

nubilalis (Hubner)). Genes encoding insecticidal crystal proteins from *Bacillus thuringiensis* subsp. *kurstaki* have been inserted into the corn chromosome. A selectable genetic marker encoding phosphinothricin acetyltransferase also been introduced into the corn chromosome but only 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 plant genomes.

EAs were prepared before granting the permits for Event 176 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 do not address several issues that are of relevance to the unconfined growth of Event 176 Corn. With respect to these new issues, APHIS concludes the following:

1. Event 176 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. Event 176 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 Event 176 Corn into wild or cultivated sexually-compatible plants is extremely unlikely, and such rare events should not increase the weediness potential of any resulting progeny or adversely impact biodiversity.
4. Seeds of Event 176 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. Event 176 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 pests.
6. Cultivation of Event 176 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 Event 176 Corn will be just as safe to grow as traditionally-bred lepidopteran insect resistant 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 Event 176 Corn were no longer considered a regulated article under regulations at 7 CFR Part 340.

II. BACKGROUND

Development of Event 176 Corn. Ciba has submitted a "Petition for Determination of Non-regulated Status" to the USDA, APHIS for corn plants that contain a gene that protects the corn plants against the feeding damage caused by the larvae of European corn borer. Ciba requested a determination from APHIS that the Event 176 Corn, and any progeny derived from hybrid crosses between this line and other non-transformed corn varieties, no longer be considered regulated articles under 7 CFR Part 340.

European corn borer (ECB) damage to corn plants results in stalk lodging, dropped ears, and damaged grain. Yield reductions due to ECB infestations are estimated to

exceed \$50 million annually in the State of Illinois alone. *B. thuringiensis* subsp. *kurstaki* produces a family of related toxins (delta-endotoxin) that when ingested by susceptible lepidopteran insects result in their death. These toxins are produced in crystalline structure in and during the bacterial spore formation. Preparations of *B. thuringiensis* containing delta-endotoxins are used 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. Ciba Seeds has modified the corn plant to produce in green tissues and pollen cells a specific delta-endotoxin, called cryIA(b). During field testing of Event 176 Corn that express cryIA(b), ECB infestations were significantly reduced as compared to the nontransgenic control plants. The expression of the two copies of the cryIA(b) genes are under the control either a pollen-specific promoter derived from calcium- dependent protein kinase or green tissue-specific promoter phosphoenolpyruvate carboxylase. Both promoters were isolated from corn plants. The termination sequences for both of genes was from cauliflower mosaic virus (CaMV), a known plant pest.

Event 176 Corn has also been transformed with the gene from *Streptomyces hygroscopicus* that encodes the enzyme phosphinothricin acetyltransferase and serves as a selectable marker enabling identification of the transformed plant cells. This gene is fused to 35S promoter sequence and termination sequence from CaMV.

These two genes were introduced into Event 176 Corn via microprojectile bombardment transformation. This is a well- characterized procedure that has been used for nearly a decade for introducing various genes of interest directly into plant genomes.

Event 176 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 (USDA No. 92-042-01, 92- 127-01, 92-140-01, 93-014-01, 93-120-08, 93-363-01, 94-076-10, and 94- 347-05). Event 176 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 Event 176 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 plants.

APHIS Regulatory Authority. APHIS regulations at 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. Event 176 Corn described in the Ciba petition has been considered a regulated article because noncoding DNA regulatory sequences and portions of the plasmid vector 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. Event 176 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, Ciba has submitted to EPA an application to register this plant-pesticide, i.e., cry IA gene and its controlling sequences in Event 176 Corn. On December 8, 1993, EPA announced receipt of this application (EPA File Symbol 524-UTU) in the Federal Register (58 FR 64582-64583). 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 practice, it will not generally 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. Ciba has submitted to the EPA a pesticide petition (PP 3F4273) proposing to amend 40 CFR part 180 to establish a tolerance exemption for residues of the plant pesticide active ingredient Btk CPB control protein as expressed in plant cells. On December 8, 1993, EPA announced receipt of this petition [58 FR 64583-64584]. 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 Event 176 Corn as a regulated article under APHIS regulations. The developer of Event 176 Corn, Ciba Seeds, submitted a petition to USDA, APHIS requesting that APHIS make a determination that Event 176 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 (40 CFR 1500-1508) and the pursuant implementing regulations published by the Council on Environmental Quality (42 USC 4331 et seq.; 40 CFR 1500-1508; 7 CFR Part 1b; 44 FR 50381-50384; and 44 FR 51272-51274).

