Notices

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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. 00–078–2]

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Monsanto Company corn designated as Event MON 863, which has been genetically engineered for insect resistance, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms and products. Our determination is based on our evaluation of data submitted by Monsanto Company in its petition for a determination of nonregulated status, our analysis of other scientific data, and comments received from the public in response to a previous notice. This notice also announces the availability of our written determination document and our finding of no significant impact.

EFFECTIVE DATE: October 8, 2002.

ADDRESSES: You may read a copy of the determination, an environmental assessment and finding of no significant impact, the petition for a determination of nonregulated status submitted by Monsanto Company, and all comments received on the petition and the environmental assessment in our reading room. The reading room is located in room 1141, USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure that someone is available to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–8365. 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 17, 2001, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 01–137–01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for corn (*Zea mays* L.) designated as Corn Rootworm Protected Corn Event MON 863 (MON 863), which has been genetically engineered for resistance to the larvae of certain corn rootworm (CRW) species. The Monsanto petition stated that the subject corn should not be regulated by APHIS because it does not present a plant pest risk.

On March 14, 2002, APHIS published a notice in the **Federal Register** (67 FR 11458–11459, Docket No. 00–078–1) announcing that the Monsanto petition and an environmental assessment (EA) were available for public review. This notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn and food products derived from it. APHIS received 1,383 comments on the petition and the EA during the 60-day comment period, which ended May 13, 2002. The comments were received from private individuals, farmers (including corn growers and organic farmers), universities, seed companies, State governors, State department of agriculture directors, State corn growers' associations, State and regional agricultural business and trade associations, a national corn growers' association, an organic trade association, a State seed association, a consumer group, an environmental organization, a university cooperative extension specialist, an agronomic consultant, and a corn product manager. There were 542 comments in support of the subject petition, and 841 were opposed. The comment letters in support of deregulation for MON 863 stressed the environmental benefits of using MON 863 to control CRW, including the reductions in pesticide use and user exposure to toxic chemicals, reductions in farm labor time and costs, the effectiveness and consistency of MON 863 in controlling CRW, and the advantages to growers in increased yields and crop quality. Other comments in favor of deregulation for the subject corn concerned the absence of evidence of plant pest and environmental risk presented by MON 863.

The comments in opposition to deregulation for MON 863 corn included allegations concerning the potential for polluting the purity of organically grown corn, the inevitability of the development of insect resistance to *Bacillus thuringiensis* (Bt) and the consequent loss to organic farmers of the spray form of Bt, the toxic effects of Bt-containing pollen on nontargets, the potential for upsetting the microbial balances in the soil, the possible development of human allergic reactions to Bt corn, and the need for a moratorium on genetically engineered crops due to the alleged inadequacy of U.S. regulation of genetically engineered crops. One commenter contended that a full environmental impact assessment was required prior to commercial growing of MON 863 corn because allowing large-scale commercialization of this corn constituted a major Federal action significantly affecting the environment. The commenter further found the EA inadequate in its treatment of the potential for the development of insect resistance to the Cry 3Bb1 protein, the unavailability to the public of certain information on nontarget effects, the failure to address the cumulative issue of gene stacking through cross-pollination, the failure to address the susceptibility of MON 863 to corn stunt disease, the failure to adequately address the impacts on organic farmers of contamination by transgenic varieties, the failure to address the economic impacts on U.S. corn farmers of the loss of European markets, and the failure to address the environmental impacts of the illegal grant of certain genetic resources from the public trust into the possession of commercial entities. One additional comment concerned the need for study of the impacts of Bt corn in the ruminant and human diets and the potential for lateral gene flow in the enteric milieu. We have provided responses to these comments as an attachment to our finding of no significant impact, which is available from the person listed under **FOR FURTHER INFORMATION CONTACT.**

MON 863 corn has been genetically engineered to express a Cry3Bb1 insecticidal protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kumamotoensis* (*Bt kumamotoensis*). The petitioner stated that the Cry3Bb1 protein is effective in controlling the larvae of CRW pests (Coleoptera, *Diabrotica* spp.). The subject corn also contains the *nptII* marker gene derived from the bacterium *Escherichia coli*. The *nptII* gene encodes neomycin phosphotransferase type II and is used as a selectable marker in the initial laboratory stages of plant cell selection. Expression of the added genes is controlled in part by gene sequences from the plant pathogens cauliflower mosaic virus and *Agrobacterium tumefaciens*. Particle gun acceleration technology was used to transfer the added genes into the recipient inbred yellow dent corn line A634.

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

Determination

Based on its analysis of the data submitted by Monsanto, a review of other scientific data, field tests of the subject corn, and comments submitted by the public, APHIS has determined that MON 863 corn: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than corn developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not harm threatened or endangered species or organisms, such as bees, that are beneficial to agriculture; and (5) will not cause damage to raw or processed agricultural commodities. Therefore, APHIS has concluded that the subject corn and any progeny derived from hybrid crosses with other nontransformed 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 Monsanto's MON 863 corn 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 or its progeny. However, importation of MON 863 corn 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 was 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 MON 863 corn and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and FONSI are available upon request from the individual listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Done in Washington, DC, this 17th day of October 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02–26923 Filed 10–22–02; 8:45 am]

BILLING CODE 3410–34–P

Approval ofMonsanto Petition (01-137-01p) Seeking a Determination of
Non-regulated Status for Bt *CryBb1* Insect Resistant Corn Line MON 863

Environmental Assessment and
Finding of No Significant Impact

October 2002

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA) has prepared an environmental assessment (EA) prior to approving a petition (APHIS number 01-137-01p) for a determination of nonregulated status received from Monsanto Company (Monsanto) under APHIS regulations at 7 CFR Part 340. The subject of this petition, corn line MON 863, is genetically engineered for insect resistance by the insertion of the *CryBb1* gene encoding a protein which is toxic to coleopteran insects in the corn rootworm complex. It is also genetically engineered to express a selectable marker, the enzyme neomycin phosphotransferase which confers antibiotic resistance. On 3/14/02, APHIS published a notice in the Federal Register (67 FR 11458-11459, Docket no. 00-078-1) announcing the availability of the petition and EA for public review and comment. During the designated 60 day comment period ending on 5-13-02, APHIS received 1383 comments. APHIS' analysis of and response to these comments is included as an attachment to this finding. Based on the analysis carried on in the EA and our response to the comments, APHIS has reached a finding of no significant impact (FONSI) to the environment from its determination that corn lineMON 863, and progeny derived from it, shall no longer be considered regulated articles. This determination is attached to the EA as Appendix E.

Cindy J. Smith
Acting Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date:
OCT 08 2002

APHIS' Analysis and Response to Comments Received on Petition 01-137-01p and the EA.

A total of 1383 comments were submitted during the designated 60-day comment period by private individuals, farmers, including corn growers and organic farmers, universities, seed companies, State governors, State department of agriculture directors, State corn growers' associations, State and regional agricultural business and trade associations, a national corn growers association, an organic trade association, a State seed association, a consumer group, an environmental organization, a university cooperative extension specialist, an agronomic consultant, and a corn product manager. The majority of comments, both those supporting and those in opposition to the subject petition, were form letters submitted by e-mail from private individuals. The comment letters in support of deregulation for MON 863 totaled 542. These stressed the environmental benefits of using MON 863 to control CRW, including the reductions in pesticide use and user exposure to toxic chemicals, reductions in farm labor time and costs, the effectiveness and consistency of MON 863 in controlling CRW, and the advantages to growers in increased yields and crop quality. Other comments in favor of the subject corn concerned the absence of evidence of plant pest and environmental risk presented by MON 863.

The comments in opposition to deregulation for MON 863 corn, totaling 841, included allegations concerning the potential for polluting the purity of organically grown corn, the inevitability of the development of insect resistance to Bt and the consequent loss to organic farmers of the spray form of Bt, the toxic effects of Bt-containing pollen on nontargets, the potential for upsetting the microbial balances in the soil, the possible development of allergic reactions to Bt corn, and the need for a moratorium on genetically engineered crops due to the alleged inadequacy of U.S. regulation of genetically engineered crops. One commenter contended that a full environmental impact assessment (EIS) was required prior to commercial growing of MON 863 because allowing large scale commercialization of this corn constituted a major federal action affecting the environment. The commenter further found the EA inadequate in its treatment of the potential for the development of insect resistance to the Cry 3Bb1 protein, the unavailability to the public of certain information on nontarget effects, the failure to address the cumulative issue of gene stacking through cross-pollination, the failure to address the susceptibility of MON 863 to corn stunt disease, the failure to adequately address the impacts on organic farmers of contamination by transgenic varieties, the failure to address the economic impacts on U.S. corn farmers of the loss of European markets, and the failure to address the environmental impacts of the illegal grant of certain genetic resources from the public trust into the possession of commercial entities. Further characterization of and response to those comments in opposition are given below.

