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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. 98-009-2]

Pioneer Hi-Bred International, Inc.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Male Sterility and Glufosinate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Pioneer Hi-Bred International, Inc., corn lines designated as 676, 678, and 680, which have been genetically engineered for male sterility and tolerance to the herbicide glufosinate as a marker, are no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Pioneer Hi-Bred International, Inc., in its petition for a determination of nonregulated status and an analysis of other scientific data. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: May 14, 1998.

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

FOR FURTHER INFORMATION CONTACT: Dr. Subhash Gupta, Biotechnology and Biological Analysis, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-8761. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: mkpeterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 97-342-01p) from Pioneer Hi-Bred International, Inc. (Pioneer), of Johnston, IA, seeking a determination that corn lines designated as 676, 678, and 680, which have been genetically engineered for male sterility and tolerance to the herbicide glufosinate as a marker, do not present a plant pest risk and, therefore, are not regulated articles under APHIS regulations in 7 CFR part 340.

On February 18, 1998, APHIS published a notice in the **Federal Register** (63 FR 8161-8162, Docket No. 98-009-1) announcing that the Pioneer 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 corn lines 676, 678, and 680 and food products derived from them. In the notice, APHIS solicited written comments from the public as to whether these corn lines posed a plant pest risk. The comments were to have been received by APHIS on or before April 20, 1998. APHIS received no comments on the subject petition during the designated 60-day comment period.

Analysis

Corn lines 676, 678, and 680 have been genetically engineered to contain a *dam* gene derived from *Escherichia coli*. The *dam* gene expresses a DNA adenine methylase enzyme in specific plant tissue, which results in the inability of the transformed plants to produce anthers or pollen. The subject corn lines also contain the *pat* selectable marker gene isolated from the bacterium *Streptomyces viridochromogenes*. The *pat* gene encodes a phosphinothricin acetyltransferase (PAT) enzyme, which, when introduced into a plant cell, inactivates glufosinate. Linkage of the *dam* gene, which induces male sterility, with the *pat* gene, a glufosinate tolerance gene used as a marker, enables identification of the male sterile line for the production of hybrid seed. The subject corn lines were transformed by the particle gun process, and expression of the introduced genes is controlled in part by gene sequences derived from the plant pathogen cauliflower mosaic virus.

Corn lines 676, 678, and 680 have been considered regulated articles under APHIS regulations in 7 CFR part 340 because they contain regulatory gene sequences derived from a plant pathogen. However, evaluation of field data reports from field tests of the subject corn lines conducted under APHIS notifications since 1995 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of these corn lines.

Determination

Based on its analysis of the data submitted by Pioneer and a review of other scientific data and field tests of the subject corn lines, APHIS has determined that corn lines 676, 678, and 680: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become a weed than corn lines developed by traditional breeding techniques; (3) are unlikely to increase the weediness potential for any other cultivated or wild species with which they can interbreed; (4) will not cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture. Therefore, APHIS has concluded that corn lines 676, 678, and 680 and any progeny derived from hybrid crosses with other corn varieties will not exhibit new plant pest properties, i.e., properties substantially different from any observed for the subject corn lines already field tested, or those observed for corn in traditional breeding programs.

The effect of this determination is that Pioneer's corn lines designated as 676, 678, and 680 are no longer considered regulated articles under APHIS'

regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of Pioneer's corn lines 676, 678, or 680 or their progeny. However, the importation of the subject corn lines or seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

National Environmental Policy Act

An environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that Pioneer's corn lines 676, 678, and 680 and lines developed from them 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 May 1998.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–14260 Filed 5–28–98; 8:45 am]

BILLING CODE 3410–34–P

USDA/APHIS Petition 97-342-01p for Determination of Nonregulated Status for Genetically Engineered Corn Lines 676, 678, and 680

Environmental Assessment and
Finding of No Significant Impact

May 1998

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 genetically engineered male sterile and glufosinate-tolerant corn lines designated as 676, 678, and 680. APHIS received a petition from the Pioneer Hi-Bred International, Inc., regarding the status of corn lines 676, 678, and 680 as regulated articles 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 for its determination that male sterile and glufosinate-tolerant corn lines 676, 678, and 680 shall no longer be regulated articles.

