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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 02-006-2]

Monsanto Co.; Extension of Determination of Nonregulated Status for Canola Genetically Engineered for Glyphosate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to extend to one additional canola event our determination that a canola line developed by Monsanto Company, which has been genetically engineered for tolerance to the herbicide glyphosate, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our decision is based on our evaluation of data submitted by Monsanto Company in its request for an extension of a determination of nonregulated status, an analysis of other scientific data, and a comment received from the public in response to a previous notice. This notice also announces the availability of our finding of no significant impact.

EFFECTIVE DATE: January 2, 2003.

ADDRESSES: You may read copies of the extension request, the environmental assessment and finding of no significant impact, and the comment received on an earlier notice of the availability of the environmental assessment in our reading room. The reading room is located in room 1141 of the 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 someone is there 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. James White, Biotechnology Regulatory Services, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5940. To obtain a copy of the extension request 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.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

Background

On November 20, 2001, APHIS received a request for an extension of a determination of nonregulated status (APHIS No. 01-324-01p) from Monsanto Company (Monsanto) of St. Louis, MO, for a canola (*Brassica napus* L.) transformation event designated as glyphosate-tolerant canola event GT200 (GT200), which has been genetically engineered for tolerance to the herbicide glyphosate. Monsanto requested an

extension of a determination of nonregulated status that was issued for Roundup Ready® canola line RT73, the antecedent organism, in response to APHIS petition number 98-216-01p (see 64 FR 5628-5629, Docket No. 98-089-2, published February 4, 1999). Based on the similarity of GT200 to the antecedent organism RT73, Monsanto requested a determination that glyphosate-tolerant canola event GT200 does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On February 28, 2002, APHIS published a notice in the **Federal Register** (67 FR 0247-0248, Docket No. 02-006-1) announcing that an environmental assessment (EA) for the Monsanto extension request had been prepared and was available for public comment. APHIS received one comment on the subject EA during the 30-day comment period, which ended April 1, 2002. The comment, which was from a consumer organization, urged denial of the subject extension request based on alleged deficiencies in the environmental assessments prepared for the antecedent organism and event GT200 canola. We have provided a response to this comment in an addendum to the finding of no significant impact (FONSI). The EA and FONSI are available from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Analysis

Like the antecedent organism, canola event GT200 has been genetically engineered to express an enzyme, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), from *Agrobacterium* sp. strain CP4, and the glyphosate oxidoreductase (GOX) gene/protein from *Ochrobactrum anthropi* strain LBAA, both of which impart tolerance to the herbicide glyphosate. The subject canola and the antecedent organism were produced through use of the *Agrobacterium tumefaciens* method to transform the parental canola variety Westar. Expression of the added genes in GT200 and the antecedent organism is controlled in part by gene sequences derived from the plant pathogen figwort mosaic virus.

Canola event GT200 and the antecedent organism were genetically engineered using the same

transformation method and contain the same enzymes that make the plants tolerant to the herbicide glyphosate. Accordingly, we have determined that canola event GT200 is similar to the antecedent organism in APHIS petition number 98-216-01p, and that canola event GT200 should no longer be regulated under the regulations in 7 CFR part 340.

The subject canola has been considered a regulated article under APHIS regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogens. However, GT200 has been approved for unconfined environmental release and food and feed use in Canada since 1997, with no subsequent reports of deleterious effects on plants, nontarget organisms, or the environment.

Determination

Based on an analysis of the data submitted by Monsanto and a review of other scientific data, APHIS has determined that canola event GT200: (1) Exhibits no plant pest characteristics; (2) is no more likely to become a weed than non-transformed traditional varieties; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it 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 canola event GT200 and any progeny derived from crosses with other canola varieties will be as safe to grow as canola that is not subject to regulation under 7 CFR part 340.

Because APHIS has determined that the subject canola event does not present a plant pest risk based on its similarity to the antecedent organism, Monsanto's canola event GT200 will no longer be 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 field testing, importation, or interstate movement of the subject canola event or its progeny. However, importation of canola event GT200 and seeds capable of propagation is 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 any potential environmental impacts associated with the proposed extension of a determination of nonregulated status. 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 FONSI with regard to the determination that Monsanto's canola event GT200 and events developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of Monsanto's extension request and the EA and FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 26th day of November 2002.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 01-060-2]

Vector Tobacco; Availability of Determination of Nonregulated Status for Tobacco Genetically Engineered for Reduced Nicotine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Vector Tobacco (USA) Ltd. tobacco designated as Vector 21-41, which has been genetically engineered for reduced nicotine, 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 Vector Tobacco (USA) Ltd. 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: September 16, 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 Vector Tobacco (USA) Ltd., and all comments received on the petition and the environmental assessment in our reading room. The reading room is located in room 1141 of the 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 someone is there 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. Susan Koehler, Biotechnology Regulatory Services, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-4886. 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.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2001, the Animal and Plant Health Inspection (APHIS) received a petition (APHIS Petition No. 01-121-01p) from Vector Tobacco (USA) Ltd. (Vector) of Durham, NC, requesting a determination of nonregulated status under 7 CFR part 340 for tobacco (*Nicotiana tabacum* L.) designated as Vector 21-41, which has been genetically engineered to produce a very low level of nicotine. The Vector petition states that the subject tobacco should not be regulated by APHIS because it does not present a plant pest risk.

On February 12, 2002, APHIS published a notice in the **Federal Register** (67 FR 6480-6481, Docket No. 01-060-1) announcing that the Vector petition was available for public review. In the notice, APHIS solicited comments from the public on whether this tobacco presents a plant pest risk. APHIS also made available for public comment an environmental assessment for the proposed determination of nonregulated status. APHIS received 45 comments on the petition and the environmental assessment during the 60-day comment period which ended April 15, 2002. The comments were received from tobacco farmers, tobacco companies, State