1. **Because corn is an open pollinating crop, pollen may contaminate other corn crops, in particular organically grown corn.**

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 660 feet is considered to be an adequate minimum separation distance for production of 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/biotechnology/main/index.html*).

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 Cry3Bb* coleopteran resistant; and (c) based on the insect resistance management (IRM) plan, farmers will be educated about recommended management practices. Several transgenic corn lines resistant to lepidopteran insects are already in widespread use by farmers. Transgenic herbicide tolerant varieties of corn are also available.

2. Insects will be come resistant to the Bt corn and thus organic farmers will lose the use of that same Bt in its traditional form.

Organic farmers do not use traditional Bt formulations to control corn rootworms so this argument is not valid. Further, use of corn rootworm protected transgenic corn will not result in the loss of any other tool currently used by organic farmers to control pests. The active ingredient in MON 863 corn is based on the *Cry3Bb* protein, which is fundamentally different from the proteins in Bt formulations that organic farmers use to control lepidopteran pests. Theses are CryI proteins which come from different Bt strains than does MON 863. Even if resistance did develop to the *Cry3Bb* protein in MON 863 corn, there would be no effect on the CryI proteins used to control lepidopteran pests.

Even though organic farmers would not be affected, insect resistance management (IRM) strategies are considered to be of crucial importance, to protect this type of Bt as a resource for combating one of the most destructive insect pests of corn. Monsanto is conducting research to identify appropriate IRM strategies. These will be developed in cooperation with experts in the government and in academia. The IRM strategy will be submitted to the EPA prior to commercialization. IRM strategies deployed with the commercialization of transgenic lepidopteran resistant corn and cotton have been effective in preventing the development of resistance in these pest populations.

3. Bt pollen will be toxic to non-target organisms

USDA examined data submitted by the applicant on the toxicity of Cry3Bb1 protein toward a diverse group of organisms. No toxicity was found toward channel catfish, cladoceran, collembola, adult and larval ladybeetles of the species, *coleomegilla maculata*, adult ladybeetles of the species *Hippodamia convergens*, adult and larval honeybees, green lacewing larvae, parasitic wasps, and earthworms. These data are as expected, since the Cry3Bb1 protein has specificity toward only certain insects in the family Chrysomelidae in the order Coleoptera.

Given the very narrow spectrum of activity of the Cry3Bb1 toxin, there was no expectation of activity toward Monarch butterflies. Even so, Monsanto examined monarch larvae fed on mikweed leaves dusted with varying pollen concentrations. Larvae were then observed for mortality, development, and weight gain over time. These experiments showed no negative effects from ingestion of MON 863 pollen on survival, development, weight gain, or leaf consumption when compared to either non-Bt pollen or no pollen.

4. The use of MON 863 corn may upset microbial balances in the soil.

The comment is general and does not describe any specific changes or resulting negative impacts. Microbial populations in agricultural ecosystems are different that those in natural settings. Agricultural practices such as tillage, irrigation, application of chemicals for pest control, fertilization, and even choice of crop can all affect microbial populations. APHIS acknowledges that adoption of MON 863-derived lines, along with any concomitant changes in agricultural practices, such as reduced chemical usage, could have an effect on microbial populations. We do not know of any evidence of compelling arguments to suggest a negative impact from any changes that may occur.

5. MON 863 corn may cause allergic reactions

EPA is primarily responsible for assessing the safety of plant-incorporated pesticides in human food and animal feed. 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. The FDA enforces the tolerances set by the EPA. On May 11, 2001, EPA granted a tolerance exemption for Cry3Bb1 (66 *FR* 24061-24066, May 11, 2001), the active ingredient in MON 863 corn. The exemption concluded that there was a reasonable certainty of no harm from consumption of the protein, as it is digestible in gastric fluid and not considered an allergen.

6. APHIS should impose a moratorium on genetically engineered crops due to alleged inadequacy in regulation.

APHIS has no authority to impose a moratorium on genetically engineered crops. Under the coordinated framework, APHIS is just one agency that evaluates genetically engineered crops. APHIS determines on a case-by-case basis whether genetically engineered plant lines pose a plant pest risk, and then considers whether a decision to deregulate would have a significant environmental impact.

7. APHIS should have written a full Environmental Impact Statement

APHIS' NEPA Implementing Procedures (7 CFR 372) do not indicate that this type of action is of the class of actions normally requiring the preparing of an EIS. It is characteristic of the class of actions normally requiring an EA, but not necessarily an EIS. APHIS' analysis documented in the EA (and in the response to comments) does not indicate that a significant impact to the environment is likely; therefore the preparation of an EIS is not necessary. APHIS has previously de-regulated several lines of genetically engineered corn, some of which expressed Bt proteins. This was the first corn line that expressed a Bt protein active against coleopteran insects. APHIS concludes that a decision to de-regulate MON 863 corn, when combined with previous decisions to deregulate other genetically engineered crops with totally different traits, uses, and markets, will not influence or cause a significant cumulative impact to the human environment which would warrant the preparation of an EIS.

8. APHIS did not adequately address the issue of insect resistance management in the EA

Insect resistance management is coordinated by the EPA. As previously stated, MON 863 corn will not be commercialized until a management plan has been approved. EPA is organizing a Scientific Advisory Panel in August 2002 to address the insect resistance management plan for this corn line.

9. Economic impacts due to potential loss of European markets

The Plant Protection Act (Title IV, Pub. L. 106-224, 114 Stat. 438, 7 U.S.C. 7701-7772) grants APHIS authority to regulate genetically engineered plants that may pose a plant pest risk. When genetically engineered plants are determined not to pose such a risk they can be de-regulated through the petition process. There is no provision for consideration of economic impacts in making the determination. Several lines of genetically engineered corn have already been de-regulated and are present in shipments of U.S. commodity corn.

In the interest of meeting certain market needs, USDA's Agricultural Marketing Service and Grain Inspection, Packers and Stockyards Administration published an Advance Notice of Proposed Rulemaking on November 30, 2000 in the *Federal Register* (65 FR 71272- 71273) concerning the possible further development of additional testing and standardization for seeds and commodities designed to differentiate products such as non-biotechnology-derived commodities. Federal, State, private, and international groups involved in seed certification all allow for some level of accidental, incidental, or adventitious presence of off-types even in the purest seed categories, such as foundation and breeder seed. Even at present, there are options for buyers who do not want genetically engineered corn. Some overseas buyers of U.S. agricultural goods choose to contract with U.S. producers to deliver agricultural goods grown to certain specifications. These are then "identity preserved" during processing and shipment

10. The EA does not address susceptibility to corn stunt disease.

This comment is apparently based on the observation in the petition of corn stunt disease in a very small percentage of MON 863 plants at one single location. At this location the disease was observed on only 2 percent of the MON 863 plants, but not on the controls. However, the field test consisted of a large percentage of MON 863 plants and a small percentage of control plants and chance alone likely account for the observation. More importantly, no corn stunt disease was observed at any of 30 other sites. Corn stunt disease was not addressed in the EA, because the data do not support a conclusion of any changes in susceptibility of plants to corn stunt disease or any other disease or insect pest.

11. The EA does not address environmental impacts of illegal grant of certain genetic resources from the public trust into possession of commercial entities.

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

USDA/APHIS Decision on Monsanto Petition 01-137-01P Seeking a Determination of Nonregulated Status for Bt *cry3Bb1* Insect Resistant Corn Line MON 863

Environmental Assessment

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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 01-137-01p) from the Monsanto Company (Monsanto) regarding the regulatory status of genetically engineered (transformed) coleopteran insect resistant corn derived from their transformation event MON 863 (designated hereafter as MON 863 corn). This corn is currently a regulated article under USDA regulations at 7 CFR Part 340, and as such, interstate movements, importations, and field tests of MON 863 corn have been conducted under permits issued or notifications acknowledged by APHIS. Monsanto petitioned APHIS requesting a determination that MON 863 corn does not present a plant pest risk, and therefore MON 863 corn and its progeny derived from crosses with other nonregulated corn should no longer be regulated articles under these APHIS regulations.

The MON 863 corn has been genetically modified to express a modified *Cry3Bb1* gene from *Bacillus thuringiensis (Bt)* subsp. *kumamotoensis*. This gene encodes an insecticidal protein that protects the corn plants against the feeding damage of larvae of the corn rootworm complex comprised of *Diabrotica* species. While insecticidal proteins previously engineered into corn controlled pests in the insect order Lepidoptera, the *Diabrotica* species targeted by this protein belong to the order Coleoptera. As with the previous Bt Cry proteins, Cry3Bb has a high degree of specificity for the target pest. MON 863 corn also expresses in plants the selectable marker *nptII*. The neomycin phosphotransferase type II (NPTII) enzyme uses ATP to phosphorylate neomycin and related aminoglycoside antibiotics resulting in their inactivation. A fragment containing the *Cry3Bb1* and *nptII* expression cassettes was excised from the plasmid vector and introduced into the corn genome using particle gun acceleration technology.