Rebecca A. Bech
Assistant Director
Scientific Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: MAY 14 1998

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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) before deciding on the regulatory status of genetically engineered male sterile and glufosinate-tolerant corn lines designated as 676, 678, and 680. The developer of the transgenic corn lines, Pioneer Hi-Bred International, Inc., (Pioneer) petitioned APHIS requesting a determination on the regulated status of male sterile and glufosinate-tolerant corn lines 676, 678, and 680 that have been regulated articles under APHIS regulations. Interstate movements and field tests of transgenic corn lines have been conducted under notifications acknowledged by APHIS. Pioneer petitioned APHIS for a determination that the transgenic corn lines 676, 678, and 680 do not present plant pest risk and should, therefore, no longer be regulated articles under APHIS regulations at 7 CFR Part 340.

Male sterile and glufosinate-tolerant corn lines 676, 678, and 680 have been developed to provide a more reliable system to generate hybrid seed corn by genetically engineering a plant to be male sterile. As described in the petition, these corn lines have been genetically engineered to contain a *dam* gene derived from *Escherichia coli*. The *dam* gene expresses a DNA adenine methylase enzyme (Brooks et al., 1983) in specific plant tissue, which results in the inability of the transformed plants to produce anthers or pollen. The subject corn lines also contain the *pat* selectable marker gene isolated from the bacterium *Streptomyces viridochromogenes*. The *pat* gene encodes a phosphinothricin acetyl transferase (PAT) enzyme, which, when introduced into a plant cell, confers tolerance to the herbicide glufosinate. Linkage of the *dam* gene, which induces male sterility, with the *pat* gene, a glufosinate tolerance gene used as a marker, enables identification of the male sterile line for use in the production of hybrid seed. The subject corn lines were transformed by the particle gun process, and expression of the introduced genes is controlled in part by gene sequences derived from the plant pathogen cauliflower mosaic virus (CaMV).

The subject corn lines have been evaluated in field trials conducted since 1995 under APHIS notifications. In the process of reviewing the applications for the U.S. field trials of these corn lines, APHIS determined that the trials, which were conducted under conditions of reproductive and physical containment or isolation, would not present a risk of plant pest introduction or dissemination. However, several issues that are of relevance to the unconfined growth of corn lines 676, 678, and 680 were not addressed in our previous reviews. With respect to these new issues, APHIS concludes the following:

1. Corn lines 676, 678, and 680 exhibit no plant pathogenic properties. Although components of 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. Corn lines 676, 678, and 680 are no more likely to become a weed than male sterile corn that has been 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 male sterility would enable corn to become a weed pest.

3. Multiple barriers, including sterility of these lines, insure that gene introgression from corn lines 676, 678, and 680 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 corn lines 676, 678, and 680 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. Corn lines 676, 678, and 680 exhibit no significant potential to either harm threatened or endangered species or organisms beneficial to the agricultural ecosystem.

Therefore, after a review of the available evidence, APHIS believes that corn lines 676, 678, and 680 will be just as safe to grow as 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 corn lines 676, 678, and 680 and their progeny derived from crosses with other nonregulated corn were no longer considered regulated articles under regulations at 7 CFR Part 340.

II. BACKGROUND

Pioneer has submitted a "Petition for Determination of Non-regulated Status" for corn plants that contain a gene encoding a protein that blocks pollen development, thereby producing a male sterile plant. Pioneer requested a determination from APHIS that corn lines 676, 678, and 680, and any progeny derived from hybrid crosses between these lines and other corn varieties, no longer be considered regulated articles under 7 CFR Part 340.

Development of corn lines 676, 678, and 680. Virtually all corn grown in the U.S. for food and feed is hybrid corn. Hybrid corn, unlike their inbred parents, are vigorous, uniform, and productive due to heterosis (hybrid vigor). A number of hybrid corn seed production systems are used to ensure hybridization by forced pollination between the female and male parental corn lines. Artificial emasculation (detasseling) and male sterility genetic-based systems are currently the most popular. Detasseling involves the physical removal of the tassel from the female plant, either manually or in combination with mechanical devices. The detasseling is probably the most difficult to manage of any of the steps in hybrid corn seed production (Wych, 1988) because the time period is so short. Manual detasseling is labor intensive and expensive.

Male sterile plants can be produced genetically via traditional breeding. One type of sterility is encoded in the nucleus while the other is cytoplasmically inherited. One problem with these sterility genes is that they lack a selectable marker that would allow their identification in a hybrid seed breeding program prior to flowering. If some of the female fertile plants are male-fertile, their pollen cannot be eliminated prior to flowering. This pollen could compete with the pollen from the intended male fertile plants and result in seed that is not the intended hybrid seed.

