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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. 95-067-2]

Northrup King Co.; Availability of Determination of Nonregulated Status for Corn Line 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 a corn line developed by the Northrup King Company designated as Bt11 that has been genetically engineered for insect resistance is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Northrup King Company in its petition for a determination of nonregulated status, an analysis of other scientific data, and our review of comments received from the public in response to a previous notice announcing our receipt of the Northrup King Company's petition. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: January 18, 1996.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and all written comments received regarding 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 asked to call in advance of visiting at (202) 690-2817.

FOR FURTHER INFORMATION CONTACT: Dr. Subhash Gupta, Biotechnologist, Biotechnology Permits, BBEP, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1237; (301) 734-7612. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-7612.

SUPPLEMENTARY INFORMATION:

Background

On July 14, 1995, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 95-195-01p) from the Northrup King Company (Northrup King) of Golden Valley, MN, seeking a determination that a corn line designated as Bt11 that has been genetically engineered for resistance to the European corn borer (ECB) does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On September 7, 1995, APHIS published a notice in the Federal Register (60 FR 46573-46574, Docket No. 95-067-1) announcing that the Northrup King 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 the subject corn line posed a plant pest risk. The comments were to have been received by APHIS on or before November 6, 1995.

APHIS received a total of 106 comments on the subject petition during the designated 60-day comment period from seed companies, individuals, farmers and farm seed dealers, agricultural products companies, State departments of agriculture, an agricultural council, a growers association, and a university. All of the comments were favorable to the petition.

Analysis

Corn line Bt11 has been genetically engineered to contain the *cryIA(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki* (Btk), which expresses a delta-endotoxin insecticidal protein known to be effective against certain lepidopteran insects, including ECB. Corn line Bt11 also contains the *pat* gene isolated from *Streptomyces viridochromogenes* that encodes a selectable marker, the phosphinothricin-N-acetyltransferase (PAT) enzyme. When introduced into the plant cell, the PAT enzyme can inactivate glufosinate herbicides. Expression of the introduced genes is controlled by the 35S promoter derived from the plant pathogen cauliflower mosaic virus and a NOS terminator derived from the nopaline synthase gene of *Agrobacterium tumefaciens.*

Corn line Bt11 has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains regulatory gene sequences derived from plant pathogens. However, evaluation of field data reports from field tests of the subject corn line conducted under APHIS permits or notifications since 1992 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the subject corn plants' release into the environment.

Determination

Based on its analysis of the data submitted by Northrup King and a review of other scientific data, comments received, and field tests of the subject corn line, APHIS has determined that corn line Bt11: (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) should not cause damage to raw or processed agricultural commodities; (5) will not harm other organisms, including agriculturally beneficial organisms and threatened and endangered species; and (6) should not reduce the ability to control insects in corn and other crops. Therefore, APHIS has concluded that corn line Bt11 and any progeny derived from hybrid crosses with other nontransformed corn varieties will be just as safe to grow as traditionally bred corn lines that are not regulated under 7 CFR part 340.

The effect of this determination is that a corn line designated as Bt11 is no longer considered a regulated article

under APHIS' regulations in 7 CFR part 340. Therefore, the notification requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of corn line Bt11 or its progeny. However, the importation of the subject corn line or seeds capable of propagation is 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 (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; 60 FR 6000–6005, February 1, 1995). Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that corn line Bt11 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 22nd day of January 1996.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–1507 Filed 1–26–96; 8:45 am]

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USDA/APHIS Petition 95-195-01 for Determination of Nonregulated Status for Bt11 Corn

Environmental Assessment and
Finding of No Significant Impact

January 1996

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 Bt11 corn. APHIS received a petition from the Northrup King Company regarding the status of Bt11 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 lepidopteran insect resistant Bt11 corn shall no longer be a regulated article.

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U.S. Department of Agriculture
Date: JAN 18 1996

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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 regulated status of a genetically engineered line of lepidopteran insect resistant corn designated hereafter as Bt11 corn. The developer of Bt11 corn, the Northrup King Company (Northrup King) petitioned APHIS requesting a determination on the regulated status of Bt11 corn which is a regulated article under USDA regulations. Interstate movements and field tests of Bt11 corn have been conducted under permits issued by or notifications acknowledged by APHIS. Northrup King has petitioned APHIS for a determination that Bt11 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.

