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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. 96-095-2]

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Monsanto Company's corn line designated as MON 802, which has been genetically engineered for insect resistance and glyphosate herbicide tolerance, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Monsanto Company in its petition for a determination of nonregulated status and an analysis of other scientific data. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: May 27, 1997.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, and the petition may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are requested to call before visiting on (202) 690-2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. James Lackey, BSS, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-8713. 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: mkpeterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On November 12, 1996, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 96-317-01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination that a corn line designated as MON 802, which has been genetically engineered for insect resistance and glyphosate herbicide tolerance, does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On December 18, 1996, APHIS published a notice in the **Federal Register** (61 FR 66650-66651, Docket No. 96-095-1) announcing that the Monsanto petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn line and food products derived from it. In the notice, APHIS solicited written comments from the public as to whether this corn line posed a plant pest risk. The comments were to have been received by APHIS on or before February 18, 1997. APHIS received no comments on the subject petition during the designated 60-day comment period.

Analysis

Corn line MON 802 has been genetically engineered to express a CryIA(b) insect control protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* (Bt). The petitioner stated that the Bt delta-endotoxin protein is effective in protecting the subject corn line from damage caused by the European corn borer throughout the growing season. The subject corn line also expresses the CP4 EPSPS protein isolated from *Agrobacterium* sp. strain CP4 and the GOX protein cloned from *Achromobacter* sp. strain LBAA, which, when introduced into the plant cell, confer tolerance to the herbicide glyphosate. The particle acceleration method was used to transfer the added genes into the parental corn line, and their expression is controlled in part by the intron from the corn *hsp70* gene and by gene sequences from the plant pathogens *Agrobacterium tumefaciens* and cauliflower mosaic virus. The *nptII* selectable marker gene is present in the subject corn line under the control of a bacterial promoter, but is not expressed in the plant.

The subject corn line has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogens. However, evaluation of field data reports from field tests of the corn line conducted under APHIS notifications since 1993 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of corn line MON 802.

Determination

Based on its analysis of the data submitted by Monsanto, a review of other scientific data, and field tests of the subject corn line, APHIS has determined that corn line MON 802: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than corn lines developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture; and (6) should not reduce the ability to control insects in corn or other crops when cultivated. Therefore, APHIS has concluded that the subject corn line 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 are not subject to regulation under 7 CFR part 340.

The effect of this determination is that Monsanto's corn line MON 802 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 field testing, importation, or interstate movement of the subject corn line or its progeny. However, importation of corn line MON 802 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 environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (NEPA)(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 Monsanto's corn line MON 802 and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Done in Washington, DC, this 30th day of May 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–14876 Filed 6–5–97; 8:45 am]

BILLING CODE 3410–34–P

USDA/APHIS Petition 96-317-01p for Determination of Nonregulated Status
for Insect-Resistant/Glyphosate-Tolerant Corn Line MON 802

Environmental Assessment and
Finding of No Significant Impact

May 1997

The Animal and Plant Health Inspection Service (APHIS) of the U. S. Department of Agriculture has prepared an environmental assessment before issuing a determination of nonregulated status for a genetically engineered corn line called MON 802 corn. APHIS received a petition from the Monsanto Company regarding the status of MON 802 corn as a regulated article under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition, supporting documentation, and other relevant scientific information. Based upon the analysis documented in this environmental assessment, APHIS has reached a finding of no significant impact on the environment from its determination that insect resistant/glyphosate tolerant MON 802 corn shall no longer be a regulated article.

John H. Payne, Ph.D.
Director
Biotechnology and Scientific Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: MAY 2 7 1997

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

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

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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) before deciding on the regulatory status of a genetically engineered line of insect resistant/glyphosate tolerant corn designated hereafter as MON 802 corn. The developer of MON 802 corn, the Monsanto Company (Monsanto), petitioned APHIS requesting a determination on the regulated status of MON 802 corn. This corn line is currently a regulated article under USDA regulations. Interstate movements, importations, and field tests of MON 802 corn have been conducted under permits issued or notifications acknowledged by APHIS. Monsanto has petitioned APHIS for a determination that MON 802 corn does not present a plant pest risk and should therefore no longer be a regulated article under the APHIS regulations found at 7 CFR Part 340.

MON 802 corn has been developed in an effort to protect corn plants against the feeding damage of European corn borer (*Ostrinia nubilalis* (Hubner)) larvae, and to make corn tolerant to applications of the herbicide glyphosate.

MON 802 corn is genetically modified to contain four different genes, three of which are expressed in the plant: (1) the *cryIA(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki (B.t.k.)*, which encodes an insecticidal protein; (2) the *CP4 EPSPS* gene derived from *Agrobacterium* sp. strain CP4 which encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme highly tolerant to inhibition by glyphosate and with high catalytic activity; (3) the *gox* gene from *Achromobacter* sp., which encodes the enzyme glyphosate oxidoreductase (GOX); and (4) the *nptII* gene, which encodes for neomycin phosphotransferase II. The *nptII* gene confers resistance to the antibiotics kanamycin and neomycin. It is not expressed in the transformed corn plants.

This petition is similar to the previous Monsanto petitions 95-093-01p, approved on August 22, 1995, and 96-017-01p, approved March 15, 1996. These previous petitions also involve *cryIA(b)*, *CP4 EPSPS*, and *gox*; however, in these previous petitions, the plasmid vectors are slightly different, and the glyphosate tolerance is only used as a selectable marker.

MON 802 corn has previously been field tested under permit and notification. All field trials were performed under conditions of reproductive confinement. This EA addresses issues that are of relevance to the unconfined planting of MON 802 corn, and APHIS concludes the following:

1. MON 802 corn exhibits no plant pathogenic properties. Although DNA from pathogenic organisms were used in their development, these corn plants are not infected by these organisms nor can these plants incite disease in other plants.

