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.

ÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄ John H. Payne, Ph.D. Acting Director Biotechnology, Biologics, and Environmental Protection Animal and Plant Health Inspection Service U.S. Department of Agriculture Date: TABLE OF CONTENTS

I. SUMMARY 1

II. BACKGROUND 2

III. PURPOSE AND NEED 5

IV. ALTERNATIVES 5

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS 5

VI. CONCLUSION 10

VII. LITERATURE CITED 11

VIII. PREPARERS AND REVIEWERS 12

IX. AGENCY CONTACT 12

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 CaMV.

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 acknowledgements 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 acknowledgement 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

Baker, H. G. 1965. Characteristics and modes of origin of weeds, pp. 147-168. In: The Genetics of Colonizing Species. Baker, H. G., and Stebbins, G. L. (eds.), Academic Press, New York.

Crockett, L. 1977. Wildly Successful Plants: North American Weeds. University of Hawaii Press, Honolulu, Hawaii. 609 pp.

de Wet, J. M. J., Harlan, J. R. 1975. Weeds and Domesticates: Evolution in the Man-Made Habitat. Economic Botany 29:99-107.

Galinat, W. C. 1988. The Origin of Corn, pp. 1-31. In: Corn and Corn Improvement, Third Edition. Sprague, G. F., Dudley, J. W. (eds.). American Society of Agronomy, Crop Science Society of America, and Soil Science Society of America, Madison, WI.

Gould, F. W. 1968. Grass Systematics. McGraw Hill, New York et alibi. 382 pp.

Holm, L., Pancho, J. V., Herbarger, J. P., Plucknett, D. L. 1979. A Geographical Atlas of World Weeds. John Wiley and Sons, New York. 391 pp.

Ignoffo, C. M., Garcia, C. 1978. UV-photoinactivation of cells and spores of Bacillus thuringiensis and effects of peroxidase on inactivation. Environmental Entomology 7:270-272.

Keeler, K. 1989. Can genetically engineered crops become weeds? Bio/Technology 7:1134-1139.

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

Tiedje, J. M., Colwell, R. K., Grossman, Y. L., Hodson, R. E., Lenski, R. E., Mack, R. N., Regal, P. J. 1989. The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations. Ecology 70:298-315.

West, A. W. 1984. Fate of the insecticidal, proteinaceous parasporal crystal of Bacillus thuringiensis in soil. Soil Biol. Biochem. 16:357-360.

Wilkes, H. G. 1972. Maize and its wild relatives. Science 177:1071-1077. VIII. PREPARERS AND REVIEWERS

Biotechnology, Biologics, and Environmental Protection

John Payne, Ph.D., Acting Director

Biotechnology Permits

Arnold Foudin, Ph.D., Deputy Director Subhash Gupta, Ph.D., Biotechnologist (Preparer and Petition Coordinator) David S. Heron, Ph.D., Biotechnologist Susan Koehler, Ph.D., Biotechnologist James Lackey, Ph.D., Biological Safety Officer Vedpal Malik, Ph.D., Biotechnologist H. Keith Reding, Ph.D., Biotechnologist Sivramiah Shantharam, Ph.D., Microorganisms Branch (Reviewer) James L. White, Ph.D., Plants Branch

Biotechnology Coordination and Technical Assistance

L. Val Giddings, Ph.D., Senior Geneticist Shirley P. Ingebritsen, M.A., Program Analyst Quentin B. Kubicek, Ph.D. Plant Pathologist (Reviewer) Michael A. Lidsky, J.D., L.L.M., Deputy Director Michael Schechtman, Ph.D., Senior Microbiologist Frank Y. Tang, Ph.D., J.D., Biotechnologist

Environmental Analysis and Documentation

Carl Bausch, J.D., Deputy Director

IX. AGENCY CONTACT

Kay Peterson, Regulatory Analyst Biotechnology, Biologics, and Environmental Protection USDA, APHIS 4700 River Road, Unit 147 Riverdale, MD 20737-1237

Phone: (301) 734-7612 Fax: (301) 734-8669