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Notices

Federal Register

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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.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 00-078-2]

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

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SUMMARY: We are advising the public of our determination that the Monsanto Company corn designated as Event MON 863, which has been genetically engineered for insect resistance, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms and products. Our determination is based on our evaluation of data submitted by Monsanto Company in its petition for a determination of nonregulated status, our analysis of other scientific data, and comments received from the public in response to a previous notice. This notice also announces the availability of our written determination document and our finding of no significant impact.

EFFECTIVE DATE: October 8, 2002.

ADDRESSES: You may read a copy of the determination, an environmental assessment and finding of no significant impact, the petition for a determination of nonregulated status submitted by Monsanto Company, and all comments received on the petition and the environmental assessment

in our reading room. The reading room is located in room 1141, USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure that someone is available to help you, please call (202) 690-2817 before coming.

APHIS documents published in the Federal Register, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-8365. 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: [Kay.Peterson@aphis.usda.gov](mailto:Kay.Peterson@aphis.usda.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

On May 17, 2001, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 01-137-01p) from Monsanto Company (Monsanto) of St. Louis, MO, requesting a determination of nonregulated status under 7 CFR part 340 for corn (*Zea mays* L.) designated as Corn Rootworm Protected Corn Event MON 863 (MON 863), which has been genetically engineered for resistance to the larvae of certain corn rootworm (CRW) species. The Monsanto petition stated that the subject corn should not be regulated by APHIS because it does not present a plant pest risk.

On March 14, 2002, APHIS published a notice in the Federal Register (67 FR 11458-11459, Docket No. 00-078-1) announcing that the Monsanto petition and an environmental assessment (EA) were available for public review. This notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn and food products derived from it. APHIS received 1,383 comments on the petition and the EA during the 60-day comment period, which ended May 13, 2002. The comments were received from private individuals, farmers (including corn growers and organic farmers), universities, seed companies, State governors, State department of agriculture directors, State corn growers' associations, State and regional agricultural business and trade associations, a national corn growers' association, an organic trade association, a State seed association, a consumer group, an environmental organization, a university cooperative extension specialist, an agronomic consultant, and a corn product manager. There were 542 comments in support of the subject petition, and 841 were opposed. The comment letters in support of deregulation for MON 863 stressed the environmental benefits of using MON 863 to control CRW, including the reductions in pesticide use and user exposure to toxic chemicals, reductions in farm labor time and costs, the effectiveness and consistency of MON 863 in controlling CRW, and the advantages to growers in increased yields and crop quality. Other comments in favor of deregulation for the subject corn concerned the absence of evidence of plant pest and environmental risk presented by MON 863.

The comments in opposition to deregulation for MON 863 corn included allegations concerning the potential for polluting the purity of organically grown corn, the inevitability of the development of insect resistance to *Bacillus thuringiensis* (Bt) and the consequent loss to organic farmers of the spray form of Bt, the toxic effects of

Bt-containing pollen on nontargets, the potential for upsetting the microbial balances in the soil, the possible development of human allergic reactions to Bt corn, and the need for a moratorium on genetically engineered crops due to the alleged inadequacy of U.S. regulation of genetically engineered crops. One commenter contended that a full environmental impact assessment was required prior to commercial growing of MON 863 corn because allowing large-scale commercialization of this corn constituted a major Federal action significantly affecting the environment. The commenter further found the EA inadequate in its treatment of the potential for the development of insect resistance to the Cry 3Bb1 protein, the unavailability to the public of certain information on nontarget effects, the failure to address the cumulative issue of gene stacking through cross-pollination, the failure to address the susceptibility of MON 863 to corn stunt disease, the failure to adequately address the impacts on organic farmers of contamination by transgenic varieties, the failure to

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address the economic impacts on U.S. corn farmers of the loss of European markets, and the failure to address the environmental impacts of the illegal grant of certain genetic resources from the public trust into the possession of commercial entities. One additional comment concerned the need for study of the impacts of Bt corn in the ruminant and human diets and the potential for lateral gene flow in the enteric milieu. We have provided responses to these comments as an attachment to our finding of no significant impact, which is available from the person listed under FOR FURTHER INFORMATION CONTACT.

MON 863 corn has been genetically engineered to express a Cry3Bb1 insecticidal protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kumamotoensis* (*Bt kumamotoensis*). The petitioner stated that the Cry3Bb1 protein is effective in controlling the larvae of CRW pests (*Coleoptera*, *Diabrotica* spp.). The subject corn also contains the nptII marker gene derived from the bacterium *Escherichia coli*. The nptII gene encodes neomycin phosphotransferase type II and is used as a selectable marker in the initial laboratory stages of plant cell selection. Expression of the added genes is controlled in part by gene sequences from the plant pathogens cauliflower mosaic virus and *Agrobacterium tumefaciens*. Particle gun acceleration technology was used to transfer the added genes into the recipient inbred yellow dent corn line A634.

The subject corn has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. This corn has been field tested since 1998 in the United States under APHIS notifications. In the process of reviewing the notifications for field trials of the subject corn, APHIS determined that the vectors and other elements were disarmed and 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.

#### Determination

Based on its analysis of the data submitted by Monsanto, a review of other scientific data, field tests of the subject corn, and comments submitted by the public, APHIS has determined that MON 863 corn: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than corn developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other

cultivated or wild species with which it can interbreed; (4) will not harm threatened or endangered species or organisms, such as bees, that are beneficial to agriculture; and (5) will not cause damage to raw or processed agricultural commodities. Therefore, APHIS has concluded that the subject corn and any progeny derived from hybrid crosses with other nontransformed corn varieties will be as safe to grow as corn in traditional breeding programs that is not subject to regulation under 7 CFR part 340.

The effect of this determination is that Monsanto's MON 863 corn is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the subject corn or its progeny. However, importation of MON 863 corn 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 EA was 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 MON 863 corn and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and FONSI are available upon request from the individual listed under the FOR FURTHER INFORMATION CONTACT section of this notice.

Done in Washington, DC, this 17th day of October 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

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