Field trials of MON 863 corn have been conducted under the APHIS notification procedure (7 CFR Part 340.3). Performance standards for such field trials require that the regulated article and its offspring must not persist in the environment after completion of the test. In accordance with APHIS procedures for implementing the National Environmental Policy Act (NEPA) (7 CFR Part 372), this EA has been prepared prior to issuing a determination of nonregulated status for MON 863 corn in order to specifically address the potential for impact to the human environment through the unconfined cultivation and use in agriculture of the regulated article.

II. BACKGROUND

A. Development of MON 863 corn.

Monsanto has submitted a "Petition for Determination of Non-regulated Status" to the USDA, APHIS (APHIS number 01-137-01p) for genetically engineered corn plants that are resistant to the feeding damage caused by a coleopteran pest complex known as corn rootworms (CRW). A complex of *Diabrotica* species comprise what is known as the CRW complex. The CRW complex includes: western corn rootworm (WCRW: *D. virgifera virgifera*), Mexican corn rootworm (MCRW: *D. virgifera zeae*), northern corn rootworm (NRCW: *D. barberi*) and the southern corn rootworm (SCRW: *D. undecimpunctata howardi*). The larvae damage corn by feeding on the roots, thereby inhibiting the ability of the plant to absorb water and nutrients from the soil (Reidell, 1990). This leads to harvesting difficulties due to lodging of the weakened plants (Spike and Tollefson, 1991). CRW is one of the most destructive pests to corn and accounts for a significant quantity of synthetic pesticide usage, with over 15 million acres being treated with organophosphate, carbamate, and pyrethroid insecticides in the year 2000. Seasonal losses due to CRW have been estimated at a billion dollars when taking into account both the costs of chemical controls and crop losses. Monsanto has submitted data indicating economically significant levels of control against the two most destructive pests of the complex, WCRW and NCRW, and a somewhat lower but still statistically significant levels of control for the less important SCRW.

Monsanto used recombinant DNA techniques to produce and introduce into corn a restriction fragment containing the *cry3Bb1* gene from *Bacillus thuringiensis* subsp. *kumamotoensis*, thereby rendering the corn line resistant to CRW. Regulatory elements for the *cry3Bb1* gene were derived from the plant pathogenic virus cauliflower mosaic virus (CaMV), and from rice and wheat. The plant selectable marker *nptII* from *Escherichia coli* transposon Tn5, which confers resistance to aminoglycoside antibiotics, was also introduced on the fragment. Regulatory sequences associated with *nptII* were derived from CaMV and the plant pathogenic bacterium *Agrobacterium tumefaciens*. Regulatory sequences associated with *Cry3Bb1* gene or the *nptII* marker gene are not transcribed and do not encode proteins. The DNA was introduced into corn cells using particle acceleration methodology. Plant cells containing the introduced DNA were then selected by culturing in the presence of the aminoglycoside antibiotic paromomycin. Because the transformed cells contain some sequences from plant pathogens, they are explicitly subject to regulation under 7 CFR Part 340.

MON 863 corn has been field tested in the United States since 1998 as authorized by USDA notifications listed in Appendix A. The list is comprised of more than 200 sites in diverse regions of the U.S. including the major corn growing areas of the Midwest and winter nurseries in Hawaii and Puerto Rico. Field tests conducted under APHIS oversight allow for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after the completion of the test. Data are gathered on multiple parameters and are used by the applicants to evaluate agronomic characteristics and product performance and are used by APHIS to determine if the new variety poses 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. MON 863 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.

MON 863 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 March 19, 2001, the EPA announced the receipt of an application filed by Monsanto to register the pesticide product *Bt* Cry3Bb protein and the genetic material necessary for its production in corn (66 *FR* 15435-15436, March 19, 2001). 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.

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. The FDA enforces the tolerances set by the EPA. On May 11, 2001, EPA granted a tolerance exemption for Cry3Bb1 (66 *FR* 24061-24066, May 11, 2001). The exemption concluded that there was a reasonable certainty of no harm from consumption of the protein, as it is digestible in gastric fluid and not considered an allergen.

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. Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g. labeling) are resolved prior to commercial distribution of a bioengineered food. Monsanto initiated the consultation for MON 863 with FDA on September 1, 2000, and submitted on September 25, 2000 a summary of their assessment to the FDA indicating no changes in composition, safety or other relative parameters. The consultation for MON 863 corn as food and feed was completed on December 31, 2001 indicating that the FDA has no unresolved issues with respect to marketing of MON 863 for human food and animal feed.

III. <u>PURPOSE AND NEED</u>

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 MON 863 corn as a regulated article under APHIS regulations. The developer of MON 863 corn, Monsanto, submitted a petition requesting that APHIS make a determination that corn transformation event MON 863, and any progeny derived from crosses of event MON 863 with other nonregulated corn varieties, no longer be considered regulated articles under 7 CFR Part 340.

IV. ALTERNATIVES

A. No Action: Continuation as a Regulated Article

Under the "no action" alternative, APHIS would come to a determination that MON 863 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 MON 863 corn and its progeny.

B. Determination of Nonregulated Status

Under this alternative, MON 863 corn and its progeny would no longer be considered regulated articles under 7 CFR Part 340. Permits or notifications to APHIS would no longer be required for introductions in the United States and its territories of MON 863 corn or its progeny. Unrestricted cultivation of the lines would be permitted by APHIS. Such a determination, however, does not preclude any restriction on the cultivation of this corn that might be placed by other regulatory agencies also having authority.

C. Determination of Nonregulated Status, in Part

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

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

Approval of the petition with geographic restrictions. APHIS might determine that the regulated article poses no significant risk in certain geographic areas, but may pose a significant risk in others. In this case, APHIS may choose to approve the petition with a geographic limitation stipulating that the approved lines could only be grown in certain geographic areas based on the identification of site-specific risks.

V. POTENTIAL ENVIRONMENTAL IMPACTS

The potential environmental impacts of alternatives A and B, as described above in section IV are presented in this section.

Alternative A, Non Action.
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 MON 863 corn and any progeny derived from it.

Historically, crop rotation has provided highly effective protection from CRW damage. More recently, however, several factors have begun to limit its effectiveness. First, many growers prefer to grow corn continuously, a practice which necessitates higher inputs of chemical insecticides. Second, it has now been demonstrated that both the NCRW and the WCRW exhibited extended diapauses in which some eggs can survive through the non-corn rotation to attack corn in a subsequent season (Ostlie, 1987; Tollefson, 1988; Gray *et al.*, 1998). Third, a new strain has developed in central Illinois and northern Indiana that can survive and replicate on soybean, the crop most often rotated with corn in the corn belt (Onstad and Joselyn, 1999; O'Neal et al., 1999). This strain has spread rapidly since it was first observed in 1993, and it is expected to continue to spread throughout the corn belt.

As a result of these factors, and the very damaging nature of the pest, chemical insecticide usage has increased in past years to the extent that CRW is now the most significant corn pest in the U.S. from the standpoint of pesticide usage. The most common chemical regime is the application of a granular insecticide at planting, either banded or in-furrow. In some cases sprays are applied for adult suppression. National Agricultural Statistics Service (NASS) statistics compiled from 15 top corn producing states in the Midwest indicate that 30% of this acreage was treated with insecticide registered for corn rootworm control. It is difficult to surmise how much of this application was for the corn rootworm control as these insecticides used alone or in combination also control other pests such as black cutworms. A 1995 survey conducted in Iowa, the leading corn producing state which accounts for 17.5% of all U.S. production, indicated that growers used chemicals to control CRW 22 % of the time. Data from NASS indicated that there were 14 products registered for CRW control 1999. The most widely used insecticides are from the organophosphate or synthetic pyrethroid classes of chemistry.

Widespread use of chemical insecticides has raised concerns for worker safety, water contamination, and other environmental risks. Appendix C contains environmental fate and toxicity data on three of the most commonly used synthetic chemicals and the Cry3Bb1 protein. One of the synthetic chemicals, Turbufos, can leach through the soil, leading to concerns about ground water contamination. The other two chemicals bind to soil and are relatively immobile. For the two immobile compounds, persistence in the soil ranged from just under a month to several months depending on the chemical, application method, and conditions. Available toxicity data varied among the synthetic chemicals, but each showed some degree of toxicity to non-target test organisms. All three appeared to be highly toxic to fish.

If APHIS chooses Alternative A, then crop rotation and the numerous chemical insecticides described above will continue to comprise the options for CRW control.

Alternative B, Determination of Nonregulated Status.