2. MON 802 corn is no more likely to become a weed than corn which has been developed by traditional breeding techniques. Corn is not a weed in the U.S., and there is no reason to believe that the introduced genes would enable corn to become a weed pest.

3. Multiple factors ensure that gene introgression from MON 802 corn into wild plants in the United States and its territories is extremely unlikely. Even in other regions, potential gene introgression from MON 802 corn into wild relatives is not likely to increase the weediness potential of any resulting progeny nor adversely effect genetic diversity of related plants any more than would introgression from traditional corn hybrids.

4. MON 802 corn is substantially equivalent in composition, quality and other characteristics to nontransgenic corn and should have no adverse impact on raw or processed agricultural commodities.

5. MON 802 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture, or other nontarget organisms, and will not affect threatened or endangered species.

6. Cultivation of MON 802 corn should not reduce the ability to control insects in corn or other crops.

Therefore, after a review of the available evidence, APHIS believes that MON 802 corn will be just as safe to grow as traditionally-bred corn varieties not subject to regulation under 7 CFR Part 340. APHIS concludes that there will be no significant impact on the human environment if MON 802 corn and its progeny were no longer considered a regulated article under 7 CFR Part 340.

II. BACKGROUND

Development of MON 802 corn. Monsanto has submitted a "Petition for Determination of Non-regulated Status" to the USDA, APHIS for genetically engineered corn plants that are resistant against the feeding damage caused by the larvae of the European corn borer (ECB) and tolerant to applications of the herbicide glyphosate. Monsanto requested a determination from APHIS that MON 802 corn, and any progeny derived from crosses between this line and other nonregulated corn varieties, no longer be considered a regulated article under 7 CFR Part 340.

ECB damage to corn plants results in stalk lodging, dropped ears, and damaged grain. *B. thuringiensis* subsp. *kurstaki* (*B.t.k.*) bacteria produce a group of related toxins (delta-endotoxins) that when ingested by susceptible lepidopteran insects result in their death. These toxins are produced as crystalline inclusions during bacterial

spore formation. Preparations of *B. thuringiensis* containing delta-endotoxin are used as foliar applied biopesticides. However, they are not routinely effective against ECB because the insect feeds inside the plants where the foliar applied biopesticide cannot reach. Monsanto has modified the corn plant to produce a specific delta-endotoxin protein which is identical to the insecticidally active, trypsin-resistant core of CryIA(b) protein that is naturally encoded by the gene *cryIA(b)* derived from *B.t.k.* Field testing has demonstrated that MON 802 corn plants are significantly protected from ECB feeding damage throughout the season. The *cryIA(b)* gene was transferred on a plasmid vector designated by Monsanto as PV-ZMBK15.

The herbicide glyphosate kills plant cells by inhibition of the enzyme EPSPS. Glyphosate tolerance can be conferred by either overproduction of EPSPS or expression of glyphosate-tolerant EPSPS or glyphosate oxidase in plants. MON 802 corn has been transformed with the *CP4 EPSPS* gene derived from *Agrobacterium* sp. strain CP4 which encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme highly tolerant to inhibition by glyphosate and with high catalytic activity. MON 802 corn has also been transformed with the *gox* gene from *Achromobacter* sp., which encodes the enzyme glyphosate oxidoreductase (GOX). This enzyme degrades glyphosate. These two enzymes allow MON 802 corn to be protected against herbicide damage when glyphosate is used for weed control in the crop. The gene *CP4 EPSPS* was transferred on plasmid vector PV-ZMBK15, along with the *cryIA(b)* gene. The *gox* gene was transferred on a second plasmid vector, PV-ZMGT03.

MON 802 corn has been field tested since 1993 in the major corn growing regions of the United States and Puerto Rico under notifications acknowledged by APHIS. This line has been evaluated extensively to confirm that it exhibits the desired agronomic characteristics and does not pose a plant pest risk. Although the field tests of MON 802 corn have been conducted in agricultural settings, the acknowledgment of notifications for the tests have stipulated physical and reproductive confinement from other sexually compatible plants.

APHIS Regulatory Authority. APHIS regulations under 7 CFR Part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act, (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act, (7 U.S.C. 151-164a, 166-167) as amended, 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 802 corn described in the Monsanto petition 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 Process 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.

Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Regulatory Authority. MON 802 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 be registered before distribution or sale, unless exempt by EPA regulation. Accordingly, Monsanto has submitted to EPA an application to register the product corn borer-resistant corn containing insecticidal Bt protein which contains the plant pesticide active ingredient Cry IA(b) delta endotoxin and the genetic material necessary for its production in corn. 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. Monsanto has also received registration from EPA (EPA Reg. No. 524-445) for glyphosate use over-the-top on glyphosate tolerant corn.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq.*) as amended by the Food Quality Protection Act of 1996 (P.L. 104-179), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA; and the FDA enforces the tolerances set by the EPA. On August 2, 1996 (61 *FR* 40338), EPA granted a tolerance exemption for CryIA(b) and CP4 EPSPS. A tolerance exemption for GOX is currently under review by EPA.

The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992, and appears at 57 *FR* 22984-23005. Consultation with the FDA on corn line MON 802 has been completed (see petition p. 14).

III. PURPOSE AND NEED

APHIS has prepared this EA before making a determination on the status of MON 802 corn as a regulated article under APHIS regulations. The developer of MON 802 corn, Monsanto Company, submitted a petition to

APHIS requesting that APHIS make a determination that MON 802 corn no longer be considered a regulated article under 7 CFR Part 340.

