

Dated: July 31, 2003.

A.J. Yates,

Administrator, Agricultural Marketing Service.

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 250

Donation of Foods for Use in the United States, its Territories and Possessions and Areas Under its Jurisdiction

CFR Correction

In Title 7 of the Code of Federal Regulations, parts 210 to 299, revised as of January 1, 2003, on page 466, § 250.30 is corrected by reinstating paragraph (f)(1) introductory text. The reinstated text reads as follows:

§ 250.30 State processing of donated foods.

* * * * *

(f) * * *

(1) The processing contract may provide for substitution of donated foods as defined in § 250.3 except that donated beef and donated pork shall not be substitutable. Any substitution of commercial product for commodities other than beef, pork, or poultry is subject to a 100-percent yield requirement. Under the 100-percent yield requirement, the processor is responsible for any manufacturing losses.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. 03-038-1]

Introductions of Plants Genetically Engineered to Produce Industrial Compounds

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending our regulations regarding genetically engineered organisms to require that introductions of plants genetically

engineered to encode compounds for industrial use be conducted only under permit. Prior to this interim rule, such introductions could be accomplished under notification, an expedited permitting procedure. This action is necessary to strengthen our regulations for introductions of this small subgroup of genetically engineered plants.

DATES: This interim rule is effective August 6, 2003. We will consider all comments that we receive on or before October 6, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03-038-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 03-038-1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 03-038-1" on the subject line.

You may read any comments that we receive on this docket 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. John Turner, Director, Policy Division, BRS, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1238; (301) 734-8365.

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" (referred to below as the regulations), govern the introduction (importation, interstate movement, or release into the environment) of any organism or product altered or produced through genetic engineering that is a plant pest

or that there is reason to believe is a plant pest, or any product which contains such an organism that is unclassified and/or whose classification is unknown. The regulations refer to such organisms as "regulated articles."

With certain limited exceptions, the introduction of any regulated article is prohibited unless that introduction is authorized by a permit or, for specific classes of regulated articles, the Administrator of the Animal and Plant Health Inspection Service (APHIS) has been notified of the introduction in accordance with § 340.3 of the regulations, which provides for the use, under certain circumstances, of an expedited permitting procedure called notification.

The notification option was added to the regulations in 1993 (58 FR 17044-53043, Docket No. 92-156-02) in order to expedite introductions for certain types of low risk plants with which APHIS had considerable regulatory experience. Under the notification procedure, the regulated article to be introduced must be a plant, and the types of genetic modifications to the plant must meet the eligibility criteria described in § 340.3(b). Development of those criteria was based upon the types of genetic modifications that APHIS had reviewed and evaluated many times over the preceding years of issuing permits.

At the time the regulations were amended to provide for the use of notification, the types of genetically engineered plants that had industrial uses were typically those in which nutritional components, such as oil content, were being engineered. Since APHIS had significant regulatory experience with the types of traits then being introduced into these plants, industrial plants were eligible for the notification option. In contrast, the notification regulations in § 340.3(b)(4)(iii) prohibited the use of notification for introductions of plants genetically engineered to encode compounds for pharmaceutical use, thus continuing to require a permit for such introductions, because of our lack of regulatory experience and scientific familiarity with these types of introduced traits.

Recently, a number of introductions of plants engineered to produce compounds intended for industrial use have been for traits different than what we were seeing in 1993. The more recent introductions have been for non-food, non-feed traits with which APHIS has little regulatory experience or scientific familiarity. For purposes of this rule, plants engineered to produce industrial compounds include those