A decision to choose alternative B, deregulation of MON 863 corn, is addressed below. The unrestricted cultivation and distribution of MON 863 corn is compared to that for other corn not subject to regulation by APHIS 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 MON 863 corn 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 MON 863 corn.

For the transformation process, plant cells from the publicly available inbred corn line A634 were used as the recipient material. Inbred A634 was produced by the Minnesota Agricultural Experiment Station and released in 1965. The cultured plant cells were transformed using particle acceleration methodology (Klein et al., 1987, Gordon-Kamm et al., 1990). The particle delivered DNA was then incorporated into one or more plant chromosomes. The introduced DNA contained the *nptII* gene which encodes resistance to aminoglycoside antibiotics, thereby allowing for selection of transformed cells by growing them in the presence of the antibiotic paromomycin.

APHIS analyzed data that demonstrates that MON 863 corn plants regenerated from the transformation event designated MON 863 contain one copy of the following genetic elements from the plasmid PV-ZMIR13. These elements were: (1) the coding sequence of a synthetic variant of CRY3Bb1 insecticidal protein from *Bacillus thuringiensis* subsp. *kumamotoensis* whose transcription is directed by a promoter comprised of four tandem copies of a 21 base pair sequence designated as activating sequence-1 (AS1) from CaMV and a single portion of the 35S promoter, also from CaMV. Non-coding sequences associated with the *cry3Bb1* are a leader sequence for the chlorophyll a/b binding protein from wheat (wt CAB), and a sequence of the wheat heat shock protein 17.3 (tahsp17 3') which ends transcription and directs polyadenylation; and (2) the *nptII* marker gene derived from *E. coli* transposon Tn5 that encodes the NPTII protein which confers resistance to aminoglycoside antibiotics. Non-coding sequences associated with the *nptII* gene included the 35S promoter from CaMV and the NOS 3' terminator sequence from *Agrobacterium tumefaciens.* Although CaMV and *A. tumefaciens* are plant pathogens, the sequences included in MON 863 corn cannot cause plant disease. They do not encode infectious entities and serve a purely regulatory function for the genes of interest. These sequences have a history of safe use in genetically engineered plants. The donor organism for the *cry3Bb1, Bacillus thuringiensis* subsp. *kumamotoensis,* is a soil-inhabiting bacterium and is not a plant pathogen. The wild type *cry3Bb1* gene has been redesigned to increase insecticidal activity, optimize codon usage, and to facilitate linkage to a suitable plant-effective promoter. Monsanto sequenced the nucleotides comprising the insert and deduced the amino acid sequence to conclude that the Cry3Bb1 variant differs from the wild type by 7 amino acids. This difference results in a protein sequence homology of 98.9 percent. The donor organism for the *nptII* gene is the transposon Tn5 from *E. coli*, a coliform bacterium found commonly in the guts of humans and other animals. *E. coli* is not a plant pathogen. Due to the unique restriction site for the excision of the *nptII* gene from *E. coli*, the gene cassette also contains a 153 bp portion of the bleomycin binding protein gene, *ble.* Due to the lack of a unique 5' mRNA cap and start codon necessary for ribosome assembly in eukaryotic organisms such as corn, it is highly unlikely that the partial *ble* fragment could be translated. In the unlikely event that the partial fragment was translated, a functional protein is not predicted since the protein structure would not allow for necessary dimerization, and also because many of the residues involved in bleomycin binding are absent. Conversely, the NPTII protein is fully functional and allows for the selection of transformed cells in the laboratory following the transformation procedure.

The initial germplasm designated as transformation event MON 863 was used in a breeding program to produce commercially viable hybrid corn lines with the newly introduced traits. APHIS analyzed data and information submitted in the petition that characterized the nature, stability, inheritance, and expression of the inserted genetic constructs and their encoded proteins in different generations of plants derived from MON 863. DNA analysis of corn grains supports the conclusion that (1) MON 863 corn contains within its genomic DNA (nuclear chromosomes) a single copy of the intact gene cassette which contains both the *cry3Bb1* and *nptII* genes and their associated noncoding regulatory regions; and (2) these genetic constructs were stably and predictably inherited according to Mendel's laws over three generations of cross-fertilizations and two generations self-pollinations (see Petition Section V.B. Table 6). Data characterizing the expression of the encoded Cry3Bb1 and nptII proteins in lines derived from event MON 863 (see Petition Section V.,C. Tables 7 and 8) indicate that the proteins are expressed at varying levels throughout the plant. Levels of the Cry3Bb1 protein begin to decline in root tissues after 49 days, but larval feeding takes place prior to this decline when expression levels are relatively high. Analyses using Southern blots indicate a single insertion site, intact expression cassettes, and single copy numbers of both the *cry3Bb1* and the *nptII* genes (see Petition Section V.A. Figures 4-11). No apparent fusion or truncated proteins were detected. Data in the petition support the conclusion that hybrids derived from line MON 863 exhibit the expected trait of corn rootworm control conferred by the production of the insecticidal protein, Cry3Bb1 (see Petition Section VI, C Figure 17 and Table 12).

Data submitted to APHIS from field tests conducted at 31 sites from 1998-2000 indicate no difference in insect or disease susceptibility. Other field studies were conducted in 2000 with six hybrid lines produced from MON 863 to examine agronomic equivalency of MON 863 hybrids with similar non-transformed controls . These field tests, conducted at multiple locations in the important corn growing states of Illinois, Iowa, and Nebraska, examined nine key parameters (e.g. stand counts, plant height, yield, etc). Each parameter was measured at 7 to 15 locations for each of the six hybrids. The data do not show any biologically significant trends and indicate that the MON 863 differs agronomically only in the intended trait of resistance to certain coleoperan pests.

In addition to field studies on agronomic parameters, Monsanto analyzed grain of MON 863 corn for compositional changes as a part of their submission to FDA in the consultation process. While FDA uses these data as an indicator of nutritional changes, APHIS views them as a general indicator of unintended changes. MON 863 corn is compared to a nontransgenic control and to the commercial range for components such as minerals, vitamins, fatty acids, carbohydrate, protein, and fat (see Petition, appendix B). The data indicate no changes in composition of MON 863 corn and provide additional evidence that MON 863 corn will not exhibit unexpected and unintended effects.

B. Potential impacts based on the relative weediness of MON 863 corn.

APHIS assessed whether MON 863 corn is any more likely to become a weed than the nontransgenic recipient corn line, or other corn currently cultivated. The assessment encompasses a thorough consideration of the basic biology of corn and an evaluation of unique characteristics of MON 863 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).

MON 863 corn exhibits no characteristics that would cause it to be more weedy than the parent corn line. In field tests conducted in 2000 at multiple sites in Illinois, Iowa and Nebraska, no differences were observed between six hybrids developed from MON 863 and their nontransgenic counterparts which might increase the plants ability to compete or persist as a weed. In addition, no unusual characteristics that would suggest increased weediness were noted in the 31 other trials conducted in multiple U.S. states and territories from 1998-2000. Monsanto performed a growth chamber study to evaluate dormancy and germination characteristics of MON 863 seeds compared to a nontransgenic control and four conventional reference corn hybrids. Several parameters relating to germination and viability were measured under 4 temperature regimes. No biologically significant differences were noted, and in all cases the values for the transgenic seeds were in the range observed for the four reference hybrids.

Monsanto evaluated seeds from MON 863 corn to determine if there was any change in dormancy or germination, as these could indicate a change in weediness (see Petition, Appendix C section 24). No changes were detected. Likewise, no changes in the gross morphology of pollen were observed (see Appendix C, section 25). Changes in pollen morphology might indicate changes in the pollen to travel or cross-pollinate other corn plants.

The introduced trait, coleopteran insect resistance, is not expected to cause MON 863 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. MON 863 corn is still susceptible to other insect pests and diseases of corn (see Petition Section VI A, Tables 9.10, and 11). It is unchanged in its susceptibility to injury by commercially available herbicides.

C. Potential impacts from gene introgression from MON 863 corn into its sexually-compatible relatives.

APHIS evaluated the potential for gene introgression to occur from MON 863 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 with other members of the genus *Zea*, and to a much lesser degree with members of the genus.

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; however, a fairly rare, sparsely dispersed feral population of teosinte has been reported in Florida. 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). Teosinte is described to be susceptible to many of the same pests and diseases which attack cultivated corn (Sánchez and Ruiz, 1997, see discussion).

All teosinte members can be crossed with cultivated corn to produce fertile F_1 hybrids (Doebley, 1990a; Wilkes, 1967). 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). 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 (Kato Y., 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 and 1990b; 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). Gene introgression from MON 863 corn into teosinte would require that varieties be developed, and approved for cultivation in locations where these teosintes are located. Since MON 863 corn does not exhibit characteristics that cause it to be any more weedy than other cultivated corn, its potential impact due to the limited potential for gene introgression into teosinte is not expected to be any different from that of other varieties of cultivated.