This EA was prepared in compliance with the National Environmental Policy Act of 1969, as amended (NEPA), (42 USC 4321 *et seq.*) and the pursuant implementing regulations (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372).

IV. ALTERNATIVES

A. No Action.

Under the Federal "no action" alternative, APHIS would not come to a determination that MON 802 corn is no longer a regulated article under the regulations at 7 CFR Part 340. Permits or acknowledgement of notifications from APHIS would still be required for introductions of MON 802 corn. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of MON 802 corn.

B. Determination that MON 802 corn is no longer a regulated article.

Under this alternative, MON 802 corn would no longer be a regulated article under the regulations at 7 CFR Part 340. Permits or acknowledgment of notifications from APHIS would no longer be required for introductions of MON 802 corn. A basis for this determination would include a "Finding of No Significant Impact" under the National Environmental Policy Act of 1969, as amended (42 USC 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372).

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

This EA addresses potential environmental impacts from a determination that MON 802 corn should no longer be considered a regulated article under APHIS regulations at 7 CFR Part 340. This EA considers the genotypic and phenotypic characteristics of MON 802 corn, and the potential environmental impacts that might be associated with the unconfined cultivation of MON 802 corn, i.e., cultivation without intentional physical and reproductive confinement from other sexually compatible plants.

Additional technical information is included in the determination document appended to this EA, and incorporated by reference. This includes detailed discussions of the biology of corn, the genetic components used in the construction of MON 802 corn, and the analyses that lead APHIS to conclude that MON 802 corn has no potential to pose a plant pest risk.

A. Potential impacts based on increased weediness of MON 802 corn relative to traditionally bred corn.

Although various definitions of the term "weed" have been proposed in the scientific literature, the salient point is that a plant can be considered a weed when it is growing where humans do not want it (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). Baker (1965) lists 12 common attributes that can be used to assess the likelihood that a plant species will behave as a weed. Keeler (1989) and Tiedje et al. (1989) have analyzed and adapted Baker's list to develop admittedly imperfect guides to the weediness potential of transgenic plants; both authors emphasize the importance of looking at the parent plant and the nature of the specific genetic changes.

Cultivated corn is not considered a weed and is unlikely to become a weed. Corn is a highly inbred, well-characterized plant that is not 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 (e.g., it does not propagate vegetatively; it does not compete well with other plant species in the environment; it is not an invasive, colonizing species; and it does not have special adaptions for dispersal).

Furthermore, corn has been grown throughout the world without any report that it is a serious weed. 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).

The parent plant of the MON 802 corn is an agricultural crop plant that exhibits no significant weedy characteristics. The introduced genetic constructs and new traits, i.e., lepidopteran insect resistance conferred by the *cryIA(b)* gene and tolerance to glyphosate herbicide conferred by the *CP4 EPSPS* and *gox* genes, are not expected to cause MON 802 corn to become a weed. In the United States, corn that is grown in rotation with soybeans may volunteer on occasion. Volunteers of line MON 802 can be controlled using physical methods or with the use of other herbicides that are not based on glyphosate and which are registered for use on the crop, as appropriate.

APHIS considered data and observations provided in the petition on the agronomic performance and disease and insect susceptibility of MON 802 lines evaluated in field tests conducted from 1993 to 1996 in twenty U.S. states and Puerto Rico. The MON 802 corn has retained the agronomic characteristics of the parental corn. The transgenic line provided significant protection from damage from the European corn borer (*Ostrinia nubilalis*). Some protection from Southwestern corn borer (*Diatraea grandiosella*) and corn earworm (*Heliothis zea*) was noted. No significant differences were observed in resistance to a number of other significant insect pests or diseases compared to nontransgenic controls. Field data reports and data on agronomic

traits do not indicate that MON 802 lines exhibit agronomic traits which would cause them to pose a greater threat as weeds than conventional hybrid corn lines.

B. Potential impacts on the sexually-compatible relatives of corn arising from pollination by MON 802 corn: Biodiversity.

The species *Zea mays* is native to Mexico and Central America. Researchers believe that the domestication of *Z. mays* was centered in a region of Mexico near Mexico City (Galiant, 1988). Zea is a genus of the family Poaceae or Gramineae (the grass family) that contains four described species: *Z. mays*, cultivated corn and teosinte; *Z. diploperennis*, diploperennial teosinte; *Z. luxurians*; and *Z. perennis*, a perennial teosinte. Annual teosinte and corn are genetically compatible, and in areas of Mexico and Guatemala where they coexist they have been reported to produce hybrids. Indeed, corn was derived from teosinte (*Zea mays* subsp. *mexicana*) probably more than 8,000 years ago. Cultivated corn and wild diploid and tetraploid members of *Zea* can be crossed to produce fertile F_1 hybrids. Currently, however, introgressive hybridization in the wild is limited, in part, by several factors including differences in flowering time, block inheritance, developmental morphology and timing of the reproductive structures, dissemination, and dormancy (Galinat, 1988), though research suggests introgression has occurred in the past (Doebley, 1990; Giddings et al., 1990). First-generation hybrids show substantially reduced reproductive capacity which acts as a significant constraint on introgression. Seed from the F_1 hybrids does not disseminate well, and the F_1 hybrids do not produce seed of a quality that farmers find particularly useful for either human or animal consumption. Therefore, in spite of occasional gene flow over historical time, maize and teosinte have maintained separate identities in Mesoamerica for thousands of years, with modern corn being entirely dependent on human intervention for its persistence. During the transformation of cultivated corn from teosinte, corn gained several valuable agronomic traits, but lost the ability to survive in the wild. Furthermore, although corn can produce hybrids with teosinte, teosinte is not present in the U. S. Corn Belt where the risk of introgression is thus zero.

