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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 96-098-2]

Dupont Agricultural Products; Availability of Determination of Nonregulated Status for Genetically Engineered Soybeans

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Dupont Agricultural Products' soybeans designated as sublines G94-1, G94-19, and G168 derived from transformation event 260-05 which have been genetically engineered to produce high oleic acid oil, 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 Dupont Agricultural Products 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 7, 1997.

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.

FOR FURTHER INFORMATION CONTACT: Dr. Ved Malik, BSS, 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 January 8, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 97-008-01p) from Dupont Agricultural Products (Dupont) of Wilmington, DE, seeking a determination that soybeans designated as sublines G94-1, G94-19, and G168 derived from transformation event 260-05 (sublines G94-1, G94-19, and G168) which have been genetically engineered to produce high oleic acid oil, do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On February 28, 1997, APHIS published a notice in the **Federal Register** (62 FR 9155-9156, Docket No. 96-098-1) announcing that the Dupont petition had been received and was available for public review. The notice also discussed the role of APHIS and the Food and Drug Administration in regulating the subject soybean sublines and food products derived from them. In the notice, APHIS solicited written comments from the public as to whether these soybean sublines posed a plant pest risk. The comments were to have been received by APHIS on or before April 29, 1997. APHIS received no comments on the subject petition during the designated 60-day comment period.

Analysis

Sublines G94-1, G94-19, and G168 have been genetically engineered to contain the GmFad2-1 gene, which causes a coordinate silencing of itself and the endogenous GmFad2-1 gene. Suppression of the GmFad2-1 gene in developing soybeans prevents the addition of a second double bond to oleic acid, resulting in a greatly increased oleic acid content only in the seed. Oil from this seed contains an abundance of monosaturated oleic acid (82-85 percent), a reduced concentration of polysaturated fatty acids, and lower palmitic acid content. While the subject soybean sublines also contain the GUS and Amp marker

genes, tests indicate that these genes are not expressed in the soybean plants. The added genes were introduced into meristems of the elite soybean line A2396 by the particle bombardment method, and their expression is controlled in part by gene sequences from the plant pathogens *Agrobacterium tumefaciens* and cauliflower mosaic virus.

The subject soybean sublines have been considered regulated articles under APHIS' regulations in 7 CFR part 340 because they contain gene sequences derived from plant pathogens. However, evaluation of field data reports from field tests of these soybeans 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 sublines G94-1, G94-19, and G168.

Determination

Based on its analysis of the data submitted by Dupont and a review of other scientific data and field tests of the subject soybeans, APHIS has determined that sublines G94-1, G94-19, and G168: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become weeds than soybean 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 harm threatened or endangered species or other 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 soybean sublines and any progeny derived from hybrid crosses with other nontransformed soybean varieties will be as safe to grow as soybeans in traditional breeding programs that are not subject to regulation under 7 CFR part 340.

The effect of this determination is that Dupont's soybean sublines G94-1, G94-19, and G168 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 the subject soybean sublines or their progeny. However,

importation of soybean sublines G94-1, G94-19, and G168 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, as amended (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). Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that Dupont's soybean sublines G94-1, G94-19, and G168 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 14th day of May 1997.

Donald W. Luchsinger,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97-13115 Filed 5-19-97; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 97-006-2]

Calgene, Inc.; Availability of Determination of Nonregulated Status for Genetically Engineered Cotton

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Calgene, Inc., cotton lines designated as BXN[®] with Bt cotton lines derived from transformation events 31807 and 31808 which have been genetically engineered for tolerance to the herbicide bromoxynil and resistance to lepidopteran insect pests, 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 Calgene,

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: April 30, 1997.

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.

FOR FURTHER INFORMATION CONTACT: Dr. James White, BSS, 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 January 13, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 97-013-01p) from Calgene, Inc., (Calgene) of Davis, CA, seeking a determination that cotton lines designated as BXN[®] with Bt cotton lines derived from transformation events 31807 and 31808 (events 31807 and 31808), which have been genetically engineered for bromoxynil herbicide tolerance and lepidopteran insect pest resistance, do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On February 21, 1997, APHIS published a notice in the **Federal Register** (62 FR 7996-7997, Docket No. 97-006-1) announcing that the Calgene petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject cotton lines and food products derived from them. In that notice, APHIS solicited written comments from the public as to whether these cotton lines posed a plant pest risk. The comments were to have been received by APHIS on or before April 22, 1997. During the designated 60-day comment period, APHIS received no comments on the subject petition.

Analysis

Events 31807 and 31808 have been genetically engineered to express a nitrilase enzyme isolated from *Klebsiella pneumoniae* subsp. *ozaenae*, which degrades the herbicide bromoxynil, and a CryIA(c) insect control protein originally derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* HD-73 (Bt). The subject cotton lines also express the *nptII* gene, which codes for the enzyme neomycin phosphotransferase and has been used as a selectable marker in the development of the transgenic cotton plants. Expression of the added genes is controlled in part by noncoding DNA sequences derived from the plant pathogens *Agrobacterium tumefaciens* and cauliflower mosaic virus. The *Agrobacterium* transformation method was used to transfer the added genes into the Coker 130 parental cotton plants.

The subject cotton lines have been considered regulated articles under APHIS' regulations in 7 CFR part 340 because they contain gene sequences derived from plant pathogens. However, evaluation of field data reports from field tests of the cotton lines conducted under APHIS notifications since 1994 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of events 31807 and 31808.

Determination

Based on its analysis of the data submitted by Calgene and a review of other scientific data and field tests of the subject cotton plants, APHIS has determined that events 31807 and 31808: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become weeds than cotton 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; (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture; and (6) should not reduce the ability to control insects in cotton or other crops when cultivated. Therefore, APHIS has concluded that the subject cotton lines and any progeny derived from hybrid crosses with other nontransformed cotton varieties will be as safe to grow as cotton in traditional breeding programs that are not subject to regulation under 7 CFR part 340.