The Bt11 corn has been developed in an effort to protect corn plants against the larvae of the European corn borer (*Ostrinia nubilalis* (Hubner)). The *cryIA(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki* (Btk) strain HD-1 encoding insecticidal crystal protein has been inserted into the corn chromosome. The source of this gene has been claimed to be Confidential Business Information by the applicant. A selectable genetic marker encoding a phosphinothricin-N-acetyltransferase (PAT) enzyme has also been introduced into the corn chromosome in order to facilitate selection of transformed cells in the laboratory. The genes were introduced via a well-characterized procedure that results in direct introduction of genes into the plant genome.

EAs were prepared before granting the permits for Bt11 corn field trials. Previous EAs addressed questions pertinent to plant pest risk issues concerning the conduct of field trials under physical and reproductive confinement, but they did not address issues that are of relevance to the unconfined growth of Bt11 corn. With respect to these new issues, APHIS concludes the following:

1. Bt11 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. Bt11 corn is no more likely to become a weed than insect-resistant corn which could potentially be developed by traditional breeding techniques. Corn is not a weed in the U.S., and there is no reason to believe that resistance to insects would enable corn to become a weed pest.

3. Multiple barriers insure that gene introgression from Bt11 corn into wild plants is extremely unlikely, and such rare events should not increase the weediness potential of any resulting progeny.

4. Bt11 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. Bt11 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture, nontarget organisms, and will not affect threatened or endangered species.

6. Cultivation of Bt11 corn should not reduce the ability to control insects in corn and other crops.

Therefore, after a review of the available evidence, APHIS believes that Bt11 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 Bt11 corn and its progeny were no longer considered regulated articles under the regulations.

II. BACKGROUND

Development of Bt11 corn. Northrup King has submitted a "Petition for Determination of Non-regulated Status" to the USDA, APHIS for corn plants containing a gene that protects corn plants against the feeding damage caused by the larvae of the European corn borer. Northrup King requested a determination from APHIS that Bt11 corn, and any progeny derived from crosses between this line and other non-transformed corn varieties, no longer be considered a regulated article under 7 CFR Part 340.

European corn borer (ECB) damage to corn plants results in stalk lodging, dropped ears, and damaged grain. *B. thuringiensis* subsp. *kurstaki*, a bacterium produces a family of related toxins (delta-endotoxin) that when ingested by susceptible lepidopteran insects result in their death. These toxins produced are crystals 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. Northrup King has modified the corn plant to produce in green tissues and pollen cells a specific delta-endotoxin, called *cryIA(b)*. During the field testing of Bt11 corn, ECB infestations were significantly reduced as compared to the nontransgenic control

plants. The expression of the one copy of the *cryIA(b)* gene is under the control of a promoter derived from cauliflower mosaic virus (CaMV). The gene expresses throughout the plant. The termination sequences is from *Agrobacterium tumefaciens*, a known plant pest.

Bt11 corn has also been transformed with a gene from the bacterium, *Streptomyces viridochromogenes* that encodes the PAT enzyme and serves as a selectable marker enabling identification of the transformed plant cells. This gene is fused to 35S promoter sequence and a termination sequence from *A. tumefaciens*.

These two genes were introduced into Bt11 corn by a method claimed to be Confidential Business Information by the Northrup King.

Bt11 corn has been field tested since 1992 in the major corn growing regions of the United States under permits and acknowledgment of notifications by APHIS. Total 3 permits have been issued and 42 notifications have been acknowledged. Bt11 corn has been evaluated extensively in laboratory, greenhouse, and field experiments to confirm that it exhibits the desired agronomic characteristics and does not pose a plant pest risk. Although the field tests of Bt11 corn have been conducted in agricultural settings, the permit conditions and acknowledgment of notifications for the tests have stipulated physical and reproductive confinement from other sexually compatible plants.