To generate a male sterile corn plant, a *dam* gene derived from *Escherichia coli* was engineered into corn. The *dam* gene expresses a DNA adenine methylase enzyme (Brooks et al., 1983) in specific plant tissue, which results in the inability of the transformed plants to produce anthers or pollen resulting in a male sterile plant. A selectable genetic marker encoding phosphinothricin acetyl transferase from *Streptomyces viridochromogenes* was introduced into the corn chromosome to facilitate selection of transformed cells in the laboratory and identification of male fertile plants during plant breeding. The genes were introduced via a well-characterized procedure that results in direct introduction of genes into plant genome. Thus, the advantage of corn lines 676, 678, and 680 is that their male-sterility can be verified, by the expression of the marker gene phosphinothricin acetyl transferase, prior to flowering.

Corn lines 676, 678, and 680 have been field tested by Pioneer and its partners in the major corn growing regions of the United States under acknowledgments of notifications since 1995. Corn lines 676, 678, and 680 have been evaluated extensively in laboratory, greenhouse, and field experiments to confirm that they exhibit the desired agronomic characteristics and do not pose a plant pest risk. Although the field tests of corn lines 676, 678, and 680 have been conducted in agricultural settings, the acknowledgment of notifications for the tests have stipulated physical and reproductive confinement.

APHIS Regulatory Authority. APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority under 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, affect 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 regulations and is also a plant pest, or there is reason to believe that it is a plant pest. Corn lines 676, 678, and 680 described in the Pioneer petition have been considered regulated articles 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. Thereafter, 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. Corn lines 676, 678, and 680 may also be subject to regulation by other agencies. The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered before distribution or sale, unless exempt by EPA regulation. In cases in which the genetically modified plants allow for a new use of an herbicide or involve a different use pattern for the herbicide, the EPA must approve the new or different use. Glufosinate has been registered to use on glufosinate tolerant corn under the FIFRA (February 26, 1997). In making such an approval, the EPA considers the possibility of adverse effects to human health and the environment from the use of this herbicide. When the use of the herbicide on the genetically modified plant would result in an increase in the residues of the herbicide in a food or feed crop for which the herbicide is currently registered, or in new residues in a crop for which the herbicide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq.*). The Food and Drug Administration (FDA) enforces tolerances set by the EPA under the FFDCA. The EPA has granted an exemption from the requirement of a tolerance for phosphinothricin acetyl transferase and the genetic material necessary for its production in corn and on all raw agricultural commodities.

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 corn lines 676, 678, and 680 as regulated articles under APHIS regulations. The developer of corn lines 676, 678, and 680, Pioneer has submitted a petition to USDA, APHIS requesting that APHIS make a determination that corn lines 676, 678, and 680 shall no longer be considered regulated articles under 7 CFR Part 340. This EA was prepared in compliance 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).

IV. ALTERNATIVES

A. No Action.

Under the Federal "no action" alternative, APHIS would not come to a determination that corn lines 676, 678, and 680 are no longer a regulated articles under the regulations at 7 CFR Part 340. Notifications to APHIS would still be required for introductions of corn lines 676, 678, and 680. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of corn lines 676, 678, and 680.

B. Determination that corn lines 676, 678, and 680 are no longer regulated articles.

Under this alternative, corn lines 676, 678, and 680 would no longer be regulated articles under the regulations at 7 CFR Part 340. Notifications from APHIS would no longer be required for introductions of corn lines 676, 678, and 680. 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).

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

This EA addresses potential environmental impacts from a determination that corn lines 676, 678, and 680 should no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340. This EA discusses the genetic modification, and the potential environmental impacts that might be associated with the unconfined cultivation of corn lines 676, 678, and 680.

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 corn lines 676, 678, and 680, and the analyses that lead APHIS to conclude that corn lines 676, 678, and 680 have no potential to pose plant pest risks.

A. Potential impacts based on increased weediness of corn lines 676, 678, and 680 relative to other male sterile 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 listed as a noxious weed species by the Federal Government (7 CFR Part 360).

The parent plant of the transgenic corn lines 676, 678, and 680 is an agricultural crop plant that exhibits no appreciable weedy characteristics. The relevant introduced trait, male sterility, is unlikely to increase weediness of corn lines 676, 678, and 680. There is no indication that the presence of a specific DNA adenine methylase enzyme, will convert corn into a weed. Corn plants have also been transformed with a gene phosphinothricin acetyl transferase, 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 indicate that glufosinate will be used in the cultivation of corn. No other attributes of corn lines 676, 678, and 680 suggest that they will be any more "weedy" than the present corn cultivars that are the result of traditional breeding. Corn lines 676, 678, and 680 have retained the agronomic characteristics of the parental corn. Pioneer has provided data regarding seed germination rates, yield characteristics, disease and pest susceptibilities, compositional analyses, and numerous other test reported in the Pioneer' application that support APHIS' conclusion that corn lines 676, 678, and 680 are just as safe to grow as any other male sterile corn.