The closest relative to *Zea* is *Tripsacum*, a genus of seven species, three of which occur in the United States (Gould, 1968). *Tripsacum* differs from *Zea* in many respects, including chromosome number (N=9 for *Tripsacum*, N=10 for *Zea*). All species of *Tripsacum* can cross with *Zea*, but only with difficulty, and the resulting hybrids are often sterile (Galinat 1988).

Our analysis of the biology of cultivated lepidopteran insect-resistant or herbicide tolerant corn and its relatives leads us to predict that the environmental impacts of cultivation of MON 802 corn would be no different from such impacts attributable to similar varieties produced by traditional breeding techniques. Non-cultivated varieties of *Zea* sp. have coexisted and co-evolved in the Americas

over millennia. Even if MON 802 corn were to be cultivated in agricultural regions around centers of *Zea* diversity, there is no reason to expect impacts from MON 802 corn to be significantly different from those arising from the cultivation of any other variety of insect resistant or herbicide tolerant corn.

International traffic of MON 802 corn would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC). The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (105 countries as of October 1996). The treaty, administered by a Secretariat housed with the United Nations Food and Agriculture Organization in Rome, came into force on April 3, 1952. It establishes standards to facilitate the safe movement of plant materials across international boundaries. The IPPC has also led to the creation of Regional Plant Protection Organizations such as the North American Plant Protection Organization (NAPPO). Trading partners of the United States will be kept informed of USDA regulatory decisions through NAPPO and other fora. Mexico possesses many wild *Zea* populations and thus may be concerned with the potential for introgression of genes from domesticated *Zea mays* into these wild populations where such genes may reasonably be expected to have a negative impact. However, Mexico regulatory process requires a full evaluation of transgenic plants before they can be introduced into their environment.

It should be noted that all the existing national and international regulatory authorities and phytosanitary protocols that currently apply to introductions of new corn varieties internationally will apply to MON 802 corn.

C. Potential impacts on nontarget organisms, including beneficial organisms such as bees and earthworms, and threatened or endangered organisms.

Consistent with its statutory authority and requirements under NEPA, APHIS evaluated the potential for MON 802 corn plants and plant products to have damaging or toxic effects directly or indirectly on nontarget organisms. This includes those that are recognized as beneficial to agriculture and to those that are recognized as threatened or endangered in the United States. APHIS also considered potential impacts on other "nontarget" pests (pests other than lepidopteran insects that feed on corn), since such impacts could have an impact on the potential for changes in agricultural practices. Field data reports submitted by Monsanto indicate that no differences were observed for the control of insects other than certain lepidopteran pests. The impact of such effects on agricultural practices will be discussed in the subsequent section.

There is no reason to believe that deleterious effects or significant impacts on nontarget organisms, including beneficial organisms, would

result from the *CP4 EPSPS* or *gox* genes introduced into corn line MON 802. The enzymes encoded by these genes have no known insecticidal activity.

1) Potential impact on beneficial and other nontarget organisms.

Data provided with the petition and the scientific literature indicate that MON 802 corn and the CryIA(b) protein, in particular, should not have a significant potential to harm organisms beneficial to agricultural ecosystems.

Most of the *B. thuringiensis* subspecies *kurstaki* insecticidal protein toxins, including CryIA(b), have been shown to be very selective for lepidopteran insects (MacInstosh et al., 1990; Aronson et al., 1986; Whitely and Schnepf, 1986; Klausner, 1984: Dulmage, 1981). They bind specifically to the mid-gut of lepidopteran insects (Van Rie et al., 1990; Van Rie et al., 1989; Hofmann et al., 1988a and 1988b: and Wolfersberger et al., 1986). As such, they are not expected to adversely effect 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. These organisms are also not expected to be affected by the *CP4 EPSPS* or *gox* genes.

2) Potential impact on threatened and endangered arthropods

No endangered or threatened lepidopteran insect, as listed in 50 CFR 17.11 and 17.12, feeds on corn plants.

APHIS concludes that MON 802 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture or other nontarget organisms, and will not affect threatened or endangered species.

D. Potential impacts on agricultural and cultivation practices.

No direct plant pest effects on agricultural and cultivation practices are expected as the result of the use of the MON 802 corn and its progeny. Indirect plant pest effects on agricultural practices such as the potential development of insect populations resistant to CryIA(b) protein are addressed by the EPA during the registration of the plant pesticide.

E. MON 802 corn will not cause damage to raw or processed agricultural commodities.

It is APHIS opinion that characteristics of MON 802 corn reveal no difference in any component that could have an indirect plant pest effect on any agricultural commodity.

VI. CONCLUSION

APHIS has evaluated information from the scientific literature as well as data submitted by Monsanto that characterized MON 802 corn. After careful analysis, APHIS has identified no significant impact to the environment from a determination that MON 802 corn should no longer be a regulated article under APHIS regulations at 7 CFR Part 340. That finding is supported by the following conclusions:

1. MON 802 corn exhibits no plant pathogenic properties. Although DNA from pathogenic organisms were used in their development, these corn plants are not infected by these organisms nor can these plants incite disease in other plants.

2. MON 802 corn is no more likely to become a weed than corn which has been developed by traditional breeding techniques. Corn is not a weed, and there is no reason to believe that the introduced genes would enable corn to become a weed pest.

3. Multiple factors ensure that introgression from MON 802 corn into wild plants in the United States and its territories is extremely unlikely. Potential introgression from MON 802 corn into wild relatives is not likely to increase the weediness potential of any resulting progeny nor adversely effect genetic diversity of related plants any more than would introgression from traditional corn hybrids.