APHIS Regulatory Authority. APHIS regulations 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. Bt11 corn described in the Northrup King petition has been considered a regulated article because noncoding DNA regulatory sequences are 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, the Agency can grant the petition in whole or in part. Therefore, APHIS permits 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. Bt11 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, Northrup King has submitted to EPA an application to register this plant-pesticide, i.e., *cry IA* gene and its regulatory sequences in Bt11 corn. On November 1, 1995, EPA announced receipt of this application (EPA File Symbol 67979- E) in the Federal Register (60 **FR** 55574). The EPA has not yet announced its final decision on this registration application. Before a product may be registered as a pesticide under FIFRA, it must be shown that when used in accordance with widespread and commonly recognized practices, it will not cause unreasonable adverse effects on the environment.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA; and the FDA enforces the tolerances set by the EPA. Northrup King has submitted to the EPA a pesticide petition (PP 4G44 09) proposing to amend 40 CFR part 180 to establish a tolerance exemption for residues of the plant pesticide that is expressed in plant cells. On February 15, 1995, EPA announced receipt of this petition [60 **FR** 8658 amended March 15, 1995 60 **FR** 13984]. The EPA has not yet announced its decision on this petition.

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.

III. PURPOSE AND NEED

APHIS has prepared this EA before making a determination on the status of Bt11 corn as a regulated article under APHIS regulations. The developer of Bt11 corn, Northrup King Company submitted a petition to USDA/APHIS requesting that APHIS make a determination that Bt11 corn shall no longer be considered a regulated article under 7 CFR Part 340.

This EA was prepared in compliance with the National Environmental Policy Act (NEPA) of 1969 (42 USC 4321 *et seq.*) and the pursuant implementing regulations published by the Council on Environmental Quality (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372; 60 FR 6000-6005, February 1, 1995).

IV. ALTERNATIVES

A. No Action.

Under the Federal "no action" alternative, APHIS would not come to a determination that Bt11 corn is no longer a regulated article under the regulations at 7 CFR Part 340. Permits from APHIS would still be required for introductions of Bt11 corn. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of Bt11 corn.

B. Determination that Bt11 Corn is no longer a regulated article.

Under this alternative, Bt11 corn would no longer be a regulated article under the regulations at 7 CFR Part 340. Permits from APHIS would no longer be required for introductions of Bt11 corn. A basis for this determination would include a "Finding of No Significant Impact" under the National Environmental Policy Act of 1969 (42 USC 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372; 60 FR 6000-6005, February 1, 1995).

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

This EA addresses potential environmental impacts from a determination that Bt11 corn should no longer be considered a regulated article under APHIS regulations at 7 CFR Part 340. Previous EAs prepared by APHIS with the issuance of permits for field tests of Bt11 corn have addressed various attributes of this corn. This EA discusses the genetic modification, and the potential

environmental impacts that might be associated with the unconfined cultivation of Bt11 corn.

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 Bt11 corn, and the analyses that lead APHIS to conclude that Bt11 corn has no potential to pose plant pest risks.

A. Potential impacts based on increased weediness of Bt11 Corn relative to traditionally bred insect resistant 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 adapted and analyzed 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.

The cultivated corn is not considered a weed pest and is unlikely to become a weed pest. Corn is considered a highly inbred, well-characterized crop plant that is not persistent in undisturbed environments without human intervention. Although corn volunteers are not uncommon, they are easily controlled using herbicides or mechanical means. Corn also possess few of the characteristics of plants that are notably successful weeds (e.g., it does not produce abundant, long-lived seed; it does not propagate vegetatively; it does not compete well with other plant species in the environment).

Furthermore, corn has been grown for centuries throughout the world without any reports that it is a serious weed pest. 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 Bt11 corn is an agricultural crop plant that exhibits no appreciable weedy characteristics. The relevant introduced trait, lepidopteran insect resistance, is unlikely to increase weediness of Bt11 corn. There is no indication that the presence of a *cryIA(b)* gene in resulting Bt11 corn will convert it into a weed. The corn plants have also been transformed with a selectable marker gene *pat* that confers resistance to the herbicide glufosinate. This gene has no known involvement in plant disease or damage. Also, its use

does not result in the presence of the herbicide in corn. No other attribute of Bt11 corn suggests that it be any more "weedy" than the present corn cultivars that are the result of traditional breeding. The Bt11 corn has retained the agronomic characteristics of the parental corn. The provided data on seed germination rates, yield characteristics, disease and pest susceptibilities, compositional analyses in the Northrup King application support APHIS' conclusion that Bt11 corn is just as safe to grow as any other insect resistant corn.