The genus *Tripsacum* contains up to 16 recognized species, most of which are native to Mexico, Central and South America, but three of which exist as wild and/or cultivated species in the U.S. Though many of these species occur where corn might be cultivated, gene introgression from MON 863 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. Furthermore, none of the sexually compatible relatives of corn in the U.S. are considered to be weeds in the U.S.

(Holm et al., 1979), therefore, the unlikely acquisition of a single pesticide gene would not be expected to transform them into a weed.

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

Potential impacts on monarch butterflies

A 1999 study by Losey et al. reported that pollen from a certain line of Bt corn was harmful to monarch butterflies when dusted onto milkweed leaves under laboratory conditions at a single concentration. The study was highly limited in its usefulness, as it did not account for the many variables that affect monarch butterfly populations under natural conditions. For example, corn pollen is heavy and does not travel long distances from its source and is diluted as it moves. Within the corn fields, milkweeds are controlled by farmers as a part of their routine weed control practices. The EPA has concluded that the other two most widely planted varieties for corn borer control would not be deposited on milkweed plant with toxic amounts. The risk of a significant impact on monarch populations from Bt corn is therefore very low. This conclusion is consistent with the findings of several scientists which were published as several reports in the Proceedings of the National Academy of Sciences (PNAS) and summarized in an accompanying risk assessment by Sears et al. (2001).

In addition to these considerations, the risk to monarchs is further reduced for MON 863 corn due to the spectrum of activity of the insecticidal protein. The Cry3Bb protein has activity against certain insects in the order coleoptera as opposed to proteins in the Cry1 class which have activity against certain members insects in the order lepidoptera, the taxon which includes moths and butterflies. Even so, Monsanto performed laboratory experiments to determine if monarch butterflies could be affected from corn pollen from MON 863 corn. In these experiments, treatment groups of monarch larvae fed on mikweed leaves dusted with varying pollen concentrations. Larvae were then observed for mortality, development, and weight gain over time. These experiments showed no negative effects from ingestion of MON 863 pollen on survival, development, weight gain, or leaf consumption when compared to either non-Bt pollen or no pollen.

Potential Impact on Other Non-target Species

Like the Cry1 class of insecticidal proteins, the specificity of the Cry3Bb1 insecticidal activity is dependent upon their binding to specific receptors present in the insect mid-gut (Lambert, et al., 1996; Van Rie et al., 1990; Van Rie et al., 1989; Hoffmann et al., 1988a and 1988b; and Wolfersberger et al., 1986). The Cry3Bb1 has activity only against select beetle (Order Coleoptera) species within the family Chrysomelidae, namely CRW and Colorado potato beetle. Monsanto conducted a series of diet bioassays to characterize the insecticidal specificity of Cry3Bb1 (see Petition Section VII B, Table 23). Test species were: Colorado potato beetle, western corn rootworm, cowpea weevil, red flower beetle, cotton boll weevil, pepper weevil, rice weevil, corn earworm, and the European corn borer. These bioassays confirmed the high specificity of Cry3Bb within the order Coleoptera.

Likewise, the Cry3Bb1 protein is not expected to adversely affect most other invertebrates and all vertebrate organisms, including non-target birds, mammals and humans, because they would not be expected to contain the receptor protein found in the midgut of target insects. To evaluate the potential of MON 863 corn to have damaging or toxic effects on representative terrestrial and an aquatic species, APHIS evaluated data from a series of ecological toxicology experiments (see Petition Section VII, E Table 25 and Appendix C, sections 8-23). The test organisms were channel catfish, and several invertebrate beneficial organisms including: cladoceran, collembola, adult and larval ladybeetles of the species, *coleomegilla maculata*, adult ladybeetles of the species *Hippodamia convergens*, adult and larval honeybees, green lacewing larvae, parasitic wasps, and earthworms. These non-target organisms were fed leaf tissue, grain, or pollen containing purified protein from the same variant gene used in MON 863 corn and were also fed an artificial diet containing a recombinant B.T. strain expressing the protein. No adverse effects were observed at the maximum concentrations to which the various test organisms would be exposed from corn.

Monsanto collected data from a field experiment to assess possible effects of growing MON 863 corn on the relative abundance of certain beneficial insects. Results indicated that soil dwelling Aranae (spiders), Carabidae (ground beetle) and foliage dwelling beneficial insects *Coleomegilla maculata* (ladybird beetle), *Orius insidiosus* (minute pirate bug), and *Macrocentrus grandii* (macrocentrus) were at least as abundant in MON 863 plots as in the control plots indicating no impact of introduced genes. For some insects, MON 863 corn appeared to have a lesser impact than did conventional pest management schemes involving chemical insecticides.

The plant selectable *nptII* marker gene and the regulatory elements also do not pose a significant risk to non-target organisms. The *nptII* gene has a long history of safe use and has no known toxicity to non-target organisms. The various regulatory elements are not expressed in the plant, and therefore there is no reason to believe that deleterious effects or significant impacts would result from their use.

Appendix C of this environmental assessment is a summary table in which MON 863 corn is compared to conventional chemical insecticides used to control corn rootworms. The comparison encompasses environmental fate and potential nontarget effects. In general, MON863 compares favorably to these products with respect to the potential for harm in the environment. In addition, Monsanto's studies indicate that Cry3Bb1 protein is readily degraded in simulated gastric fluid and simulated intestinal fluid and is therefore not likely to be an allergen (see petition Appendix C, Section 9). Accordingly, EPA has ruled that there is reasonable certainty of no harm from consumption of the Cry3Bb1 protein and that it is not considered an allergen (66 *FR* 24061-24066, May 11, 2001). For this reason, allergic reactions in nontarget species are considered to be highly unlikely.

Potential Impact on threatened and endangered species
APHIS coordinates review of petitions with other agencies that have regulatory oversight on that same product. With respect to threatened and endangered species, EPA plays a leadership role in the evaluation. EPA is currently evaluating the MON 863 corn for Monsanto's pending application for registration of the new Bt pesticide. EPA has thoroughly examined all threatened and endangered beetles that occur in counties where corn is grown. None of these beetles had corn fields as breeding habitats.

E. Potential impacts on agricultural and cultivation practices

APHIS considered potential impacts associated with the cultivation of rootworm-resistant MON 863 corn on current agricultural practices, in particular, those currently associated with control corn rootworm in corn. The potential impact on organic farming and on minorities and children were also considered.

Impact on current agricultural practices

Monsanto has provided data which indicate that MON 863 corn expresses modified Cry3Bb protein in root tissues to provide control of corn rootworms. The availability of this product is likely to have an impact on current control practices for corn rootworm. Both crop rotation and the use of chemical insecticides are important strategies. Crop rotation has been effective while being environmentally favorable. But chemical control remains an important strategy also for several reasons. One reason is extended diapuase in which some eggs can survive through the non-corn rotation to attack corn in a subsequent season (Ostlie, 1987; Tollefson, 1988; Gray et al., 1998). Extended diapuase has been observed for both the NCRW and the WCRW. Another is that a new strain has developed in central Illinois and northern Indiana that can survive and replicate on soybean, the crop most often rotated with corn in the corn belt (Onstad and Joselyn, 1999; O'Neal et al., 1999). This strain has spread rapidly since it was first observed in 1993 and it is expected to continue to spread throughout the corn belt. And yet another reason is that many growers simply prefer to grow corn continuously, a practice which necessitates higher inputs of chemical insecticides. As a result of these factors and the very damaging nature of the pest, chemical insecticide usage has increased. The most common chemical regime is the application of a granular insecticide at planting, either banded or in-furrow. In some cases sprays are applied for adult suppression. The USDA National Agricultural extension Service (NASS) statistics compiled from 15 top corn producing states in the Midwest indicate that 30% of this acreage were treated with insecticide registered for corn rootworm control. It is difficult to surmise how much of this application was for the corn rootworm control as these insecticides used alone or in combination also control other pests such as black cutworms. A 1995 survey conducted in Iowa, the leading corn producing state which accounts for 17.5% of all U.S. production, indicated that growers used chemicals to control CRW 22 % of the time. The most widely used insecticides are from the organophosphate or synthetic pyrethroid classes of chemistry. It is therefore expected that availability of a practical and economical alternative to chemical insecticides for CRW control would result in a significant reduction in application of such chemicals.

MON 863 corn could be incorporated into current integrated pest management practices as an additional tool for control. Fields are typically scouted for adult CRW in the late summer or early fall. Economic thresholds are then used in making decisions about control strategies for the following spring planting season. MON 863 offers an alternative to organophosphate and pyrethroid insecticide applications in cases where thresholds indicate CRW control is needed and the grower chooses to grow corn. No new or specialized equipment or skills would be needed to use the new technology. Reduced pesticide usage by the growers would carry the accompanied benefits of reduced needs for the manufacture, transport, storage and disposal of hazardous chemicals and containers.

