidae) in contact with residues of insecticides on cotton. Powell, J.E.; Scott, W.P.(1991) Environmental entomology v. 20 (1): p. 346-348; 1991 Feb.

3. Chlorpyrifos Data: Pesticide Information Profiles, EXTOXNET Extension Toxicology Network. Revised June 1996. http://ace.orst.edu/cgi-bin/mfs/01/pips/chlorpyr.htm.
Chemical Fact Sheet for : Chlorpyrifos, Fact Sheet Number: 37, Date Issued: September 30, 1984 available at *http://pmep.cce.cornell.edu/profiles/insect-mite/cadusafos-cyromazine/chlorpyrifos/index.html.*

4. Permethrin Data: Pesticide Information Profiles, EXTOXNET Extension Toxicology Network. Revised June 1996. *http://ace.orst.edu/cgi-bin/mfs/01/pips/permethr.htm?8#mfs* ; Insecticide Fact Sheet, Coalition for Alternatives to Pesticides/NCAP, P.O.Box 1393, Eugene, Oregon,. J. of Pesticide Reform, Summer, 1998, v. 18, no. 2141. *http://www.safe2use.com/poisons-pesticides/pesticides/permethrin/cox.htm*

5. Lambda-cyhalothrin Data: Pesticide Information Profiles, EXTOXNET Extension Toxicology Network. *http://ace.orst.edu/cgi-bin/mfs/01/pips/lambdacy.htm?6#mfs.*

6. For EDF rankings, Environmental Defense Fund. *http://www.scorecard.org/chemical-profiles/*

Appendix D. Data submitted with the petition in support of nonregulated status for Bt Cry1F corn line 1507.

Molecular Genetic Characterization
Southern analysis of the *cry1F* gene in TC1507, Fig. 5, pg. 27 (Supplemental data was also submitted to demonstrate that the 2 copies of the *cry1F* gene were linked.)
Southern analysis of the ubiquitin promoter for *cry1F* gene in TC1507, Fig. 6, pg. 28.
Southern analysis of the *pat* gene in TC1507, Fig. 7, pg. 29.
Southern analysis of the CaMV promoter for the *pat* gene in TC1507, Fig. 8, pg. 30.
Southern analysis confirming the absence of the *nptII* gene in TC 1507, Fig. 9, pg. 31.
Summary of observed restriction fragments for the Southern analyses, Table. 4, pg. 26.
Mendelian segregation of B.t. Cry1F maize line for glufosinate tolerance in generations BC2F1 and F1 (tolerant plants were also evaluated for ECB resistance) Table 5., pg. 3 of 3, Response to deficiency 16. (See also accompanying Fig. 10 with a lineage of the generations in the analysis.)
Cry1F protein levels in tissues from line 1507 hybrids by ELISA , Table 6., pg. 37.
PAT protein levels in tissues from line 1507 hybrids by ELISA, Table 7., pg. 38.
Cry1F protein characterization in tissues from line 1507 hybrids - Western blots of both SDS-gels, Fig.11, pp.41-42 and Native gels, Fig. 12, pp. 43-44.
PAT protein characterization in tissues from line 1507 hybrids - Western blots of SDS-gels, Fig.13, pp.45-46
Phenotypic Characterization and Evidence to Support a Lack of Unintended Effects
Efficacy Data, i.e., resistance to lepidopteran insects and tolerance to glufosinate-ammonium herbicide (CBI Petition appendix Volume 17 and Response to Deficiency #3 dated July 19, 2000, Table B and A, respectively).
Agronomic Performance Traits between a line 1507 hybrid and an appropriate hybrid control grown without insecticides in various field trials across the United States in 1999, Table 8, pg. 48. 14 Traits evaluated. See also field data reports.
Seed Germination under optimal conditions and under cold stress, Table 9, pg. 49.
Compositional and Nutritional analysis: Whole-plant forage data on proximate analysis (for protein, fat, fiber, and ash). Grain data on proximate analysis, mineral analysis, fatty acid composition, amino acid analysis, vitamin content, and antinutrient content (phytic acid and trypsin inhibitor). Response to Deficiency 18.