B. Potential impacts on the sexually-compatible relatives of corn arising from pollination by Bt11 corn.

The species *Z. mays* is native to Mexico and Central America. Zea is a genus of the family Gramineae (the grass family) that consists of some 4 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 they freely hybridize when in proximity to each other. Wilkes (1972) stated that hybrids represent a significant gene exchange between wild weedy plant (i.e. teosinte) and a cultivated relative (i.e. corn). The F1 hybrid of teosinte by corn is robust and fertile and is capable of backcrossing to corn. Corn easily crosses with teosinte, but teosinte is not present in the U. S. Corn Belt. In other words, cultivated corn have been transformed from teosinte, *Z. mays* subsp. *mexicana* more than 8000 years ago. During this transformation, cultivated corn gained several valuable agronomic traits, but lost the ability to survive in the wild.

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 corn in many respects, including chromosome number (N=9), in contrast to *Zea* (N=10). 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 corn and its relatives leads us to predict that the environmental impacts of cultivation of Bt11 corn in most of the places in the world would be no different from such impacts attributable to similar varieties produced with traditional breeding techniques. Non-cultivated varieties of *Zea* sp. have coexisted and co-evolved in the Americas over millennia. Even if Bt11 corn were to be cultivated in agricultural regions around centers of *Zea* diversity, there is no reason to expect impacts from Bt11 corn to be significantly different from those arising from the cultivation of any other variety of insect resistant corn.

International traffic of Bt11 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 (102 countries as of December 1995). The treaty, now 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). Our trading partners will be kept informed of our regulatory decisions through NAPPO and other fora. Our decision in no way prejudices regulatory action in any other country. Mexico, possesses many wild *Zea mays* populations and thus is concerned with the introgression of genes from domesticated *Zea mays* into these wild populations. Therefore, Mexico's 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 Bt11 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 Bt11 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, since such impacts could have an impact on the potential for changes in agricultural practices.

There is no reason to believe that deleterious effects or significant impacts on nontarget organisms, including beneficial organisms, would result from the *pat* gene used as a selectable marker during development of this line.

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

APHIS evaluated the results of several studies designed to compare the impact on nontarget organisms of Bt11 corn and *cryIA(b)* as reported in Section III Under Relevant Experimental Data on page 22 of this petition and as suggested in the scientific literature (Ignoffo and Garcia, 1978; West, 1984) and also from our review of data submitted by the Monsanto Company: Bt11 corn should not have any effects on beneficial or nontarget organisms.

Other invertebrates and all vertebrate organisms, including non-target birds, mammals and humans, are not expected to be affected by the *pat* or *Btk* insect control protein, because they would not be expected to contain the receptor protein found in the midgut of target insects.

2). Potential impact on threatened and endangered arthropods

No endangered or threatened lepidopteran insect, as listed in 50 CFR 17.11 and 17.12, feed on corn plants. APHIS concludes that Bt11 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture, 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 Bt11 corn and its progeny.

E. Bt11 Corn will not cause damage to processed agricultural commodities.

In APHIS' opinion, the components and processing characteristics of Bt11 corn reveal no difference in any component that could have an indirect plant pest effect on any processed plant commodity.

VI. CONCLUSION

APHIS has evaluated information from the scientific literature as well as data submitted by Northrup King Co. that characterized Bt11 corn. After careful analysis, APHIS has identified no significant impact to the environment from issuance of a determination that Bt11 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. Bt11 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. Bt11 corn is no more likely to become a weed than insect-resistant corn which 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 insects would enable corn to become weed pests.