B. Potential impacts on the sexually-compatible relatives of corn arising from pollination by corn lines 676, 678, and 680.

APHIS evaluated the potential for gene introgression to occur from corn lines 676, 678, and 680 to sexually compatible wild relatives and considered whether such introgression would result in increased weediness. Cultivated corn, or maize, *Zea mays* L. subsp. *mays*, is sexually compatible with other members of the genus *Zea*, and to a much lesser degree with members of the genus *Tripsacum* as described in the Determination Section IV.

Wild diploid and tetraploid members of *Zea* collectively referred to as teosinte are normally confined to the tropical and subtropical regions of Mexico, Guatemala, and Nicaragua; however, a fairly rare, sparsely dispersed feral population of teosinte has been reported in Florida. The Mexican and Central America teosinte populations primarily exist within and around cultivated maize fields; they are partially dependent on agricultural niches or open habitats, and in some cases are grazed upon or fed to cattle which distribute the seed. While some teosinte may be considered to be weeds in certain instances, they are also used by some farmers for breeding improved maize (Sánchez and Ruiz, 1997, and references therein).

All teosinte members can be crossed with cultivated corn to produce fertile F_1 hybrids (Doebley, 1990; Wilkes, 1967; and Jesus Sánchez, personal communication with Susan Koehler, 1998). In areas of Mexico and Guatemala where teosinte and corn coexist, they have been reported to produce hybrids. Of the annual teosintes, *Z. mays* ssp *mexicana* forms frequent hybrids with maize, *Z. luxurians* hybridizes only rarely with maize, whereas populations of *Z. mays* ssp. *parviglumis* are variable in this regard (Wilkes, 1977; Doebley, 1990). Fewer fertile hybrids are found between maize and the perennial *Z. perennis* than are found with *Z. diploperennis* (J. Sánchez, personal communication with Susan Koehler, 1998). Research on sympatric populations of maize and teosinte suggests introgression has occurred in the past, in particular from maize to *Z. mays* ssp. *luxurians* and *Z. mays* ssp. *diploperennis* and from annual Mexican plateau teosinte (*Z. mays* ssp. *mexicana*) to maize (KatoY., 1997 and references therin).

Nonetheless, in the wild, introgressive hybridization from maize to teosinte is currently limited, in part, by several factors including distribution, differing degrees of genetic incompatibility, differences in flowering time in some cases, block inheritance, developmental morphology and timing of the reproductive structures, dissemination, and dormancy (Doebley, 1990; Galinat, 1988). First-generation hybrids are generally less fit for survival and dissemination in the wild, and show substantially reduced reproductive capacity which acts as a significant constraint on introgression. Gene introgression from corn lines 676, 678, and 680 into teosinte would require that varieties be developed, and approved for cultivation in locations where these teosintes

to be cultivated in agricultural regions around centers of *Zea* diversity, there is no reason to expect impacts from corn lines 676, 678, and 680 to be significantly different from those arising from the cultivation of any other variety of male sterile corn.

Any international trade with corn lines 676, 678, and 680 would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC). The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (105 countries as of October 1996). The treaty, now administered by a Secretariat housed within 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 have prepared guidelines. These signatories includes Mexico, which has in place a regulatory process requiring a full evaluation of corn lines 676, 678, and 680 before they can be introduced into the 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.

All the considerable, existing national and international regulatory authorities and phytosanitary protocols that apply to introductions of new male sterile varieties apply equally to those covered by this analysis.

D. 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 corn lines 676, 678, and 680, and plant products derived from it, to have damaging or toxic effects directly or indirectly on nontarget organisms, particularly those that are recognized as beneficial to agriculture and to those that are recognized as threatened or endangered in the United States.

Pioneer's analysis of corn lines 676, 678, and 680 identified no toxic components that are present in concentrations significantly different from concentrations in nontransgenic corn. The genetic modification in corn lines 676, 678, and 680 does not result in the production of new proteins, enzymes, or metabolites in the plant that are known to have toxic properties. The plants also do not exhibit any pathogenic properties.

APHIS concludes that the unconfined growth of corn lines 676, 678, and 680, and products derived from them, will have no deleterious effects on organisms recognized as beneficial to agriculture (e.g., earthworms, honey bees) or on other organisms, including any species recognized as threatened or endangered in the United States.