4. MON 802 corn is substantially equivalent in composition, quality and other characteristics to nontransgenic corn and should have no adverse impact on raw or processed agricultural commodities.

5. MON 802 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture, or other nontarget organisms, and will not affect threatened or endangered species.

6. Cultivation of MON 802 corn should not reduce the ability to control insects in corn or other crops.

Therefore, APHIS concludes that MON 802 corn will be just as safe to grow as nontransgenic corn that are not subject to regulation under 7 CFR Part 340, and that there should be no significant impact on the human environment if MON 802 corn were no longer a considered a regulated article under its regulations (7 CFR Part 340).

VII. LITERATURE CITED

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Determination of Nonregulated Status for Insect-Resistant/Glyphosate-Tolerant Corn Line MON 802

Petitioner: Monsanto Company
Petition Number: 96-317-01p

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology and Scientific Services
Riverdale, Maryland

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I. SUMMARY

APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act (FPPA), (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act (PQA), (7 U.S.C. 151-164a, 166-167) as amended, regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is no longer subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. 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.

On November 12, 1996, the Animal and Plant Health Inspection Service (APHIS) received a petition from the Monsanto Company requesting a determination that insect resistant/glyphosate tolerant corn line MON 802 (hereafter referred to as MON 802 corn) does not pose a plant pest risk and therefore, should no longer be considered a regulated article. On December 18, 1996, APHIS announced receipt of the petition in the *Federal Register* (61 *FR* 66650-66651) and stated that the petition was available for public review. APHIS invited written comments on this proposed action, to be submitted on or before February 18, 1997. Based on a review of scientific data and literature, APHIS has determined that MON 802 corn does not present a plant pest risk and is therefore no longer a regulated article under the regulations found at 7 CFR Part 340. As a result of this determination, oversight by APHIS under 7 CFR Part 340 will no longer be required for field testing, importation, or interstate movement of MON 802 corn or its progeny.

This determination has been made based on an analysis that revealed that MON 802 corn plants: 1) exhibit no plant pathogenic properties, 2) are no more likely to become a weed than corn developed by traditional breeding, 3) are unlikely to increase the weediness potential of any other plant with which they can interbreed, 4) are not likely to cause damage to processed agricultural commodities, 5) are unlikely to harm threatened or endangered species and organisms that are beneficial to agriculture, and 6) are unlikely to reduce the ability to control insect pests in corn and other crops. APHIS has also concluded that there is no reason to believe that new corn varieties derived from MON 802 corn progeny will exhibit new plant pest properties; i.e., properties substantially different from any observed for the corn line MON 802 already field tested, or those observed for corn in traditional breeding programs.

MON 802 corn has been developed in an effort to protect corn plants against the feeding damage of European corn borer (*Ostrinia nubilalis* (Hubner)) larvae, and to make corn tolerant to applications of the herbicide glyphosate.

MON 802 corn is genetically modified to contain four different genes, three of which are expressed in the plant: (1) the *cryIA(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki (B.t.k.)*, which encodes an insecticidal protein; (2) the *CP4 EPSPS* gene derived from *Agrobacterium* sp. strain CP4 which encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme highly tolerant to inhibition by glyphosate and with high catalytic activity; (3) the *gox* gene from *Achromobacter* sp., which encodes the enzyme glyphosate oxidoreductase (GOX); and (4) the *nptII* gene, which encodes for neomycin phosphotransferase II. The *nptII* gene confers resistance to the antibiotics kanamycin and neomycin. It is not expressed in the transformed corn plants. The genes were introduced into corn via particle bombardment, a technique that results in direct incorporation of genes into the plant genome. The first three genes above also have accompanying DNA regulatory sequences that modulate their expression in the corn plants. The DNA regulatory sequences were derived from corn and the plant pathogens cauliflower mosaic virus (CaMV) and *Agrobacterium tumefaciens*.

The potential environmental impacts associated with this determination have been examined in accordance with regulations implementing the National Environmental Policy Act, as amended of 1969, (42 U.S.C. 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372). An environmental assessment (EA) was prepared and a Finding of No Significant Impact (FONSI) was reached by APHIS for the determination that MON 802 corn is no longer a regulated article under its regulations at 7 CFR Part 340. This decision does not release MON 802 corn from regulations administered by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (P.L. 104-179), (21 U.S.C. 301 *et seq.*).

The body of this document consists of three parts: (1) background information that provides the legal framework under which APHIS has regulated the field testing, interstate movement, and importation of insect-resistant corn; (2) a summary of, and response to, comments provided to APHIS on its proposed action during the public comment period; and (3) analysis of the key factors relevant to APHIS decision that insect-resistant/glyphosate tolerant corn line MON 802 does not present a plant pest risk.

II. BACKGROUND

A. APHIS Regulatory Authority

APHIS regulations at 7 CFR 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act (FPPA), (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act (PQA), (7 U.S.C. 151-164a, 166-167) as amended, regulate the introduction (importation,

interstate movement, or release into the environment) of certain genetically engineered organisms and products. Under these regulations, a genetically engineered organism is deemed a regulated article if either 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 APHIS has reason to believe that the genetically engineered organism presents a plant pest risk. The FPPA gives the U.S. Department of Agriculture (USDA) the authority to regulate plant pests and other articles to prevent direct or indirect injury, disease, or damage to plants and plant products. In addition, the PQA provides an additional level of protection by enabling USDA to regulate the importation and movement of nursery stock and other plants that may harbor injurious pests.