Cry3Bb-resistant populations of previously sensitive insects may eventually develop as a result of feeding on MON 863 corn plants. Monsanto acknowledges this in the petition and is conducting research to identify appropriate insect resistant management strategies (IRM). These strategies will be developed in cooperation with experts in government and from academia. A detailed IRM strategy will be submitted to EPA for approval prior to commercialization of this product. If resistance to Cry3Bb were to develop, it would not alter the effectiveness of current agricultural practices used to control CRW.

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 Cry3Bb* coleopteran resistant; and (c) based on the insect resistance management (IRM) plan, farmers will be educated about recommended management practices. Several transgenic corn lines resistant to lepidopteran insects are already in widespread use by farmers. Transgenic herbicide tolerant varieties are also available. This particular product should not present new and different issues than those with respect to impacts on organic farmers. 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 660 feet is considered to be an adequate minimum separation distance for production of 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
Under 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 data, along with the history of safe use of microbial *Bt* products and other corn varieties expressing *Bt* proteins, establishes the safety of corn line MON 863 and its products to humans, including minorities, low income populations, and children who might be exposed to them through agricultural production and/or processing. Although traditional *Bt* products are regarded as practically non-toxic to humans, they are considered potential skin and eye irritants based on tests in which large doses of spore preparations have been applied to the eyes of rabbits or to human skin (see Appendix C). In contrast, human exposure to *Bt* proteins expressed in transgenic plants is extremely low, since proteins are produced in small quantities and are localized within the plant cells. As a result, neither skin nor eye irritation has been reported from use of previously commercialized transgenic *Bt* corn, and neither is expected from exposure to this product. Accordingly, 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.

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. Given the importance of chemical insecticides in controlling corn rootworm, cultivation of MON 863 might well result in reduced usage of certain toxic chemical insecticides, including those listed in appendix C. If so, this might have a beneficial effect on children and low income populations that might be exposed to the chemicals. These populations might include migrant farm workers and their families, and other rural-dwelling individuals are exposed to pesticides through ground-water contamination or other means of exposure. It is expected that EPA and USDA Economic Research Service would monitor the use of this product to determine impacts on agricultural practices such as chemical use as they have done previously for Bt products protecting against the European Corn Borer.

F. Potential impacts on raw or processed agricultural commodities.

Our analysis of data on agronomic performance, disease and insect susceptibility, and compositional profiles of the kernels indicate no differences between MON 863 and their nontransgenic hybrid counterparts or other standard hybrids. APHIS does not foresee either a direct or indirect plant pest effect on any raw or processed plant commodity.

G. Potential environmental impacts outside the United States associated with a determination of nonregulated status as requested by Monsanto

APHIS has also considered potential environmental impacts including biodiversity outside the United States and its territories associated with a determination of nonregulated status for MON 863 corn. Any international traffic in corn subject to this determination would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC). The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (116 countries as of June, 2001). In addition, issues that may relate to commercialization of particular agricultural commodities produced through biotechnology are being addressed in international forums. APHIS continues to play a role in working toward harmonization of biosafety and biotechnology guidelines and regulations included within the Regional Plant Protection Organization for our region, the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States. NAPPO's Biotechnology Panel advises NAPPO on biotechnology issues as they relate to plant protection. APHIS also participates regularly in biotechnology policy discussions at forums sponsored by the European Union and the Organization for Economic Cooperation and Development. APHIS periodically holds bilateral or quadrilateral discussions on biotechnology regulatory issues with other countries, most often Canada and Mexico and have participated in numerous conferences intended to enhance international cooperation on safety in biotechnology, and sponsored several workshops on safeguards for planned introductions of transgenic crops (crucifers, maize, wheat, potatoes, rice, tomatoes) most of which have included consideration of international biosafety issues.

Alternative C, Approval of the Petition in Part

Approval of some but not all of lines requested in the petition. The petition requested a determination of nonregulated status only for lines derived from the one transformation event, designated as MON 863. Therefore, APHIS can consider only that one line for approval.

Approval of the petition with geographic restrictions. EPA is currently reviewing the application to register MON 863 corn as a plant pesticide. EPA has completed a thorough analysis of risks to non-target organisms and to threatened and endangered species. After examining all threatened and endangered beetles that occur in counties where corn is grown, they have concluded that none of the beetles' breeding habitats are shared with corn. Based on this finding, APHIS finds no reason to place geographic restriction on planting of MON 863 corn.

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Appendix A. USDA Approved Field Tests with Bt *cry3Bb1* Corn Line MON 863 Listed by Notification Number.

98-033-01n
98-040-02n
98-040-04n
98-085-28n
98-098-01n
98-098-02n
98-128-13n
98-216-01n
98-229-02n
98-229-03n
98-229-04n
98-229-05n
98-229-07n
98-229-08n
98-229-09n
98-245-05n
98-247-01n
98-247-02n
98-266-03n
98-288-11n
98-302-01n
99-040-06n
99-040-07n
99-055-06n
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99-091-07n
99-095-13n
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99-112-07n
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99-124-01n
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99-126-08n
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99-133-05n
99-244-08n
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99-244-12n
99-270-03n
99-309-01n
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00-039-04n
00-042-09n
00-053-19n
00-066-08n
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00-082-08n
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00-089-11n
00-095-07n
00-095-09n
00-095-11n
00-095-13n
00-101-06n
00-103-06n
00-112-02n
00-145-01n
00-180-02n
00-214-04n
00-279-03n
00-336-01n
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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 MON 863 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. Table of Products Used or Proposed for Use in Corn Rootworm Control. Cry3Bb1 is expressed in tissues of Monsanto's corn lines.

	Cry3Bbl	Terbufos (Counter®)	Tefluthrin (Force®)	Fipronil (Combat®)
Environmental Fate	The maximum environmental concentration for organisms feeding on corn plants is predicted to be 93 ug/g based on the highest Cry3Bbl.11098 expression level measured in pollen and leaf tissue of MON 863 corn plants. The maximum environmental concentration for soil dwelling organisms is predicted to be 13.3 mg/kg based on the assumption that corn plants are tilled into the top 6" of soil at the time of maximum leaf expression for Cry3Bbl .11098 *(i.e.* 93 ptg/g). (9)	Terbufos hydrolyzes at pH 5, 7, and 9 with a half-life of 2.2 weeks. Formaldehyde was the major degradate detected in this study. Aerobic soil metabolism study indicate that terbufos degrades in silt loam soil with a half-life of 26.7 days. The major degradates detected in this study included carbon dioxide, terbufos sulfoxide, and terbufos sulfone. Terbufos residues have a half-life of less than 40 days in field plots of loam soil treated with a 15 percent granular formulation at an application rate of 1 lb ai/A. The sampling protocol was inadequate to accurately assess the dissipation of terbufos residues in field soil and a new study is required. The available data reviewed by the Agency are not sufficient to fulfill data requirements nor to assess the environmental fate of terbufos. EPA is concerned about the potential for the two degradates, terbufos sulfoxide and sulfone, to leach to groundwater, and the potential for parent terbufos and the sulfoxide and sulfone degradates to runoff to surface water. Terbufos parent degrades rapidly to the sulfoxide and sulfone metabolites, and is considered moderately mobile. Terbufos sulfoxide and sulfone are more mobile and persistent than parent terbufos. The acute DWLOCs calculated for the general U.S. population is 8.1 Fg/L. The chronic DWLOCs calculated for the general U.S. population is 1.7 Fg/L. Maximum acute and chronic estimated environmental concentrations (EECs) for parent terbufos plus the sulfoxide and sulfone degradates exceed the acute and chronic DWLOCs, respectively, in all cases.(2).	Tefluthrin is immobile in soil and, therefore, will not leach into ground water. Additionally, due to the insolubility and lipophilic nature of tefluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential Tefluthrin is immobile in soil and, therefore, will not leach into ground water. Additionally, due to the insolubility and lipophilic nature of tefluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential dietary exposure from drinking water. Plant metabolism studies indicate that tefluthrin per se is not translocated to plants but is degraded in soil to two principal metabolites that are capable of being taken up by plants. EPA has decided that Metabolite VI need not be regulated. Based on tefluthrin not being registered for residential non-food sites, EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern (MOE less than 100), and that there is reasonable certainty that no harm will result from aggregate exposure to tefluthrin residues. (3)	Soil: In lab studies, fipronil has a half-life of 122-128 days in oxygenated sandy loam soil. In field studies, dissipation half-life on soil surfaces ranged from 0.7 to 1.7 months. Half-life of fipronil applied by soil incorporation ranged from 3 to 7.3 months. Residues remain mainly in the upper 12 inches of soil. Fipronil has low soil mobility. It binds to the soil and has little potential for groundwater contamination. Anaerobic metabolism: Fipronil degrades slowly in water and sediment that lack oxygen with a half-life ranging from 116-130 days. Hydrolysis: Fipronil is stable to breakdown by water at mildly acid (lower pH) to neutral pH. It degrades with a half-life of 28 days in basic (higher pH) solutions. Photodegradation: In studies where fipronil was exposed to light, fipronil had a half-life of 3.6 hours in water and 34 days in loamy soil. Half-life is the time required for half of the compound to degrade.(6)