Because male sterile and herbicide tolerance genes would only be in half of the hybrid seeds sold to farmers, use of this male sterility system does not necessarily provide farmers herbicide tolerant corn. However, if the other parent in the hybrid breeding system was phosphinothricin-tolerant, then plants derived from that hybrid seed would be herbicide tolerant and the farmers could potentially apply the herbicide. The use of phosphinothricin-class of herbicides in the cultivation of transgenic glufosinate has been granted by EPA under its FIFRA regulations (February 26, 1997). As part of the pesticide registration process, EPA considers the impacts on the environment, including nontarget organisms.

E. Potential impacts on biodiversity.

It was determined from our analysis that genetically engineered male sterile and glufosinate-tolerant corn lines 676, 678, and 680 no more likely to become weed than corn lines developed by traditional breeding techniques, are unlikely to increase the weediness potential of any other cultivated plant or native wild species with which these lines can interbreed, and will not harm threatened and endangered species and non-target organisms. Based on this analysis, APHIS concludes that there is no potential impact of these chicory lines on biodiversity.

F. Potential impacts on agricultural and cultivation practices.

Based on its analysis, APHIS concludes that there is unlikely to be any significant adverse impact on agricultural practices associated with the use of corn lines 676, 678, and 680.

G. Corn lines 676, 678, and 680 will not cause damage to raw or processed agricultural commodities.

In APHIS' opinion, the components and processing characteristics of corn lines 676, 678, and 680 reveal no differences in any component that could have an indirect plant pest effect on any raw or processed plant commodity.

VI. CONCLUSION

APHIS has evaluated information from the scientific literature as well as data submitted by Pioneer that characterized corn lines 676, 678, and 680. After careful analysis, APHIS has made a finding of no significant impact to the environment from issuance of a determination that corn lines 676, 678, and 680 should no longer be regulated articles under APHIS regulations at 7 CFR Part 340. That finding is supported by the following conclusions:

1. Corn lines 676, 678, and 680 exhibit no plant pathogenic properties. Although components of 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. Corn lines 676, 678, and 680 are no more likely to become weeds than male sterile corn that has been 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 male sterility would enable corn to become a weed pest.

3. Multiple barriers, including sterility of these lines, insure that gene introgression from the transgenic corn lines 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 corn lines 676, 678, and 680 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. Corn lines 676, 678, and 680 exhibit no significant potential to either harm threatened or endangered species or organisms beneficial to the agricultural ecosystem.

Therefore, after a review of the available evidence, APHIS believes that corn lines 676, 678, and 680 will be just as safe to grow as 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 corn lines 676, 678, and 680 and their progeny derived from crosses with other nonregulated corn were no longer considered regulated articles under regulations at 7 CFR Part 340.

VII. LITERATURE CITED

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Response to Pioneer Hi-Bred International, Inc.'s Petition for a Determination of Nonregulated Status for Male Sterile and Glufosinate-Tolerant Corn Lines 676, 678, and 680

Prepared by
United States Department of Agriculture
Animal and Plant Health Inspection Service
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I. SUMMARY

In a petition dated December 8, 1998, Pioneer Hi-Bred International, Inc., (Pioneer) requested a determination from the Animal and Plant Health Inspection Service (APHIS) that male sterile and glufosinate-tolerant corn lines designated as 676, 678, and 680 and any progeny derived from these lines, should no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340. The male sterile corn lines 676, 678, and 680 have been considered regulated articles because they were engineered with DNA sequences derived from the plant pathogen cauliflower mosaic virus (CaMV).

Based on a review of available scientific information, APHIS has determined that corn lines 676, 678, and 680 do not present plant pest risk and therefore are no longer regulated articles under the regulations at 7 CFR Part 340. Because of this determination, oversight under these regulations will no longer be required from APHIS for field testing, importation, or interstate movement of corn lines 676, 678, and 680 or their progeny.

This determination has been made based on an analysis that revealed that corn lines 676, 678, and 680: (1) exhibit no plant pathogenic properties; (2) are no more likely to become weed than corn lines developed by traditional breeding techniques; (3) are unlikely to increase the weediness potential of any other cultivated plant or native wild species with which corn lines 676, 678, and 680 can interbreed; (4) will not harm threatened and endangered species and other organisms, such as bees, which are beneficial to agriculture; and 5) will not cause damage to raw or processed agricultural commodities. APHIS has also concluded that there is no reason to believe that progeny corn varieties derived from corn lines 676, 678, and 680 will exhibit new plant pest properties, i.e., properties substantially different from any observed for the corn lines 676, 678, and 680 already field tested, or those observed for corn in traditional breeding programs.