Before the introduction of a regulated article, a person is required under § 340.0 of the regulations to either (1) notify APHIS in accordance with § 340.3 or (2) obtain a permit in accordance with § 340.4. Introduction under notification (§ 340.3) requires that the introduction meets specified eligibility criteria and performance standards. The eligibility criteria impose limitations on the types of genetic modifications that qualify for notification, and the performance standards impose limitations on how the introduction may be conducted. Under § 340.4, a permit is granted for a field trial when APHIS has determined that the conduct of the field trial, under the conditions specified by the applicant or stipulated by APHIS, does not pose a plant pest risk.

An organism is not subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. 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 the agency determines that the regulated article does not present a risk of introduction or dissemination of a plant pest, the petition will be granted, thereby allowing for unregulated introduction of the article in question. A petition may be granted in whole or in part.

The MON 802 corn has been considered a "regulated article" for field testing under Part 340 of the regulations in part because certain noncoding regulatory sequences were derived from CaMV and *A. tumefaciens*, known plant pests. APHIS believes it prudent to provide assurance before commercialization that organisms such as MON 802 corn, which are derived at least in part from plant pests, do not pose any potential plant pest risk. Such assurance may aid the entry of new plant varieties into commerce or into breeding and development programs. The decision by APHIS that MON 802 corn is no longer a regulated article is based in part on evidence provided by Monsanto concerning the biological properties of MON 802 corn and their

similarity to other varieties of corn grown using standard agricultural practices for commercial sale or private use.

The fact that APHIS regulates genetically engineered organisms having plant pest components does not carry with it the presumption that the presence of part of a plant pest makes a whole plant a pest or that the plants or genes are pathogenic (McCammon and Medley, 1990). The approach by APHIS to plant pest risk is considerably broader than a narrow definition that encompasses only plant pathogens. Other traits, such as increased weediness, and harmful effects on beneficial organisms, such as earthworms and bees, are clearly subsumed within what is meant by direct or indirect plant pest risk. In APHIS regulations at 7 CFR Part 340, a "plant pest" is defined as: "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."

A determination that such corn plants do not present a plant pest risk can be made under this definition, especially when there is evidence that the plants under consideration: 1) exhibit no plant pathogenic properties; 2) are no more likely to become a weed than corn developed by traditional breeding; 3) are unlikely to increase the weediness potential of any other cultivated plant; 4) are not likely to cause damage to processed agricultural commodities; 5) are unlikely to harm organisms that are beneficial to agriculture or threatened and endangered species, or to adversely impact the ability to control nontarget insect pests; and 6) are unlikely to reduce the ability to control insects in corn and other crops. Evidence has been presented by Monsanto that bears on these topics. In addition, it should be established that there is no reason to believe that any new corn varieties bred from MON 802 corn will exhibit plant pest properties substantially different from any observed for corn in traditional breeding programs, or as seen in the development of MON 802 corn already field tested.

B. EPA and FDA Regulatory Authority

The corn line MON 802 is currently subject to regulations administered by the EPA and the FDA (described in Section II. C. of the Environmental Assessment) that require registration of pesticides prior to their distribution and sale and establish tolerances for pesticide residues in raw agricultural products. The APHIS decision on the regulatory status of the MON 802 corn under APHIS regulations at 7 CFR 340, in no way releases this corn and its progeny from EPA and FDA regulatory oversight.

III. COMMENTS

APHIS received no comments on this petition.

IV. ANALYSIS OF THE PROPERTIES OF MON 802 CORN

A brief discussion of corn biology follows in the next paragraph to help inform the subsequent analysis. This information is expanded in subsequent sections when it is relevant in addressing particular risk assessment issues.

Zea mays Linnaeus, known as maize throughout most of the world, and as corn in the United States, is a large, annual, monoecious grass, that is grown for human consumption, animal feed, silage, vegetable oil, sugar syrups, and other miscellaneous uses. Corn is grown commercially throughout the United States (Jewell, 1989). Corn has been cultivated since the earliest historic times from Peru to central North America. The origin is presumed to be Mexico (Gould, 1968). *Zea* is a genus of the family Gramineae or Poaceae (the grass family) containing four described species: *Z. mays*, cultivated corn and teosinte; *Z. diploperennis*, diploperennial teosinte; *Z. luxurians*; and *Z. perennis*, a perennial teosinte. Annual teosinte and corn are genetically compatible, and in areas of Mexico and Guatemala where they coexist, they have been reported to produce hybrids. Indeed, corn was derived from teosinte (*Zea mays* subsp. *mexicana*), probably more than 8,000 years ago. During the transformation process of teosinte to cultivated corn, the latter gained several valuable agronomic traits that were not expressed in teosinte, but it lost the ability to survive in the wild. Cultivated corn and wild diploid and tetraploid members of *Zea* can be crossed to produce fertile F_1 hybrids. Nonetheless, in the wild, introgressive hybridization currently is limited, in part, by several factors including differences in flowering time, block inheritance, developmental morphology and timing of the reproductive structures, dissemination, and dormancy (Galinat, 1988), although research suggests introgression has occurred in the past (Doebley, 1990; Giddings et al., 1990). First-generation hybrids are less fit and show substantially reduced reproductive capacity which acts as a significant constraint on introgression. Seed from the F_1 hybrids does not disseminate well, and they do not produce seed of a quality that farmers find particularly useful for either human or animal consumption. Therefore, in spite of occasional gene flow over historical time, maize and teosinte have maintained separate identities in Mesoamerica for thousands of years, with modern corn being entirely dependent on human intervention for its persistence. Although corn easily crosses with teosinte, teosinte is not present in the U. S. Corn Belt.