Avian toxicity	Feeding of Cry3Bb-containing grain to Bobwhite quail at 10 and 35% of their diets, respectively, resulted in no adverse effects on growth or survival (9).	Seven incidents to nontarget terrestrial organisms have been reported. Up to three of the incidents had some indication of misuse or misapplication. All the mortalities involved bird species (mostly raptors), with the exception of one incident involving red wolves in North Carolina, which is believed to be the result of an intentional poisoning. Calculated RQs for birds and mammals significantly exceed EPA's risk concern for both granular formulations. (2) Dietary Avian Toxicity: 143 and 157 ppm (from two bobwhite studies). - Avian Reproduction: Terbufos was not considered to produce avian reproductive effects based on results of a bobwhite quail study and a mallard duck study. (1)	Low toxicity to birds (4).	Fipronil has been found to be highly toxic to upland game birds, but is practically non-toxic to waterfowl and other bird species. One of the metabolites of fipronil has a higher toxicity to birds than the parent compound itself (6)
Fish toxicity	Feeding of Cry3Bb-containing grain to channel catfish at 10 and 35% of their diets, respectively, resulted in no adverse effects on growth or survival. (9)	EPA has concerns about risk to nontarget aquatic organisms from parent terbufos and the terbufos sulfoxide and sulfone degradates based on widespread fish kill incidents involving terbufos use on corn with all application methods. These concerns are further supported by standard LOC criteria, which indicate risk concerns to aquatic fish and invertebrates associated with both the clay-based (15% active ingredient) and polymer-based (20% active ingredient) granular formulations using banded applications.(2) Terbufos ranks fourth in pesticide-induced fish kills reported to the Agency, and is the leading cause of fish kills from use on corn. **Freshwater Fish Acute Toxicity**: Ranges from 0.77 to 20.00 ppb. - Freshwater Invertebrate Acute Toxicity: 0.31 ppb for Daphnia magna. - Marine/Estuarine Fish Acute Toxicity: Data gap.- Marine/Estuarine Invertebrate Toxicity: Data gap. Mollusk toxicity: Data gap (2)	Highly toxic to fish (4)	Fipronil is highly toxic to fish and aquatic invertebrates. Its tendency to bind to sediments and its low water solubility may reduce the potential hazard to aquatic wildlife (6)

Nontarget and beneficial organisms	Various "nontarget" organisms were exposed to high doses of leaf tissue, grain or pollen expressing Cry3Bb or to an artificial diet containing the purified protein for varying periods of time. They demonstrate that Cry3Bbl.11098 protein in MON 863 poses no significant risk for harm to nontarget organism populations. In all studies conducted, a NOEC was established and found to equal or exceed predicted maximum environmental concentrations. The potential toxicity of Cry3Bbl.11098 or Cry3Bbl.11231 protein was also evaluated in seven species of beneficial invertebrates: cladoceran, collembola, ladybird beetle, adult and larval honey bees, green lacewing larvae, parasitic wasps and earthworms. No adverse effects were observed at the maximum predicted environmental concentration (9).	Terrestrial Field Study (Level 1): both soil-incorporated (2 lb ai/A) and nonsoil-incorporated (1 lb/A) resulted in nontarget mortalities, with the latter application much more severe in its effects (1,2)	Data not found.	Fipronil is non-toxic to earthworms, soil microorganisms and aquatic plants. Fipronil is moderately toxic to small mammals if ingested (6).
Honeybee toxicity	**Adult Honey Bee:** Cry3Bbl.11231 in an artificial diet NOEC 2 360 ug/ml in diet NOEC > 3X predicted maximum Cry3Bbl concentration in pollen **Larval Honey Bee :** Cry3Bbl.11231 in water NOEC 2 1790 ug/ml in diet NOEC > 10X predicted maximum Cry3Bb I concentration in pollen. (9)	Not described in available studies.	High toxicity to bees (5)	Fipronil is toxic to bees and should not be applied to vegetation when bees are foraging (6).

Mammalian toxicity	**Acute toxicity**: B.t. is practically non-toxic to humans and animals. Humans exposed orally to 1000 mg/day of B.t. showed no effects.. No oral toxicity was found in rats, or mice fed protein crystals from B.t. var. israeliensis. The LD50 is greater than 5000 mg/kg for the B.t. product Javelin in rats and greater than 13,000 mg/kg in rats exposed to the product Thuricide. Single oral dosages of up to 10,000 mg/kg did not produce toxicity in mice, rats, or dogs. The dermal LD50 for a formulated B.t. product in rabbits is 6280 mg/kg. A single dermal application of 7200 mg/kg of B.t. was not toxic to rabbits. B.t. is an eye irritant; 100 grams of formulated product applied in congestion of the iris as well as redness and swelling. **Chronic toxicity**: No complaints were made by 8 men after they were exposed for 7 months. **Dietary administration** of B.t. for 13 weeks to rats at dosages of 8400 mg/kg/day did not produce toxic effects. Some reversible abnormal redness of the skin was observed when 1 mg/kg/day of formulated B.t. product was put on scratched skin for 21 days. No general, systemic poisoning was observed **Reproductive effects**: No indication. **Teratogenic effects**: No evidence. **Mutagenic effects**: There is no evidence of mutagenicity in mammalian species. **Carcinogenic effects**: It is unlikely that B.t. is carcinogenic. (8).	**Acute Oral**: Toxicity Category I (1.6 and 1.3 mg/kg for male and female rats, respectively). - **Acute Dermal**: Toxicity Category I (0.81 and 0.93 mg/kg for male and female rabbits, respectively). - **Acute Inhalation**: Toxicity Category I (< 0.2 mg/L). - **Delayed Neurotoxicity**: No evidence of acute delayed neurotoxicity at the 40 mg/kg dosage level tested in hens. - **Subchronic Feeding**: The NOEL for both systemic effects and cholinesterase inhibition in a rat subchronic study is 0.25 ppm. - **Subchronic Dermal**: The NOEL for systemic effects in a 30-day rabbit study is 0.020 mg/kg. - **Mutagenicity**: Terbufos did not exhibit mutagenic potential in the Ames assay, the in vivo cytogenetic assay, and the dominant lethal test. - **Teratogenicity**: The NOEL for developmental toxicity in a rat teratology study is 0.1 mg/kg/day. - **Reproduction**: The NOEL for reproductive effects in a three-generation rat reproduction study is 0.25 ppm. - **Oncogenicity**: None (1,2)	**Acute toxicity** studies with the technical grade of the active ingredient tefluthrin: oral LD50 in the rat is 21.8 mg/kg for males and 34.6 mg/kg for females; dermal LD50 in the rat is 316 mg/kg in males and 177 mg/kg in females; acute inhalation LC50 in the rat is 0.037 mg/l and 0.049 mg/l in male and female rats, respectively; primary dermal irritation study in the rabbit showed slight irritation; and the acute delayed neurotoxicity study did not show acute delayed neurotoxicity. In an oral toxicity study, the NOEL for female rats is 100 ppm (equivalent to approximately 5 mg/kg/day). The NOEL for skin effects in rats is 1.0 mg/kg). The NOEL for neurological effects (the observed postural effects) may be between 0.025 and 0.1 mg/kg. **Carcinogenicity**: There was no evidence of carcinogenic potential. **Mutagenicity**: There is no mutagenicity concern. **Metabolism**: In both rats and dogs, when given either 1 or 10 mg/kg, most of the radioactivity was found in the feces unchanged and most urinary metabolites were conjugated. In rats, the halflife in the liver is 4.8 days, in the fat is 13.3 days and in the blood is 10.6 days. In a study with rat fat, half of the radioactive residues could be attributed to the parent and the remaining residues consisted of a mixture of fatty acid esters of hydroxylated parent metabolites. **Neurotoxicity**: No acceptable mammalian neurotoxicity studies (3). are available.(3) (((3)	The technical product (96.5% fipronil) has a high order of toxicity with respect to ingestion and inhalation in the rat, but appears to be less toxic via skin absorption. Fipronil may cause mild irritation to the eyes and slight skin irritation. It does not sensitize the skin. Signs of toxicity in rats include reduced feed consumption, anuria (no urination), increased excitability, and seizures. Human toxicity data are not available. The major route of fipronil excretion in rats is via feces. Excretion in the feces ranges from 45-75% of the administered dose, while excretion in urine ranges from 5-25%. Fipronil showed no evidence of causing cancer in mice that were fed large daily amounts in long-term studies. However, there was an increase in thyroid tumors in both sexes of rats in the same type of studies. Human cancer data are not available. Reproduction studies in rats over several generations show that reproductive toxicity occurs at the higher doses tested. Human data on reproductive and developmental toxicity are not available (6).
Nontarget soil organism effects	The maximum environmental concentration for soil dwelling organisms is predicted to be 13.3 mg/kg based on the assumption that corn plants are tilled into the top 6" of soil at the time of maximum leaf expression for Cry3Bbl .11098 (*i.e.* 93 ptg/g). The measured NOECs from these tests exceed the maximum predicted environmental concentration by 3- to 140-fold, demonstrating an adequate margin of safety for these organisms (9).	Not described by present reports.	Not found in these reports	Not described by the present reports.

