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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. APHIS–2006–0167]

APHIS Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability of policy statement.

SUMMARY: This notice describes the Animal and Plant Health Inspection Service's (APHIS) policy for responding to low-levels of regulated genetically engineered plant materials which may occur in commercial seeds or grain. This notice is intended to provide clarification for the public and developers of genetically engineered plants on APHIS' response to such situations. The policy statement does not confer any rights upon or create any rights for any person and does not operate to bind APHIS or the public, nor does it address how other Federal agencies might respond to such situations.

ADDRESSES: Copies of the policy statement are available on the Internet at *http://www.aphis.usda.gov/biotechnology/current_initiatives.shtml*. Copies may also be obtained by contacting Dr. John Turner, Director, Policy Division, BRS, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737–1238; (301) 734–8365.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Policy Division, BRS, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737–1238; (301) 734–8365.

SUPPLEMENTARY INFORMATION:

Background

APHIS works to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered (GE) plants. Under the authority of the Plant Protection Act [1] (PPA), APHIS regulates the introduction (importation, interstate movement, and field release) of GE organisms in order to prevent direct or indirect risks to plant health and the environment.

Genetic engineering is a method used to introduce new traits into plants by moving genes from one or more organism(s) into a second organism. GE plants that can tolerate herbicides, resist insects or viruses, or enhance nutrition and provide other health or environmental benefits are examples of crops currently being grown and tested.

Plant breeding may occasionally result in low-level mixing of genes and gene products from unintended plant sources. This is true for both conventionally bred plants as well as biotechnology-derived plants. These occurrences can result from natural processes such as the movement of seeds or pollen, or human-mediated processes associated with field testing, plant breeding, or seed production. The mixing of low levels of GE plant materials may result in unauthorized introductions of regulated materials in, for example, commercial seeds and grain. The potential for these occurrences may increase with the expansion of GE crop research, development, and use. This document is intended to describe how APHIS protects agriculture and the environment by responding to situations involving a low-level mixing with commercial seeds and grains of genes and gene products from GE plants subject to regulation by APHIS under 7 CFR part 340.

Overview of the APHIS Regulatory System for GE Plants

A developer wishing to introduce a new GE plant must obtain APHIS' authorization before proceeding. Depending on the nature of the GE plant, the developer files either a notification or a permit application with APHIS. With either process, the developer must adhere to APHIS regulations and requirements to ensure, through appropriate measures, confinement of the regulated material. An applicant must submit required information on the movement, importation, or field release, which APHIS scientists review to determine whether to authorize the applicant's request. To ensure compliance with the permit or notification conditions, APHIS performs targeted inspections and audits of field tests using the relative risk of each type of trial to determine the frequency and number of inspections performed. For example, for sites where developers are cultivating GE plants engineered to produce pharmaceutical and industrial proteins, APHIS generally inspects seven times throughout field testing, including before, during, and after the field trial. APHIS also maintains oversight of the movement of regulated plants to and from field trial locations. Regulated plants must be transported according to the regulations and as described in the permit. The methods of transport are subject to verification by inspectors at the receiving facility. This permitting and notification system is designed to restrict introductions of GE plants and plant materials as long as they are regulated by the Agency.

Permits are generally more restrictive than notifications and are used for any type of GE plant that may pose an elevated risk to plant health or the environment or for which APHIS has less regulatory experience and familiarity, such as plants engineered to produce pharmaceutical or industrial compounds. In addition to detailed information on the biological properties of the GE plant, the permit applicant also must provide detailed descriptions of how field tests will be performed, including specific measures for ensuring confinement and reducing any potential risk that may be associated with the GE plant. Using this information, APHIS scientists create a set of permit conditions that applicants must meet when conducting approved field trials or transporting the GE plants.

Most GE plants qualify for, and are field tested under, the notification process. The notification process is used only for plants and traits with which APHIS has a great deal of regulatory experience and familiarity and that do not pose an elevated risk for plant

[1] The Plant Protection Act is found at 7 U.S.C. 7701 *et seq.* APHIS' biotechnology regulations are found at 7 CFR part 340.

health or the environment. To qualify for the notification process, a plant or trait must meet six safety-related eligibility criteria that center on the plant's potential to pose a risk to plant health or the environment. To ensure confinement, the developer must perform the field test in a way that meets performance standards that are specified in APHIS' regulations.[2] If a GE plant does not meet the criteria for notification, the applicant must follow the permitting process.