Analysis of Nontarget Effects
Comparison of maize-derived Cry1F protein and microbially-derived Cry1F protein used for bioassays, N-terminal sequence analysis- pg. 52., Glycosylation - CBI Appendix 1, Biological Activity - Table 10, Pg. 54.
Environmental Fate of Cry1F in Soil, CBI Appendix Vol 6., see petition pg. 55.
Colembola - 28 day Chronic exposure study, CBI Appendix 8.,see petition pg. 55.
Honeybee- dietary effects on larvae mortality and development, CBI Appendix 10, see petition pg. 56 amended.
Green Lacewing larvae - Dietary toxicity, CBI Appendix 11., see petition pg. 56 amended.
Parasitic Hymenoptera - Dietary toxicity, CBI Appendix 13., see petition pg. 56 amended.
Ladybird Beetle - Dietary toxicity, CBI Appendix 12., see petition pg. 56 amended.
Daphnia magna - Acute toxicity test, CBI Appendix 9., see petition pg. 56 amended.
Earthworm- Acute toxicity, CBI Appendix 7., see petition pg. 56 amended.
Bobwhite Quail - Dietary toxicity, CBI Appendix 15., see petition pg. 56 amended.
Monarch Butterfly (and other lepidopterans) - Nontarget exposure and risk assessment for dispersal of Cry1F pollen - CBI Appendix 5, see petition pg. 56.
Beneficial arthropod predator - field study conducted in 1999 in Johnston, Iowa, CBI Appendix 16,
Resistance management plan - CBI Appendix 19.
Mice - Acute oral toxicity, CBI Appendix 22.
Allergenicity profile - Comparison of amino acid sequence similarity of Cry1F and PAT proteins to known allergen proteins., CBI Appendix 23.
In vitro digestability of Cry1F - CBI Appendix 24.

Appendix E. Determination of non-regulated status for *Bt* Cry1F corn line 1507.

In response to a petition (designated 00-136-01P) received from Mycogen Seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc., APHIS has determined that genetically-engineered corn line 1507 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 line 1507 corn and its progeny. Importation of seed of line 1507 corn and its progeny is still, however, subject to the restrictions found in the Foreign Quarantine Notices (regulations at 7 CFR Part 319), just as they apply to other importation of corn seeds. This determination is based on APHIS' analysis of field and laboratory data and literature references provided in the petition and other relevant information as described in this environmental assessment that indicate that corn line 1507 and its progeny will not pose a plant pest risk for the following reasons: (1) They exhibit no plant pathogenic properties - although DNA from plant pathogens was used in the development of line 1507 corn, these plants are not infected by these organisms, nor can they incite disease in other plants. (2) They are no more likely to become weeds than insect or herbicide tolerant corn that is currently being cultivated. (3) Introgression from line 1507 corn into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely effect genetic diversity of related plants any more than would introgression from traditional corn hybrids. (4) They are similar in plant forage composition and in kernel composition and quality characteristics to nontransgenic corn and should have no adverse impact on raw or processed agricultural commodities. (5) They exhibit no potential to have a significant adverse impact on organisms beneficial to agriculture. (6) Compared to current agricultural practices, cultivation of line 1507 corn should not reduce the ability to control insects or weeds in corn or other crops. In addition to our finding of no plant pest risk, there will be no affect on threatened or endangered species under the conditions of the current pesticide registrations (EPA Reg. Numbers 29964-3 and 68467-2) granted for field corn originating from maize line 1507.

APHIS also has concluded that there may be new varieties bred from line 1507 corn; however they are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for corn already produced from line 1507 and field tested, or those observed for other corn varieties not considered regulated articles under 7 CFR Part 340.

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