IV. ALTERNATIVES

A. No Action.

Under the Federal "no action" alternative, APHIS would not come to a determination that Event 176 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 Event 176 Corn. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of Event 176 Corn.

B. Determination that Event 176 Corn is no longer a regulated article.

Under this alternative, Event 176 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 Event 176 Corn. A basis for this determination would include a "Finding of No Significant Impact" under the National Environmental Policy Act of 1969 (42 USC 4331 et seq.; 40 CFR 1500-1508; 7 CFR Part 1b; 44 FR 50381-50384; and 44 FR 51272-51274).

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

This EA addresses potential environmental impacts from a determination that Event 176 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 Event 176 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 Event 176 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 Event 176 Corn, and the analyses that lead APHIS to conclude that Event 176 Corn has no potential to pose plant pest risks.

A. Potential impacts based on increased weediness of Event 176 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 Event 176 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 Event 176 Corn. There is no indication that the presence of a cryIA(b) gene in resulting Event 176 Corn will convert it into a weed. The corn plants have also been transformed with a phosphinothricin acetyltransferase, which confers resistance to the herbicide glufosinate. The gene has no involvement in plant disease or damage. Also, its use does not result in the presence of the herbicide in corn and does not imply that

glufosinate will be used in the cultivation of the corn. No other attributes of Event 176 Corn suggest that it be any more "weedy" than the present corn cultivars that are the result of traditional breeding. The Event 176 Corn has retained the agronomic characteristics of the parental corn. Ciba has provided data regarding seed germination rates, yield characteristics, disease and pest susceptibilities, compositional analyses, and numerous other test reported in chapter 9 and 10 in the Ciba application that support APHIS' conclusion that Event 176 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 Event 176 Corn

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. Of the four species of *Zea*, only *Z. mays* is common in the United States. It is known only from cultivation; it occasionally is spontaneous in abandoned fields or roadsides, but is incapable of sustained reproduction outside of cultivation (Gould 1968). The other species are occasional university or experiment station research subjects. *Z. perennis* is reported as established from James Island, South Carolina (Hitchcock and Chase 1951).

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 resulting seeds are sterile (Galinat 1988).

Cultivated corn is presumed to 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. Teosinte, however, remains a successful wild grass in Mexico and Guatemala.

Despite some confusion over proper taxonomic groupings of the non-cultivated members of *Zea*, wild members maintain a successful array of annual or perennial plants with visible chromosomal peculiarities and ploidy levels, and many adaptive macroscopic phenotypes. Cultivated corn and the wild members of diploid and tetraploid *Zea* can be crossed to produce fertile F1 hybrids. Nonetheless, in the wild, introgressive hybridization does not occur because of differences in flowering time, geographic separation, block inheritance, developmental morphology and timing of the reproductive structures, dissemination, and dormancy (Galinat 1988).

The second major transformation of cultivated corn occurred in the United States in the twentieth century, and particularly since the 1930's. This transformation occurred through inbred lines for hybrid seed production, and by other methods. Almost all corn grown in the United States now comes from hybrid seed that is obtained every planting season from private enterprises; the older open-pollinated varieties are virtually unknown in commerce (Hallauer et al. 1988). This transformation has resulted in more uniform commercial plants with superior agronomic characteristics, and has contributed to the six-fold increase in per acre yields in the last sixty years.

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 Event 176 Corn anywhere in the world would be no different from such impacts attributable to similar varieties produced with traditional breeding techniques. The species *Z. mays* is native to Mexico and Central America. Non-cultivated

varieties of *Zea* sp. have coexisted and co-evolved in the Americas over millennia. Even if Event 176 Corn were to be cultivated in agricultural regions around centers of *Zea* diversity, there is no reason to expect impacts from Event 176 Corn to be significantly different from those arising from the cultivation of any other variety of insect resistant corn.