3. Multiple barriers insure that gene introgression from Bt11 corn into wild plants is extremely unlikely, and such rare events should not increase the weediness potential of any resulting progeny.

4. Bt11 corn is substantially equivalent in composition, quality and other characteristics to nontransgenic corn and should have no adverse impacts on raw or processed agricultural commodities.

5. Bt11 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture, nontarget organisms, and will not affect threatened or endangered species.

6. Cultivation of Bt11 corn should not reduce the ability to control insects in corn and other crops.

Therefore, after review of the available evidence, APHIS concludes that Bt11 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 Bt11 corn were no longer a considered regulated article under its regulations (7 CFR Part 340).

VII. LITERATURE CITED

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Response to The Northrup King Company Petition for Determination of Nonregulated Status for Insect-Resistant Bt11 Corn

Prepared by
United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology, Biologics, and Environmental Protection

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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 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.

On July 14, 1995, the Animal and Plant Health Inspection Service (APHIS) received a petition from the Northrup King Company requesting a determination that insect resistant corn (hereafter referred to as Bt11 corn) does not pose a plant pest risk and therefore, is not a regulated article. On September 7, 1995, APHIS announced receipt of the petition in the *Federal Register* (60 *FR* 46573-46574) and stated that the petition was available for public review. APHIS invited written comments on this proposed action, to be submitted on or before November 6, 1995. Based on a review of scientific data and literature, APHIS has determined that Bt11 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 under 7 CFR Part 340 will no longer be required by APHIS for field testing, importation, or interstate movement of Bt11 corn or its progeny.

Bt11 corn is genetically engineered with the gene that encodes for an insecticidal protein naturally produced by the soil bacterium, *Bacillus thuringiensis* subsp. *kurstaki* (*Btk*), and a selectable marker gene (*pat*) encoding phosphinothricin-N-acetyltransferase (PAT) enzyme from the soil bacterium *Streptomyces viridochromogenes*. These genes also have accompanying DNA regulatory sequences that modulate their expression. The DNA regulatory sequences were derived from corn and the plant pathogen cauliflower mosaic virus (CaMV) and *Agrobacterium tumefaciens*.

This determination has been made based on an analysis that revealed that Bt11 corn plants: 1) exhibit no plant pathogenic properties, 2) are no more likely to become a weed than genetically engineered insect resistant corn developed by traditional breeding, 3) are unlikely to increase the weediness potential of any other cultivated plant, 4) do not cause damage to processed agricultural commodities, 5) are unlikely to harm other organisms that are beneficial to

agriculture or to adversely impact the ability to control nontarget insect pests, or threatened and endangered species and 6) are unlikely to reduce the ability to control insects in corn and other crops. APHIS has also concluded that there is no reason to believe that new corn varieties derived from Bt11 corn progeny will exhibit new plant pest properties; i.e., properties substantially different from any observed for the corn line Bt11 already field tested, or those observed for corn in traditional breeding programs.

The potential environmental impacts associated with this determination have been examined in accordance with regulations and guidelines implementing the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372; 60 FR 6000-6005, February 1, 1995). An environmental assessment (EA) was prepared and a Finding of No Significant Impact (FONSI) was reached by APHIS for the determination that Bt11 corn is no longer a regulated article under its regulations at 7 CFR Part 340. This decision does not release Bt11 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) (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 corn 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 either 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 APHIS has reason to believe that the genetically engineered organism presents a plant pest risk. The FPPA gives 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 Section 340.0 of the regulations to either (1) notify APHIS in accordance with Section 340.3 or (2) obtain a permit in accordance with Section 340.4. Introduction under notification (Section 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 Section 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 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 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 Bt11 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 *Agrobacterium tumifaciens*, known plant pests. APHIS believes it prudent to provide assurance before commercialization that organisms such as Bt11 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 Bt11 corn is not a regulated article is based in part on evidence provided by Northrup King concerning the biological properties of Bt11 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). APHIS' approach 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 insect-resistant organisms do not present a plant pest risk can be made under this definition, especially when there is evidence that the plant under consideration: 1) exhibit no plant pathogenic properties; 2) are no more likely to become a weed than insect resistant corn developed by traditional breeding; 3) are unlikely to increase the weediness potential of any other cultivated plant; 4) do not cause damage to processed agricultural commodities; 5) are unlikely to harm other organisms that are beneficial to agriculture or to adversely impact the ability to control nontarget insect pests, or threatened and endangered species; and 6) are unlikely to reduce the ability to control insects in corn and other crops. Evidence has been presented by Northrup King 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 Bt11 corn will exhibit plant pest properties substantially different from any observed for corn in traditional breeding programs, or as seen in the development of Bt11 corn already field tested. APHIS does anticipate that there will be new corn varieties bred from Bt11 corn.