II. BACKGROUND

APHIS Regulatory Authority. APHIS regulations found at 7 CFR Part 340 (hereafter referred to as the regulations) 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. The regulations pertain to 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 regulations and is also a plant pest, or there is reason to believe that it is a plant pest. Corn lines 676, 678, and 680 have been considered "regulated articles" under Part 340 of the regulations because they have been engineered with certain noncoding regulatory sequences derived from the plant pathogens such as CaMV.

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 information 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. As a consequence of such a determination, APHIS permits would no longer be required for field testing, importation, or interstate movement of that article or its progeny.

APHIS' decision on the regulatory status of corn lines 676, 678, and 680 under APHIS' regulations at 7 CFR 340, does not release these transgenic lines and their progeny from EPA and FDA regulatory oversight. The use of glufosinate herbicide on corn is under the jurisdiction of the EPA.

III. COMMENTS

On February 18, 1998, APHIS published a notice in the Federal Register (63 FR 8161-8162, Docket No. 98-009-1) announcing that the Pioneer petition had been received and was available for public review. In the notice, APHIS solicited written comments from the public on any plant pest risk issues associated with the subject corn lines 676, 678, and 680. The comments were to have been received by APHIS on or before April 20, 1998. APHIS received no comments on the subject petition during the designated 60-day comment period.

IV. ANALYSIS OF CORN LINES 676, 678, and 680

Biology of Corn (Maize). *Zea mays* L. ssp. *mays* (2n=20), known as maize throughout most of the world, and as corn in the United States, is a large, annual, diploid, monoecious, wind-pollinated grass, that is grown for human consumption, animal feed, silage, vegetable oil, sugar syrups, and other miscellaneous uses. Corn is grown commercially throughout the United States (Jewell, 1989). Corn has been cultivated since the earliest historic times from Peru to central North America. The origin is presumed to be Mexico (Gould, 1968).

Zea is a genus of the family Gramineae (the grass family, alternatively referred to as Poaceae). In addition to cultivated corn, the genus *Zea* also includes several distinct wild taxa, all native to Mexico and Central America, which are collectively referred to

as teosintes. All teosintes can be crossed to maize, and they all form fertile hybrids with maize (Doebley, 1990; Wilkes, 1967; and Jesus Sánchez, Coordinator of Genetic Resources, The Mexican National Institute of Forestry, Agriculture, and Livestock Research, Mexico, personal communication with Dr. Susan Koehler, 1998). The distribution, and the taxonomic and evolutionary background of maize and teosintes have been reviewed (Doebley, 1990; Wilkes, 1997; Sánchez and Ruiz, 1997). Wilkes (1967) presented a classification system for teosinte which provided different geographic populations with racial designations. This classification has been modified by Iltis and Doebley (1980) and Doebley (1990) to attempt to place the taxa in a sequence which reflects their evolutionary relationships, based on morphological and ecological features and molecular systematics. As presented by Doebley (1990), *Zea* is divided into two sections, *Zea* and *Luxuriantes* Doebley & Iltis.

Section *Zea*, which includes *Zea mays* ssp. *mays*, also includes its more closely related annual, diploid (2n=20) teosintes: *Z. mays* ssp. *mexicana* (Schrader) Iltis, a large-flowered, mostly weedy teosinte distributed broadly across the central highlands of Mexico; *Z. mays* ssp. *parviglumis* Iltis and Deobley, a small-flowered, mostly wild teosinte of southern and western Mexico; and *Z. mays* ssp *huehuetenangensis* (Iltis and Doebley) Doebley, a narrowly distributed teosinte of Guatemalan western highlands.

Section *Luxuriantes* contains the other teosintes which are more clearly distinguished from maize by both morphological, biochemical, and cytogenetic characteristics, and which are more narrowly distributed. These include another annual, diploid teosinte, *Z. luxurians* (Durieu and Ascherson) Bird, found in southeastern Guatemala (Doebley, 1990) and in Oaxaca, Mexico (Sánchez and Ruiz, 1997), and two perennial teosinte species found only in Jalisco, Mexico - the diploid *Z. diploperennis* Iltis, Doebley, and Guzman, and the tetraploid (2n=40) *Z. perennis* (Hitchc.) Reeves and Mangelsdorf.