The closest generic relative to *Zea* is *Tripsacum*, a genus of seven species, three of which occur in the United States (Gould, 1968). *Tripsacum* differs from corn in many respects, including chromosome

Expression of the insect control protein and glyphosate tolerance enzymes in the MON 802 corn will not likely provide a competitive advantage sufficient to cause these to be any more "weedy" than other corn cultivars. Field data and other data submitted with the petition indicate that MON 802 corn exhibited good control of European corn borer and had some effect on Southwestern corn borer and corn earworm. 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 insects provided by this new corn line would release it from any constraint that would result in increased weediness.

The *CP4 EPSPS* and *gox* genes provide tolerance to glyphosate. Glyphosate is a broad range herbicide that is highly effective against the majority of annual and perennial grasses and broad-leaved weeds. The use of MON 802 corn would enable farmers to use glyphosate for effective control of weeds during the growing season. Use of MON 802 corn would also preclude the use of glyphosate in control of any volunteer corn in subsequent seasons. In the United States, corn that is grown in rotation with soybeans may volunteer on occasion. Volunteers of line MON 802 can be controlled using physical methods or with the use of other herbicides and which are registered for use on the crop, as appropriate. Corn is not known as a persistent weed or a plant that forms feral populations in the United States.

Because the *nptII* genes introduced into corn line MON 802 are not expressed in the plant, they are not expected to contribute to the plant phenotype, including the ability to become a weed.

APHIS considered data and observations provided in the petition on the agronomic performance and disease and insect susceptibility of MON 802 in field tests conducted from 1993 to 1996 in twenty U.S. states and Puerto Rico. Field data reports do not indicate that MON 802 lines exhibit traits which would cause them to pose any greater threat as weeds than conventional hybrid corn lines.

Based on this analysis, APHIS concludes that, with the exception of resistance to certain lepidopteran insects and tolerance to glyphosate herbicide, MON 802 corn has agronomic traits similar to those of traditionally bred corn, and it does not exhibit traits that would cause increased weediness.

C. Gene introgression from MON 802 corn into cultivated corn or its sexually compatible relatives should not increase the weediness potential of resulting progeny or impact genetic diversity any more than gene introgression from other traditional corn hybrids.

APHIS evaluated the potential for gene flow from MON 802 corn to other cultivated corn and wild relatives. Then two potential impacts that might result from this sexual transfer of genes were evaluated: first, that the traits from MON 802 corn might cause free-living relatives to

become "weedier", and second, that the transfer of genes might cause population changes that would lead to reduced genetic diversity.

The reproductive biology of corn and the distribution and sexual compatibility of its closest relatives was discussed previously. While cultivated corn is sexually compatible with and has been shown to form fertile hybrids with teosinte in areas of Mexico and Guatemala where they co-exist, teosinte is not present in the U.S. While hybridization and introgression could occur in Mexico or Guatemala if transgenic corn were to cross with native teosinte, several factors in combination effectively reduce the probability of introgression. Corn and teosinte have maintained separate identities for hundreds of years in Mesoamerica, in spite of occasional introgression (Giddings et al., 1990). Other relatives of corn in the genus *Tripsacum* occur in the U.S., but hybrids with *Zea* are difficult to obtain and are often sterile or have greatly reduced fertility. Furthermore, none of the sexually compatible relatives of corn in the U.S. are considered to be serious, principal, or common weeds in the U.S. (Holm et al., 1991); therefore it is unlikely that introgression of the *CP4 EPSPS* and *gox* genes would have any impact on their populations as they would not be routinely subject to herbicide treatments. Our analysis of the biology of cultivated lepidopteran insect resistant corn and its relatives leads us to predict that the environmental impacts of cultivation of MON 802 corn would be no different from such impacts attributable to similar varieties produced by traditional breeding techniques. Non-cultivated varieties of *Zea* sp. have coexisted and co-evolved in the Americas over millennia. There is no reason to expect impacts from MON 802 corn to be significantly different from those arising from the cultivation of any other variety of insect resistant corn.

Gene introgression into other corn cultivars via cross pollination is possible. If pollen of the MON 802 corn were transferred to any receptive corn stigma within the period of pollen viability, cross-pollination would occur. This potential transfer becomes more unlikely as distance increases from the transgenic plants, and from a practical standpoint becomes increasingly unlikely at a distance much greater than the foundation seed isolation distance of 660 feet. In the U.S., farmers generally purchase hybrid corn seed for planting from a commercial source. If pollen of MON 802 corn were to fertilize the corn in a farmer's field, this corn will likely be harvested for products or other uses and would not likely be used as seed. Therefore, fertilization of nontransgenic corn by pollen from MON 802 corn grown for sale as food or feed should not result in dissemination of the trait to seed populations used for planting.

Monsanto reported no differences in the flowering of MON 802 corn compared to the nontransgenic control plants. There is no reason to believe that the genetic constructs introduced during the transformation event would have any effect on the reproductive biology of the MON 802 corn, unless the insertions interrupted a genetic locus critical for the normal reproductive function.

Breeder seed is usually derived from self-pollinated seed at the F_8 to F_{10} generation of inbreeding (Wych, 1988). A high degree of self-pollination is ensured by planting well isolated blocks that virtually guarantee natural random sib mating. The minimum isolation distance to obtain foundation seed is one-eighth mile (660 feet) from the nearest potentially contaminating source. Other safeguards, such as natural or physical barriers or pollen donor border rows and differences in flowering dates can further reduce the probability of contamination from unwanted pollen. Fields that have not been recently planted in corn are preferred in order to minimize the appearance of volunteer corn from the previous season. Corn appears as a volunteer in some fields and roadsides, but it never has been able to establish itself outside of cultivation (Gould et al., 1994).

D. Use of MON 802 corn should have no more adverse impacts on raw or processed agricultural commodities than the parent corn.