After a GE plant has been field-tested extensively and the developer can show that the GE plant does not pose a plant pest risk, the developer may file a petition for deregulation. The developer must submit extensive information about the plant's biology and field test results. After conducting an environmental assessment (EA) or an environmental impact statement (EIS) and seeking public comment, APHIS may approve a petition for deregulation if it reaches the conclusion that the GE plant does not pose a plant pest risk.[3] Alternatively, an extension process can be used in cases where the GE plant is similar to a previously deregulated plant. The extension process, which was established in 1997 and has been used numerous times since, is based on the premise that a GE plant that is similar to a previously deregulated plant with respect to plant genotype and the expressed protein(s) is also similar in terms of any potential risk. Based on a thorough review of information in the extension request, which includes data showing similarity, APHIS may conclude that the new GE plant, like the previously deregulated GE plant, does not pose a plant pest risk and therefore will no longer be regulated.[4]

APHIS' Future Biotechnology Regulations

APHIS continually evaluates its policies and regulations and makes changes as necessary as the complexity and scope of biotechnology continue to grow. One of the key changes has been the strengthening of the requirements for the field testing of certain GE plants. As announced in a notice in the **Federal Register** on January 23, 2004 (Docket No. 03–031–2; 69 FR 3271–3272) and in a January 2004 USDA press release,[5] APHIS is preparing a draft EIS to evaluate the current regulatory system and analyze several possible changes in order to keep pace with science and to more fully utilize the authority provided by the PPA. APHIS will solicit public comments on the possible changes analyzed in the draft EIS. In any event, APHIS will continue to regulate each GE plant in a manner that is proportionate to the risks associated with that GE plant.

Interagency Coordination on Low Level Presence

APHIS works in concert with the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) to provide regulatory oversight of the development of GE organisms, consistent with the Coordinated Framework for Regulation of Biotechnology[6], adopted in 1986. The Coordinated Framework is a comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products. APHIS is responsible for protecting agriculture and the environment. FDA has primary responsibility for ensuring the safety of food (including food for animals). EPA regulates pesticides to ensure they can be used without unreasonable adverse effects on the environment, and to ensure public safety from the use of pesticides, including the residue of pesticides on food and animal feed.

The biological conditions of plant breeding, whether with conventional or GE plants, are such that there is a potential for low levels of genes and gene products to occasionally move beyond confined research sites into commercial seeds and grain that enter commerce. Recognizing this fact, the Federal Government, in an August 2002 notice in the **Federal Register**,[7] proposed measures aimed at strengthening the controls for preventing low levels of regulated materials from GE plants from entering commerce until appropriate safety standards have been met. The proposed actions to be taken by the three agencies were based on three fundamental principles:

- The level of confinement for a field test must be consistent with the level of risk associated with the introduced protein or trait;
- Field test confinement measures must be rigorous to restrict the low-level occurrence in commerce for those traits or proteins that present an unacceptable or unknown risk; and
- Regardless of risk, field test requirements should minimize out-crossing and commingling of seed.

Since the 2002 notice, FDA issued guidance for industry on early food safety assessments of new nonpesticidal proteins produced by new plant varieties intended for food use,[8] and EPA clarified its guidance for field testing of plant-incorporated protectants (pesticides intended to be produced and used in a living plant).[9] APHIS strengthened its field testing requirements for plants producing pharmaceutical or industrial compounds to ensure that regulated material from these plants is not found, even at low levels, in commerce. In addition, as discussed above, APHIS has initiated a process to amend its biotechnology regulations under 7 CFR part 340. As part of that process, the Agency will consider establishing new criteria to determine whether low levels of regulated materials would be acceptable in commercial seeds and grain based on risks to plant health, public health and the environment.

Through practical experience, APHIS has developed a policy based on current regulations for responding to the low-level presence of regulated materials in commercial seeds and grain. This policy provides the foundation for Agency actions in these cases. For purposes of transparency, this policy is set forth below for the public.

APHIS Policy on Responding to the Low-Level Presence of Regulated GE Plant Materials

APHIS requirements for both permits and notifications minimize the likelihood that regulated GE plant materials will occur in commercial seeds and grain. APHIS' policy is to respond to occurrences of regulated materials in commercial seeds and grain with remedial action that is appropriate to the level of risk and warranted by the facts in each case. In every such case, APHIS will initiate an inquiry to determine the circumstances surrounding the release, evaluate the risk attendant to the release, and determine what regulatory actions,

[2] Performance standards are found at 7 CFR 340.3(c).

[3] Deregulation requirements are found at 7 CFR 340.6.

[4] Regulatory authority to conduct extension requests is found at 7 CFR 340.6(e).

[5] USDA Press Release, ''USDA Announces First Steps to Update Biotechnology Regulations,'' January 22, 2004.

[6] Coordinated Framework for Regulation of Biotechnology, 51 FR 23302, June 26, 1986.

[7] Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants, 67 FR 50578, August 2, 2002.

[8] FDA issued its guidance in June 2006, which can be found at *http://www.cfsan.fda.gov/~dms/bioprgu2.html#ftn7*.