The closest generic relative to *Zea* is *Tripsacum*, a genus of no fewer than 16 species, most of which are native to Mexico, Central, and South America, and three of which occur in the United States (Gould, 1968; Galinat, 1988). Species occurring in the United States include: *T. floridanum* Porter ex Vassy (2n=36) which is native to Southern Florida; *T. dactyloides* including 2n=36 forms which are native to the central and western U.S., and 2n=72 forms which extend along the Eastern seaboard and along the Gulf Coast from Florida to Texas; and *T. lanceolatum* (2n=72) which occurs in the Southwestern U.S. *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 primarily male and female sterile (Galinat, 1988).

Corn is now grown worldwide and used primarily for animal feed, human food, and for the production of materials used in industry. According to agricultural statistics for 1993 and 1994, (USDA, 1994), approximately 22% of the world's total corn seed is planted in the United States, yielding 45% of the world production. In the United States corn exceeds all other major crops with regard to acres harvested and crop value.

Rationale for Development of Male Sterile Corn. Virtually all the corn grown in the U.S. for food and feed is hybrid corn. Hybrid corn, unlike their inbred parents, is vigorous, uniform and high yielding. A number of hybrid corn seed production systems are in use to ensure hybridization by forced pollination between the female and male parental corn lines. Artificial emasculation (detasseling) and male sterility genetic-based systems are currently the most poplar methods. Detasseling involves the physical removal of the tassel from the female plant, either manually or in combination with mechanical devices. Detasseling is probably the most difficult to manage of any of the steps in hybrid corn seed production (Wych, 1988). The detasseling period is short. Manual detasseling is a labor intensive and expensive operation.

Male sterile plants can be produced genetically via traditional breeding. One type of sterility genes is encoded in nucleus while the other is cytoplasmically inherited. One of the problems of using these sterility genes is that they lack a selectable marker that would allow their identification in a hybrid seed breeding program before flowering. Breeders need a simple way of eliminating the male fertile segregants before flowering to the design of an efficient hybrid seed production scheme. The most common system used today uses a mix of male sterile plants emasculated by detasseling mixed with genetically (cytoplasmically) sterile plants. Pollen is provided by a limited number of male fertile plants in the field.

Development of Corn Lines 676, 678, and 680. Male sterile and glufosinate-tolerant corn lines 676, 678, and 680 have been developed to provide a more reliable system to generate hybrid seed corn by genetically engineering a plant to be male sterile. As described in the petition, these corn lines, have been genetically engineered to contain an adenine methylase, or *dam* gene derived from *Escherichia coli* (Brooks et al., 1983). The *dam* gene expresses a DNA adenine methylase enzyme (DAM) in specific plant tissue, which results in the inability of the transformed plants to produce anthers or pollen. The subject corn lines also contain the *pat* selectable marker gene isolated from the bacterium *Streptomyces viridochromogenes*. The *pat* gene encodes a phosphinothricin acetyl transferase (PAT) enzyme (Thompson et al., 1987), which, when introduced into a plant cell, confers tolerance to the herbicide glufosinate. Linkage of the *dam* gene, which induces male sterility, with the *pat* gene, a glufosinate tolerance gene used as a marker, enables identification of the male sterile line for use in the production of hybrid seed. The subject corn lines were transformed by the particle gun process (Klein et al., 1987) and expression of the introduced genes is controlled in part by gene sequences derived from the plant pathogen CaMV.

Although corn lines 676, 678, and 680 are tolerant to the herbicide, hybrid progeny (the seeds that would be available to the farmers) developed from this line may or may not be tolerant to the herbicide. If the female parent is not herbicide tolerant, then only half of the progeny hybrid corn would carry the tolerance gene. This would mean that farmers could not apply the herbicide because 50 per cent of the plants would die. However, if the female parent in the hybrid selection scheme was glufosinate tolerant, all the progeny would herbicide tolerant and farmers could apply the herbicide. EPA has granted a registration for the use of glufosinate on glufosinate tolerant corn under the FIFRA (February 26, 1997).

A. The introduced genes, their products, and the added regulatory sequences controlling their expression do not present a plant pest risk in corn lines 676, 678, and 680.

As summarized above, the genetic construct was introduced through particle gun bombardment. Micro-projectile bombardment was used to carry purified insert DNA into plant cells. Once inserted into the chromosome of the corn plant, the introduced genes are maintained and transmitted in the same manner as any other genes as demonstrated by Mendelian data presented by applicant.