During field testing, the MON 802 corn exhibited the typical agronomic characteristics of the recipient plant, with the exception of the desired phenotypes lepidopteran resistance and tolerance to glyphosate herbicide. APHIS examined data provided on the compositional analysis of the grains from transgenic and nontransgenic corn and field observation of disease and pest susceptibilities. Based on this analysis, characteristics of MON 802 corn reveal no differences that could have an indirect plant pest effect on any raw or processed plant commodity.

E. MON 802 corn exhibits no significant potential to either harm organisms beneficial to the agricultural ecosystem, to harm threatened or endangered organisms or to have an adverse impact on the ability to control nontarget insect pests.

Consistent with its statutory authority and requirements under NEPA, APHIS evaluated the potential for MON 802 corn plants and plant products to have damaging or toxic effects directly or indirectly on nontarget organisms. This includes those that are recognized as beneficial to agriculture and those that are recognized as threatened or endangered in the United States. APHIS also considered potential impacts on other "nontarget" pests, since such impacts could have an impact on the potential for changes in agricultural practices. Target pests of the engineered CryIA(b) protein expressed in MON 802 corn lines are lepidopteran pests of corn, particularly the European corn borer. Results submitted by Monsanto indicate that no differences were observed for the control of insects other than certain lepidopteran pests.

There is no reason to believe that expression of the *CP4 EPSPS* and *gox* genes in the MON 802 corn plants, which provide tolerance to glyphosate, would have deleterious effects or significant impacts on nontarget organisms, including beneficial organisms.

1). Potential impact on beneficial and other nontarget organisms.

APHIS considered the results of several previous studies designed to compare the impact on nontarget organisms of CryIA(b). Most of the *B. thuringiensis* subspecies *kurstaki* insecticidal protein toxins, including CryIA(b), have been shown to be very selective for lepidopteran insects (MacInstosh et al., 1990; Aronson et al., 1986; Whitely and Schnepf, 1986; Klausner, 1984: Dulmage, 1981). They bind specifically to the mid-gut of lepidopteran insects (Van Rie et al., 1990; Van Rie et al., 1989; Hofmann et al., 1988a and 1988b: and Wolfersberger et al., 1986). As such, they are not expected to adversely effect 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. Furthermore, environmental fate studies cited in the petition indicate that CryIA(b) protein present in crop residues will lose bioactivity quickly upon incorporation into the soil, and that the rate of dissipation is comparable to that observed with previously registered microbial Bt. products.

2). Potential impact on threatened and endangered arthropods.

No endangered or threatened lepidopteran insects, as listed in 50 CFR 17.11 and 17.12, feed on corn plants.

Therefore, APHIS concludes that MON 802 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture or nontarget organisms, and it will not affect threatened or endangered species.

F. Cultivation of MON 802 corn should not reduce the ability to control insects in corn and other crops.

APHIS considered potential impacts associated with the cultivation of MON 802 corn on the current agricultural practices used to control insects. Monsanto claims that the transgenic line provided significant protection from European corn borer and that growers planting MON 802 insect protected corn lines will not require insecticide applications to control this insect. Resistant populations of previously sensitive insects may eventually develop as a result of feeding on MON 802 plants or from exposure to other formulations of B.t.k.-based insecticides containing the CryIA(b) protein.

A reduction in applications of nonselective insecticides used to provide some control of the sensitive pests could potentially enhance biological control options for the control of these pests as well as for pests that are not controlled by the CryIA(b) protein in these plants. A reduction in insecticide use should also reduce the risks associated with the application of some of these insecticides including risks from exposure to field workers and consumers, adverse

effects on nontarget speci s, and ground water contamination by insecticides.

APHIS concludes that development of resistance to insecticides is a potential risk associated with their use; but in this respect, cultivation of MON 802 corn should pose no greater effects on the control of insects in corn and other crops, than the widely practiced method of applying insecticides.

V. CONCLUSION

APHIS has determined that MON 802 corn that has been field tested under APHIS authority, will no longer be considered a regulated article under regulations at 7 CFR Part 340. Permits or notifications acknowledged under those regulations will no longer be required from APHIS for field testing, importation, or interstate movement of MON 802 corn or its progeny. Importation of MON 802 corn seeds is still, however, subject to the restrictions found in the Foreign Quarantine Notice regulations at 7 CFR Part 319 just as applies to any other importation of corn seeds. This determination has been made based on data collected from these approved field trials, laboratory analyses and literature references presented herein which demonstrate the following:

1. MON 802 corn exhibits no plant pathogenic properties. Although pathogenic organisms were used in their development, these corn plants are not infected by these organisms nor can these plants incite disease in other plants.

2. MON 802 corn is no more likely to become a weed than insect resistant and herbicide tolerant corn that could potentially be developed by traditional breeding techniques. Corn is not a serious, principal or common weed pest in the U.S., and there is no reason to believe that resistance to certain lepidopteran insects and tolerance to glyphosate would enable corn to become a weed pest.

3. Multiple barriers insure that gene introgression from MON 802 corn into wild plants in the United States and its territories is extremely unlikely, and such rare events should not increase the weediness potential of any resulting progeny.

4. Seeds of MON 802 corn are substantially equivalent in composition, quality and other characteristics to nontransgenic corn and should have no adverse impacts on raw or processed agricultural commodities.

5. MON 802 corn exhibits no significant potential to harm organisms beneficial to the agricultural ecosystem and will not affect threatened or endangered species.

6. Compared to current corn cultivation practices, cultivation of corn line MON 802 should not reduce the ability to control insects in corn or other crops.

APHIS has also concluded that there may be new varieties bred from MON 802 corn; however, if such varieties are developed they are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for MON 802 corn already field tested, or those observed for corn developed from traditional breeding.

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