International traffic in Event 176 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 (98 countries as of December 1992). 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. Plant biotechnology products are fully subject to national legislation and regulations, or regional standards and guidelines promulgated under the IPPC. The vast majority of IPPC signatories have promulgated, and are now administering, such legislation or guidelines. This includes Mexico, which has in place a regulatory process requiring a full evaluation of Event 176 Corn before it can be introduced into their environment. The IPPC has also led to the creation of Regional Plant Protection Organizations (RPPOs) 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.

It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary protocols that currently apply to introductions of new lepidopteran insect resistant corn varieties internationally apply equally to those covered by this analysis.

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 Event 176 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 phosphinothricin acetyltransferase 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 Event 176 Corn and cryIA(b) (These experiments are described in the petition, starting on page 180).

a). No effect on survival, immobilization, or sublethal toxicity was seen when a small aquatic insect, *Daphnia magna*, was exposed to pollen collected from Event 176 Corn as compared to pollen collected from nontransgenic control plants. Pollen was chosen as test material because it is likely to be spread by wind and land in lakes and ponds.

b). Survival rates, signs of toxicity, or loss of weight were not observed in earthworms, *Eisenia foetida*, exposed to leaf tissue from Event 176 Corn as compared to the control treatments.

c). Lady beetle (*Coleomegilla maculata*) larval development was not affected when reared on pollen collected from Event 176 Corn plants as compared to pollen from nontransgenic plants.

d). No measurable detrimental effects of ingestion of pollen collected from Event 176 Corn on larval development of honeybees (*Apis mellifera*) was reported.

e). Two lepidopteran insects (fall armyworm and black cutworm) that are not susceptible to native cryIA(b) were likewise not affected when feed cryIA(b) derived from leaf tissues. Three insects (ECB, corn earworm, and cabbage looper) that are susceptible to native cryIA(b) were also susceptible to plant-produced cryIA(b).

f). Results of monitoring of small scale field test indicated no difference in the number of total insects, or the number of specific insect Orders between Event 176 Corn and control nontransgenic corn plants. However, when comparing to insect populations on plants treated with a common chemical insecticide (permethrin) versus Event 176 Corn plants, the total numbers of beneficial insects (especially lady beetles) associated with Event 176 Corn plants were higher.

g), Results from high dose feeding studies of bobwhite quail fed a protein extract enriched in cryIA(b) isolated from Event 176 Corn demonstrated no adverse effects on the bird (Petition, starting on page 180).

h). Ciba presents results from a study using an enriched leaf extract from Event 176 Corn on the soil arthropod *Collembola*, *Folsomia candida*. This insect is one of a number of organisms that recycle plant debris in the field. When the concentrations of cryIA(b) were 200-fold higher than would be expected under natural conditions a reduction in adult survival and the number of offspring was reduced. This observation was not totally unexpected since a related *B. thuringiensis* subsp. *galleriae* has been reported to kill *Collembolla* (Atlavintye et al. 1982; Smulevitch et al. 1991; Nakamura, 1994).

Postharvest monitoring of field test with Event 176 Corn plants showed no increase in visible amount of corn debris when compared to nontransgenic plants. Organophosphate insecticides, used to control corn rootworm, reduce mortality of *Collembolla* (Thompson and Gore, 1972). APHIS concludes that there should be no significant adverse effect on *Collembolla* and no increase in corn plant debris as result of the cultivation of Event 176 Corn plants.

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

The host ranges and habitats of the lepidopteran insect species currently listed or proposed as threatened and endangered in the U.S. were examined to determine if Event 176 Corn might have an adverse impact on these species. None of these species inhabit corn fields or feed on corn. Most of the endangered species usually occur in specialized habitats. Often the habitat or unique plant that these butterflies or moths require for a successful life cycle is disappearing or threatened by human

activities (BBEP-EAD National Endangered Species Database, 1994). For example, Smith's blue butterfly lives in coastal regions around Monterey County, California. Survival of this butterfly is dependent on its larval host food plants, seacliff buckwheat and coast buckwheat. The primary factor limiting the Smith's butterfly is distribution of the two host plants.