Toxicity	Class III	Classified by EPA as Toxicity Category I	Toxicity class I for dermal, oral, inhalation exposures, and Class IV for skin irritation.	The technical form of fipronil carries the signal word "Warning.", Toxicity Class II. All formulated or end-use fipronil products in the United States have the signal word "Caution." See The Pesticide Label box (above). Formulated products contain diluted amounts of fipronil (6).
EDF's Integrated Environmental Rankings - Combined human & ecological scores (7)	Not ranked	85-100% where 0 is the lowest and 100 is the highest hazard rating (7).	Data lacking; not ranked by any system in Scorecard.	Data lacking; not ranked by any system in Scorecard.

Source of information:

1. EPA Pesticide Fact Sheet http://pmep.cce.cornell.edu/profiles/insect-mite/propetamphos-zetacyperm/terbufos/insect-prof-terbufos.html
2. Overview of Revised Terbufos Risk Assessment, Office of Pesticide Programs-- US EPA http://www.epa.gov/pesticides/op/terbufos/terbufosview.htm
3. Tefluthrin; Pesticide Tolerance ENVIRONMENTAL PROTECTION AGENCY (40 CFR Part 180) [Federal Register: November 26, 1997 (Volume 62, Number 228) http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30946.htm
4. Farm Chemicals Handbook, p. C374.
5. Ohio State University, Insect Pests of Field Crops Bulletin 545 "Toxicity of Pesticides" http://www.ag.ohio-state.edu/b45/b45_48.html
6. National Pesticide Telecommunications Network Fact Sheets. **http://www.ace.orst.edu/info/nptn/factsheets/fipronil.htm**
7. Environmental Defense Fund Scorecard. http://www.scorecard.org/chemical-profiles/
8. Extoxnet: Extension Toxicology Network, Pesticide Information Profiles **http://ace.ace.orst.edu/info/extoxnet/pips/bacillus.htm**
9. Petition for Determination of Nonregulated Status for the Regulated Article: Corn Rootworm Protected Corn Event MON 853 (2000), Monsanto Company, St. Louis, MO.

Appendix D. Data submitted with the petition in support of nonregulated status for *Bt cry3Bb1* corn line MON 863

Molecular Genetic Characterization and Stability
Southern blot of event MON 853 for analysis of insert number, Fig. 4, pg. 39.
Southern blot of event MON 853 for analysis of copy number, Fig. 5, pg. 41.
Southern blot of event MON 853 for analysis of intactness of the *cry3Bb1* cassette probed with 4-AS1 promoter and associated leader sequence and intron, Fig. 6, pg. 42.
Southern blot of event MON 853 for analysis of intactness of the *cry3Bb1* cassette probed with *cry3Bb1,* Fig. 7, pg. 43.
Southern blot of event MON 853 for analysis of intactness of the *cry3Bb1* cassette probed with tahsp17 3' transcriptional termination sequence, Fig. 8, pg. 44.
Southern blot of event MON 853 for analysis of intactness of the *nptII* cassette probed with 35S promoter Fig. 9, pg. 46.
Southern blot of event MON 853 for analysis of intactness of the *nptII* cassette probed with *nptII* coding region Fig. 10, pg. 47.
Southern blot of event MON 853 for analysis of intactness of the *nptII* cassette probed with NOS 3' termination sequence, Fig. 11, pg. 48.
Southern blot of event MON 853 confirming absence of backbone sequences, Fig. 12, pg. 50.
Summary of molecular characterization findings for event MON 863, Table 5, pg. 51.
Chi square analysis of expected and observed frequencies for the introduced trait indicating stability and predictable Mendelian inheritance in MON 863, Table 6, pg. 54.
Southern blot of event MON 853 showing stability of inserted sequences after 3 generations, Fig. 16, pg. 57.
Reports of unpublished studies supporting regulatory approval of corn rootworm protected corn even MON 863, Appendix C Sections 1-7.
Phenotypic Characterization and Evidence Supporting Absence of Unintended Effects
Measurements of Cry3Bb1 and NPTII protein levels in various tissues collected from multiple filed sites Table 7, pg. 58.
Measurements of Cry3Bb1 protein levels in tissues collected from multiple time points in the 1999 growing season, Table 8, pg. 59.
Listing of diseases observed in disease susceptibility evaluations of MON 863 in multiple U.S. field trials, Table 9, pg. 61.

Listing of insects observed in insect susceptibility evaluations of MON 863 in multiple U.S. field trials, Table 10, pg. 62.
Evaluation of disease and insect susceptibility for MON 863 in Argentina, Table 11, pg. 63
Quantitative comparison of root damage to MON 863 and a control line inflicted by three species of rootworms, fig 17, pg. 65.
Summary of efficacy data collected in 1999 field trials in which MON 863 corn was compared to non-engineered corn treated with FORCE G insecticide and an unprotected control, Table 12, pg. 66.
Agronomic parameters evaluated in MON 863 inbred equivalency trials, Table 13, pg. 68.
Summary of agronomic data collected in inbred evaluations of MON 863 and a near isogenic control, Table 14, pg.69.
Agronomic parameters evaluated in MON 863 hybrid equivalency trials, Table 15, pg. 70.
Summary of MON 863 agronomic equivalency trials conducted using 6 hybrids and isogenic control lines in multiple locations, Tables 16-22, pgs. 71-74.
Comparison of seed dormancy and germination characteristics for MON 863 as compared to nontransgenic corn seed, Table 26, pg 85.
Compositional analysis of grain collected from corn event MON 863, nontransgenic control corn, and commercial corn varieties. Appendix B, p105
Dormancy and germination evaluation of corn rootworm protected corn for an ecological assessment of weediness. Appendix C Section 24.
Morphological assessment of event MON 863 corn pollen. Appendix C Section 25.
Data on environmental consequences of introduction MON 863
Susceptibility of various insect pests to Cry3Bb extracted from recombinant Bt. strain 11231 in laboratory dietary bioassays, Table 23, pg. 79.
Percent of corn acres in the U.S. Corn Belt treated in 1999 with insecticides, Table 24, pg. 80.
Summary of results from ecological toxicity tests with Cry3Bb1 proteins, Table 25, pg. 82.
Reports of unpublished studies supporting regulatory approval of corn rootworm protected corn even MON 863, Appendix C Sections 8-23.

Appendix E. Determination of non-regulated status for MON 863 corn.

In response to a petition (designated 01-137-01p) from the Monsanto company (Monsanto), APHIS has determined that genetically engineered corn line MON 863 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 MON 863 corn and its progeny. Importation of seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR Part 319 and the Federal Seed Act regulations at 7 CFR Part 201. This determination is based on APHIS' analysis of field, greenhouse, and laboratory data and references provided in the petition and other relevant information as described in this environmental assessment that indicate that MON 863 will not pose a plant pest risk for the following reasons. (1) It exhibits no plant pathogenic properties - although a plant pathogen was used in the development of this corn, these plants are not infected by this organism, nor do they contain genetic material from this pathogen that can cause plant disease. (2) It exhibits no characteristics that would cause it to be more weedy than the non-transgenic parent corn line or other cultivated corn. (3) Gene introgression from MON 863 corn to relatives is highly unlikely in the U.S. because the only relatives which occur in the U.S. are *Tripsacum spp.* Hybrids of corn and *Tripsacum* are often sterile or of greatly fertility such that they would not persist. Furthermore, they are not considered weeds and acquisition of a single pest resistance gene would not cause them to become weeds. (4) It has no potential to have a greater damaging, harmful, or toxic effect on organisms beneficial to agriculture than does other cultivated corn. In addition to our finding of no plant pest risk, there will be no affect on threatened or endangered species resulting from a determination of non-regulated status for MON 863 corn and its progeny. (5) It is not expected to have any impact on raw or processed commodities as MON 863 corn will be highly similar to all other commodity corn with respect to processing characteristics.

APHIS acknowledges that there may be new varieties bred from MON 863 corn; however, they are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for corn descended from MON 863 corn, or those observed for other corn varieties not considered regulated articles under 7 CFR Part 340.

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