B. EPA and FDA regulatory authority

The corn line Bt11 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 its distribution and sale and establish tolerances for pesticide residues in raw agricultural products. APHIS' decision on the regulatory status of the Bt11 corn under APHIS' regulations at 7 CFR 340, in no way releases this corn and its progeny from EPA and FDA regulatory oversight.

III. RESPONSE TO COMMENTS

APHIS received 106 comments on the subject petition during the designated 60-day comment period from seed companies, individuals, farmers and farm seed dealers, agricultural products companies, State departments of agriculture, an agricultural council, a growers association, and a university. All of the comments were favorable to the petition.

IV. ANALYSIS OF THE PROPERTIES OF Bt11 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 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 (the grass family) that consists of some 4 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 they freely hybridize when in proximity to each other. Wilkes (1972) stated that hybrids represent a significant gene exchange between wild weedy plant (i.e. teosinte) and a cultivated relative (i.e. corn). The F1 hybrid of teosinte by corn is robust and fertile and is capable of backcrossing to corn. Corn easily crosses with teosinte, but teosinte is not present in the U. S. Corn Belt. Cultivated corn has been transformed from teosinte, *Z.* mays subsp. *mexicana* more than 8000 years ago. During this transformation, cultivated corn gained several valuable agronomic traits, but lost the ability to survive in the wild.

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 number (N=9), in contrast to *Zea* (N=10). All species of *Tripsacum* can cross with *Zea*, but only with difficulty and the resulting hybrids are sterile (Galinat, 1988).

A. The introduced genes, their products, and the added regulatory sequences do not present a plant pest risk in Bt11 corn.

The transformation was performed by a method claimed to be Confidential Business Information by the Northrup King Company. Bt11 corn was obtained by transforming elite inbred corn lines 2043 and 2044, with the plasmid pZ01502, containing the *cryIA(b)* and *pat* genes. The *pat* gene was cloned from the soil microorganism *Streptomyces viridochromogenes* strain Tu494. It encodes the enzyme phosphinothricin-N-acetyltransferase (PAT) which inactivates phosphinothricin, the active component in the herbicide glufosinate. Expression of this enzyme allows for selection of transformed plant cells on selective medium, as well as whole-plant tolerance to glufosinate application.

Southern blot analysis was performed using Bt11 corn DNA and the *cryIA(b)* DNA as probe. The results indicated that Bt11 transgenic lines are derived from a single insertion event containing only one gene copy of the *Bt* and *pat* gene sequences.

B. Expression of the insect control protein in the bt11 corn will not likely provide a competitive advantage sufficient to cause these plants to become any more "weedy" than other corn.

APHIS evaluated whether the Bt11 corn is any more likely to become a weed than nontransgenic control corn lines 2043 or 2044. Most definitions of weediness stress the undesirable nature of weeds from the point of view of humans; individual definitions differ in approach and emphasis (Baker, 1965). Baker defines a plant as a weed if, in any specified geographical area, its populations grow entirely or predominantly in situations markedly disturbed by man (without, of course, being deliberately cultivated) (Baker, 1965). He also described the ideal characteristics of weeds as including the following: discontinuous germination and long-lived seeds; rapid seedling growth; rapid growth to reproductive stage; long continuous seed production; self-compatibility, but not obligatory self-pollination or apomyxis; if outcrossing, use of wind or an unspecialized pollinator; high seed number under favorable conditions; high germination rates, and seed production under a wide range of environmental conditions; high tolerance or plasticity of climatic and edaphic variation; special adaptations for dispersal; good competitiveness achieved through, for example, allelochemicals or choking growth; and, if perennial, then exhibiting vigorous vegetative reproduction, brittleness either at the lower nodes or of rhizomes or rootstocks, and having the ability to regenerate from severed rootstocks. Although Baker's characteristics have been criticized by some ecologists as nonpredictive, no more broadly accepted suite of characteristics has been defined by ecologists (Williamson, 1994). In our view, there is no formulation that is clearly superior at this time. Keeler (1989) and Tiedje et al.