APHIS concludes that Event 176 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.

There are currently no commercially available corn hybrids that are resistant to ECB. Although chemical insecticides (organophosphates and pyrethroids) and foliar applied Btk formulations can be effective against ECB, applications must be applied before the insect bores into the stalk. Repeat applications are often necessary. If commercialized, Event 176 Corn could offer an important alternative to chemical insecticides. Only about 5 percent of corn acreage in the U.S. is treated with foliar Btk products. By the same token, widespread and inappropriate use of either Event 176 Corn or increased use of foliar microbial Btk products can and will most likely accelerate the appearance of ECB populations resistant to the Btk insect control protein. The rate with which resistance will develop using either strategy is difficult to predict. The rate depends on many assumptions regarding resistance management strategies, their acceptance and effective implementation by growers, the genetics of ECB resistance to this insecticide, and population and behavioral biology of ECB (Tabashnik 1994a,b; Gould et al. 1994). The implementation of an active resistance management plan that is scientifically sound and acceptable to growers should delay the onset of resistance and provide alternative strategies and methods for managing or containing resistant populations if they occur. Ciba Seeds has implemented strategies to: (1) develop genes for new insect control proteins, (2) monitor ECB susceptibilities to Event 176 Corn plants, and (3) conduct and support research relevant to ECB resistance management. Ciba has stated that it is in their best interest to delay resistance. The EPA has stated that they will work with Ciba to develop product labels and informational brochures that are consistent with resistance management, and this should help define the appropriate use of Event 176 Corn.

If resistant populations persist, insecticides based on the cryIA(b) insect control protein would no longer be effective for controlling ECB on corn (ECB is not a serious pest of other crops). To control resistant ECB populations, producers could use currently registered insecticides, possible including new delta-endotoxins.

Based on this analysis, APHIS concludes that there is unlikely to be any significant adverse impact on agricultural practices associated with the appropriate use of Event 176 Corn. Similar to the consequence of deployment of other insecticides, resistance development in insect pest populations is probable. However, cultivation of ECB-resistant corn plants should pose no greater threat to the ability to control ECB in corn, than that posed by the insecticides already in use.

E. Event 176 Corn will not cause damage to processed agricultural commodities.

In APHIS' opinion, the components and processing characteristics of Event 176 Corn reveal no differences 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 Ciba Seeds that characterized Event 176 Corn. After careful analysis, APHIS has identified no significant impact to the environment from issuance of a determination that Event 176 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. Event 176 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. Event 176 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 Event 176 Corn into wild or cultivated sexually-compatible plants is extremely unlikely, and such rare events should not increase the weediness potential of any resulting progeny or adversely impact biodiversity.
4. Seeds of Event 176 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. Event 176 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 pests.
6. Cultivation of Event 176 Corn should not reduce the ability to control insects in corn and other crops.

Therefore, after review of the available evidence, APHIS concludes that Event 176 Corn will be just as safe to grow as traditionally-bred, lepidopteran insect resistant corn varieties that are not subject to regulation under 7 CFR Part 340. APHIS concludes that there should be no significant impact on the human environment if Event 176 Corn were no longer considered a regulated article under its regulations (7 CFR Part 340).

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VIII. PREPARERS AND REVIEWERS

Biotechnology, Biologics, and Environmental Protection

Terry L. Medley, J.D., Director (Acting Associate Administrator, Animal and Plant Health Inspection Service) John Payne, Ph.D., Associate Director (Acting Director, Biotechnology, Biologics, and Environmental

Protection)

Biotechnology Permits

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

Biotechnology Coordination and Technical Assistance

Michael A. Lidsky, J.D., LL.M., Deputy Director Shirley P. Ingebritsen, M.A., Program Analyst L. Val Giddings, Ph.D., Chief, Science Policy & Coordination Branch 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

Ms. 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