Expression of the phosphinothricin acetyl transferase in corn lines 676, 678, and 680 is directed by noncoding DNA regulatory sequences derived from the plant pathogen cauliflower mosaic virus. These regulatory sequences are utilized widely in the expression of genes engineered into plants (Odell et al., 1985). Although these regulatory sequences are derived from a plant pathogen, there is no evidence to suggest that they pose a plant pest risk. These sequences do not code for a protein and are not implicated in disease pathogenesis.

B. Corn lines 676, 678, and 680 have no significant potential to become successful weed.

Corn is not considered a weed. Many of the changes involved in the domestication of corn from teosinte and wild type maize have resulted in a domestic corn plant that exhibits high yielding capacity, non-shattering of mature seed and ease in harvest, but these changes also have led to a species unable to exist on its own in the wild. Domesticated corn has also lost its perennial nature and its ability to remain viable in the soil for long periods. The many agronomic traits that make maize an outstanding crop species also make it largely dependent on humans for its survival. In the United States, corn that is grown in rotation with soybeans may volunteer on occasion.

A weed pest is a plant that grows persistently in locations where it is unwanted. Corn has been grown for centuries throughout the world without any reports that it is a

serious weed pest. In the United States, it is not a species listed under the Federal Noxious Weed Act. Corn is not classified as a serious, principal, or common weed pest (Holm et al., 1979). Corn is considered a highly domesticated, well-characterized crop plant that is not persistent in undisturbed environments without human intervention.

Evaluations of corn lines 676, 678, and 680 in laboratory, greenhouse, and field tests support the conclusion that corn lines 676, 678, and 680 have little potential to become weed pest. With the exception of the tolerance to glufosinate, corn lines 676, 678, and 680 have agronomic traits similar to those of traditionally bred male-sterile corn and do not exhibit traits that cause concern that they might become weed pests.

C. Corn lines 676, 678, and 680 will not increase the weediness potential of any other plant with which it can interbreed.

APHIS considered whether the movement of the male sterility gene and the other genes from corn lines 676, 678, and 680 to other cultivated corn or wild relatives might result in offspring that would present problems as weeds. First, the corn lines 676, 678, and 680 are male sterile, thus significantly reducing the likelihood of outcrossing. Second, the genetic integrity of commercial cultivated corn lines and varieties is carefully controlled through established plant breeding practices. These standard practices make it unlikely that this trait will be inadvertently incorporated into the germplasm of cultivated corn lines (Doebley, 1984).

D. Corn lines 676, 678, and 680 will not harm organisms beneficial to agriculture or organisms that are designated as threatened or endangered.

APHIS evaluated the potential for corn lines 676, 678, and 680 plants to harm organisms either directly or indirectly, particularly those organisms that are recognized as beneficial to agriculture. There is no reason to believe that the cultivation of corn lines 676, 678, and 680 or their progeny will exert any deleterious effects on organisms recognized as beneficial to agriculture. Likewise, cultivation of corn lines 676, 678, and 680 will not harm any species designated as threatened or endangered. Corn lines 676, 678, and 680 produce two enzymes, DNA adenine methylase and phosphinothricin acetyl transferase, that are not produced in nontransgenic corn. There is no indication that these enzymes are toxic to beneficial organisms or result in the production of toxic constituents. In addition, APHIS can envision no plausible mechanism whereby corn lines 676, 678, and 680 would be injurious or pathogenic to beneficial organisms such as bees and earthworms.

The definition of corn lines 676, 678, and 680 encompasses not only the corn lines that have already been field tested, but also new corn lines produced through conventional breeding using corn lines 676, 678, and 680 as one or both parents. APHIS believes that the analysis applied to the corn lines 676, 678, and 680 plants already field tested will apply equally well to these new corn lines, and that the data provided by Pioneer justify the conclusion that such new lines derived from corn lines 676, 678, and 680 will not present a plant pest risk. The variation in agronomic characteristics among the corn lines 676, 678, and 680 plants that have been field tested does not differ significantly from that seen in commercial cultivars of corn that have never been considered regulated articles. Therefore, there is no reason to believe that any of the progeny of corn lines 676, 678, and 680 will possess plant pest properties.

E. Corn lines 676, 678, and 680 should not cause damage to raw or processed agricultural commodities.

The characteristics of corn lines 676, 678, and 680 have no apparent attributes that could have an indirect plant pest effect on any raw or processed plant commodity. During extensive testing in the laboratory, greenhouse and in the field, plants of corn lines 676, 678, and 680 exhibited the typical agronomic characteristics of the parent corn. In APHIS' opinion, the components and processing characteristics of corn lines 676, 678, and 680 reveal no differences in any component that could have an indirect plant pest effect on any raw or processed plant commodity.

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