(1989) have adapted and analyzed 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, particularly the elite inbred lines 2043 and 2044, lack most of Baker's "weedy" characteristics (Keeler, 1989). Corn is not listed as a common, serious or principal weed or a weed of current or potential importance in the United States and/or Canada in most weed literature (Holm et al., 1991; Muenscher, 1955; USDA, 1971; Weed Science Society of America, 1992).

Expression of the insect control protein in the Bt11 corn will not likely provide a competitive advantage sufficient to cause these to be any more "weedy" than other corn cultivars. None of the characteristics of weeds described by Baker involve resistance or susceptibility to insects. More importantly, in addition to the analysis above, APHIS evaluated field data submitted by Northrup King which specifically demonstrates that Bt11 corn is no more weedy than the non-modified recipient. Control and Bt11 corn plants were routinely monitored during field trials for differences in morphological characteristics, disease and insect susceptibility. The Bt11 corn plants were healthy and exhibited significantly increased yields.

Based on evaluation of the available literature and data submitted by Northrup King , APHIS concludes that the Bt11 corn is no more likely than nontransgenic control plants to present a plant pest risk as a weed.

C. Gene introgression from Bt11 corn into wild plants is unlikely, and such rare events should not increase the weediness potential of resulting progeny.

APHIS evaluated the potential for gene flow from Bt11 corn to other cultivated and wild relatives. Then, two potential impacts that might result from this sexual transfer of genes were evaluated: first, that the traits from Bt11 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 phosphinothricin resistance trait used as a selectable marker in the Bt11 corn was considered not to pose a hazard in this analysis because plants will not be sprayed with glufosinate herbicide.

Potential for gene introgression into other corn cultivars via cross pollination is possible. If pollen of the Bt11 corn can be transferred to any receptive corn stigma within the period of pollen viability, cross-pollination will 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. Farmers purchase hybrid corn seed for planting from a commercial source. If pollen of Bt11 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 Bt11 corn grown for sale as food or feed will not result in dissemination of the trait in to seed populations used for planting.

The Northrup King Company reported no obvious differences in the flowering of Bt11 corn compared to the nontransgenic control plants. There is no reason to believe that the genetic construct introduced during the transformation event would have any effect on the reproductive biology of the Bt11 corn, unless the insertion event 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 contaminating source. Other safeguards, such as physical barriers or unharvested border rows, can further reduce the possibility of contamination. Fields that have not been recently planted in corn are preferred. This is 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 Bt11 corn should have no more adverse impacts on raw or processed agricultural commodities than the parent corn.

During field testing, the Bt11 corn exhibited the typical agronomic characteristics of the recipient plant, with the exception of the desired phenotype conferred by the *Btk* insect control protein. In APHIS' opinion, the components, quality and processing characteristics of Bt11 corn reveal no differences that could have an indirect plant pest effect on any raw or processed plant commodity.

E. Bt11 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 Bt11 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, since such impacts could have an impact on the potential for changes in agricultural practices.

There is no reason to believe that the *pat* gene conferring phosphinothricin resistance in the Bt11 corn plants that was used as a selectable marker for transformation would have deleterious effects or significant impacts on nontarget organisms, including beneficial organisms.

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

APHIS evaluated the results of several studies designed to compare the impact on nontarget organisms of Bt11 corn and *cryIA(b)* as reported in Section III Under Relevant Experimental Data on page 22 of this petition and as suggested in the scientific literature (Ignoffo and Garcia, 1978; West, 1984) and also from our review of data submitted by the Monsanto Company: Bt11 corn should not have any effect on beneficial and nontarget organisms.