[9] EPA released its draft guidance on September 29, 2006, which can be found at *http://www.epa.gov/fedrgstr/EPA-PEST/2006/September/Day-29/p16072.htm*.

including remedial and enforcement actions, are required.

If APHIS determines that action is not necessary to mitigate low-level presence of a regulated material in commerce to protect plant health or the environment, this determination does not preclude enforcement action against a company or individual for violation of APHIS regulations. APHIS will investigate and take appropriate enforcement action whenever regulated materials are detected in commerce.

APHIS coordinates closely with EPA and FDA on investigations, risk evaluations, and the determination of what remediation measures, if any, will be necessary. This cooperation is crucial and helps to ensure that there are no unresolved safety issues. Any regulatory action taken by APHIS will not preclude FDA or EPA from pursuing action under their own authorities, as necessary, to ensure the safety of food as well as to protect human health and the environment from the sale, distribution, or use of any pesticide.

APHIS has authority under the PPA to take or order remedial measures which include the authority to hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated materials if it is determined that such measures are necessary to prevent the dissemination of a plant pest within or throughout the United States.[10] Any remedial action taken would be determined on a case-by-case basis. Key considerations include the extent of the occurrence, the nature of the regulated material, as well as any potential risks to plant health or the environment. In any case where APHIS determines that an incident involving a GE plant would result in the introduction or dissemination of material that could pose a threat to plant health or the environment, remediation measures will be required. It is important to note that, due to the strict requirements that APHIS has developed in recent years for GE plants that pose elevated risks, such occurrences would be unlikely.

There are two principal situations in which APHIS may determine that action under the PPA was not necessary. Even though remedial measures would not generally be applied in these two situations, applicants field testing these types of plants must be authorized through either notifications or permits and must follow all APHIS requirements.

The first situation would be when the regulated material is derived from plants that meet all of the criteria to qualify for APHIS' notification process. The six eligibility requirements are: [11]

- The plant must not be listed on the Federal Noxious Weed list or be considered a weed in the area of proposed release.
- The introduced genetic material must be stably integrated, which means the introduced DNA must remain inside the living cell and replicate only with the plant DNA.
- The function of the introduced genetic material is known, and its presence in the regulated article does not result in a plant disease.
- The introduced genetic material does not cause the production of an infectious entity, produce substances that are known to be, or are likely to be, toxic to nontarget organisms, or produce products intended for pharmaceutical or industrial use.
- The introduced genetic sequences derived from plant viruses do not pose a significant risk of creating a new plant virus.
- The plant has not been modified to contain certain genetic material derived from animal or human pathogens. In addition, plants containing coding sequences whose products are known agents of diseases in humans or nontarget animals are not eligible.

The majority of GE plants field tested under APHIS regulations qualify for the notification process because they present minimal risk to plant health and the environment. Many of the plants that have been engineered for common traits such as pest resistance, herbicide tolerance, male sterility, and improved product quality such as delayed fruit ripening meet the criteria for notification. APHIS has extensive experience with these types of plants and has overseen thousands of field tests involving them.

The second situation in which APHIS may not take remedial action is if the GE plant is similar to another GE plant that has already been deregulated by APHIS with respect to both plant genotype and any novel protein(s) expressed. APHIS will carefully assess the GE plant material, including the plant genotype, the introduced genes, and any proteins produced. When these are sufficiently similar to those of a previously deregulated plant, APHIS is able to conclude confidently that, like the previously deregulated plant, the new GE plant poses no significant safety risk to plant health or the environment, and thus, remedial action may not be necessary.

[10] See 7 U.S.C. 7714; 7 CFR 340.0(b).

[11] The specific criteria for GE crops planted under notification are found at 7 CFR 340.3.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 26th day of March 2007.

Bruce Knight,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 07–1536 Filed 3–27–07; 2:00 pm]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 929

[Docket No. AMS–FV–06–0174; FV06–929–1 FR]

Cranberries Grown in the States of Massachusetts, et al.; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule increases the assessment rate established for the Cranberry Marketing Committee (Committee) for the 2006–2007 fiscal year and subsequent fiscal years from $0.18 to $0.28 per barrel. Authorization to assess cranberry handlers enables the Committee to incur expenses that are reasonable and necessary to administer the program. The Committee locally administers the marketing order which regulates the handling of cranberries grown in the States of Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the State of New York. The fiscal year began September 1, 2006, and ends August 31, 2007. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: *Effective Date:* This rule becomes effective March 30, 2007.

FOR FURTHER INFORMATION CONTACT: Patricia A. Petrella or Kenneth G. Johnson, DC Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, Unit 155, 4700 River Road, Riverdale, Maryland 20737; telephone: (301) 734–5243, Fax: (301) 734–5275, or E-mail at *Patricia.Petrella@usda.gov* or *Kenneth.Johnson@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW, STOP 0237, Washington, DC 20250–0237; telephone: (202) 720–