Other invertebrates and all vertebrate organisms, including non-target birds, mammals and humans, are not expected to be affected by the *Btk* insect control protein, because they would not be expected to contain the receptor protein found in the midgut of target insects.

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 Bt11 corn will not have a significant adverse impact on organisms beneficial to plants or agriculture, nontarget organisms, and will not affect threatened or endangered species.

F. Cultivation of Bt11 corn should not reduce the ability to control insects in corn and other crops.

APHIS considered potential impacts associated with the cultivation of Bt11 corn on the current agricultural practices used to control insects. Northrup King has included a section on "Management of Insect Pests with Insect Protected Corn: Recommended Approach" in its petition.

The Bt11 corn offers an additional control method. Northrup King strategies for maximizing the utility of these plants while delaying the development of insect resistance to these plants include the following:

1. Promoting the incorporation of corn line Bt11 into integrated pest management programs (IPM) that emphasize the use of cultural control practices, such as those described above, and judicious and selective use of additional insecticides only when pest populations reach the threshold for economic damage. They do not encourage the use of Bt11 corn as a stand-alone control measure.

2. Monitoring insect populations for *Btk* protein susceptibility so that development of resistance can be detected and management strategies altered accordingly.

3. High dose expression of *Btk* protein to control insect that are heterozygous for resistance alleles.

4. Deployment of non-Bt11 type corn lines or other hosts as refugia for insects that are sensitive to the *Btk* insect control protein, in order to maintain susceptible alleles in the part population.

5. Development of new insect control proteins with a distinct mode of action to be employed with the *Btk* protein.

6. Implementation of a grower education program to achieve items 1, 2, and 4 above.

APHIS evaluated the potential impact to agricultural practices associated with the use of Bt11 corn according to Northrup King strategy. As a result of Northrup King program to instruct growers on the use of cultural control practices and IPM, growers may be more likely to adopt these methods. However, growers will also need to be informed about the implementation of preferred refugia strategies and how these can be integrated with other cultural practices. Growers will be less likely to use chemical insecticides targeted at insect control, and this should reduce the risks associated with some of these insecticides. The use of Bt11 corn should increase safety to field workers and consumers, reduce toxicity to nontarget species, and lower rates of ground water contamination by insecticides. Bt11 corn plants are not likely to eliminate completely the use of chemical insecticides, particularly when they may be needed to control other serious pests. But perhaps they may encourage more selective use of insecticides against these pests.

APHIS concludes that development of resistance to insecticides is a potential associated with their use; but in this respect, cultivation of Bt11 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 Bt11 corn that has been field tested under permit, will no longer be considered regulated articles under APHIS 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 those Bt11 corn or their progeny. Importation of Bt11 corn seeds capable of propagation is still, however, subject to the restrictions found in the Foreign Quarantine Notice regulations at 7 CFR Part 319. This determination has been made based on data collected from these approved trials, laboratory analyses and literature references presented herein which demonstrate the following:

1. Bt11 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. Bt11 corn is no more likely to become a weed than insect resistant corn which 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 insects would enable corn to become weed pests.

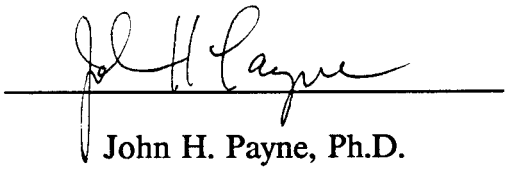
3. Multiple barriers insure that gene introgression from Bt11 corn into wild plants is extremely unlikely, and such rare events should not increase the weediness potential of any resulting progeny.

4. Seeds of Bt11 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. Bt11 corn exhibits no significant potential to either harm organisms beneficial to the agricultural ecosystem or to impair the ability of farmers to control nontarget insect pest, and will not affect threatened or endangered species.

6. Cultivation of corn line Bt11 should not reduce the ability to control insects in corn and other crops.

APHIS has also concluded that there may be new varieties bred from Bt11 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 Bt11 corn already field tested, or those observed for corn developed from traditional breeding.



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