Dated: July 31, 2003.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 03–19970 Filed 8–5–03; 8:45 am]

BILLING CODE 3410–02–P

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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[FR Doc. 03–55519 Filed 8–5–03; 8:45 am]

BILLING CODE 1505–01–D

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

plants that meet the following three criteria: (1) The plants are engineered to produce compounds that are new to the plant; (2) the new compound has not been commonly used in food or feed; and (3) the new compound is being expressed for non-food, non-feed industrial uses. Industrial uses include, but are not limited to, detergent manufacturing, paper production, and mineral recovery.

Based on the expansion of the technology and the new non-food, non-feed uses of industrial plants being developed, we believe it is prudent and necessary to remove the notification option for all industrials pending the completion of our ongoing review of part 340.

With this interim rule, which will be in effect only until December 31, 2004, we amend the regulations in part 340 to remove the notification options for such plants. Therefore, for the remainder of the 2003–2004 growing seasons all introductions of plants genetically engineered to produce industrial compounds will be conducted pursuant to APHIS' rigorous permit system. We are continuing our review of this and other issues and of the regulations in part 340 generally and will announce our plans in a document published in the **Federal Register** within the next year.

Immediate Action

Immediate action is necessary to strengthen our regulations with regard to the introductions of genetically engineered plants that encode compounds intended for industrial use because of our lack of regulatory experience and scientific familiarity with the kinds of traits in current and planned introductions. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This interim rule amends the 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.

Since 1993, only five companies and two public sector organizations have submitted notifications or applied for permits to introduce plants producing industrial compounds. From 1993 to 2001, 10 notifications of introductions of plant-made industrials (by 2 companies and 1 public sector entity) were received by APHIS. One notification was withdrawn; nine were acknowledged. In 2003, five permit applications for introductions of plant-made industrials have been received by APHIS (by three companies and one public sector entity).

It is difficult to predict how many organizations will apply for permits to introduce genetically engineered plants producing industrial compounds under the regulations in the future. Many unknowns will affect growth of the sector, including: Scientific/technological advances, consumer acceptance, market demand, production economics, the regulatory environment, intellectual property rights, and other critical factors.

Under the current notification procedure, when APHIS receives a notification, it is usually reviewed by a biotechnologist within 10 to 30 days, is forwarded to the State for further review, then returned to the applicant as either acknowledged or denied. Under the current permit procedures, it could take up to 3 months longer for each plant-made industrial compound introduction to be approved. When a permit application is received by APHIS, scientists review the application for deficiencies. If deficiencies are found, the applicant is required to respond to the noted deficiencies and the permit is either issued or denied within 120 days. The permit and proposed conditions are then sent to the State in which the introduction would occur. The State may concur or add conditions and concur.

Authorizations under notification require compliance with the performance standards described in § 340.3(c). For each notification, the responsible person must describe the procedures they will take to meet the performance standards. APHIS reviews those procedures and approves or denies the notification request. Authorizations under permit require compliance with standard permit conditions and supplemental conditions based on the risks involved in each case.

The requirement to introduce plants genetically engineered to produce industrial compounds under permit will result in an increased paperwork burden for applicants. Permits require the applicant to answer three more questions. The time per response is estimated to be 5 hours, so the total additional paperwork burden per permit could be somewhere in the neighborhood of 15 hours.

It is unlikely that the additional time for processing permits or the additional paperwork requirement would discourage applicants from applying for permits for the introduction of plants producing industrial compounds. Data on applications to introduce plants producing industrial compounds under the notification system (1993–2001) versus the permit system (2003) suggest that voluntary compliance with the permit system has not discouraged applicants thus far.

TABLE 1.—APPLICATIONS TO INTRODUCE PLANTS PRODUCING INDUSTRIAL COMPOUNDS

	Total applications	Applications per year
Notification system (1993–2001)	10	Slightly more than 1 per year.
Permit system (2003)	5	Five in the first 6 months.

Market research studies [1] indicate that approximately 60 companies and 60 research institutes are involved in biopharming (both pharmaceutical and industrial) product research and development worldwide. A subset of this group involved only in industrial or industrial/pharmaceutical biopharming research and development could be affected by this interim rule. It is unclear at this time exactly how many of them will be affected, or how many of them will qualify for consideration as small entities. The Small Business Association (SBA) defines small entities engaged in research and development in the life sciences as those with no more than 500 employees.

As of May 2003, only five companies and two research institutes had filed notifications or applied for permits to introduce plants genetically engineered to produce industrial compounds. Of the seven entities, two met the SBA criteria for small entities. Two were presumed small, and the remaining three were large organizations.

Strengthening the conditions under which plants genetically engineered to produce industrial compounds are regulated is expected to provide some benefits to all affected biotechnology companies and organizations. While it is possible that a small entity would be affected by this interim rule, the number of such entities, if any, would be few. Regardless of the number of small entities affected, however, the rule is unlikely to have any significant economic impact on them. Costs of complying with the conditions set forth in this interim rule are expected to be negligible. All currently affected entities are already in voluntary compliance with the interim rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

[1] (1) *Biopharming: The Emerging World Market of Plant-Based Therapeutics,* Theta Reports, November 2002; (2) *The Transgenic Plant Market—Profits from New Products and Novel Drugs,* Drug and Market Development Corp., August 2002; (3) *World Agricultural Biotechnology: Transgenic Crops,* Freedonia Industry Study, March 2002.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0216.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this interim rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects in 7 CFR Part 340

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and containers, Plant diseases and pests, Transportation.

■ Accordingly, we are amending 7 CFR part 340 as follows:

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

■ 1. The authority citation for part 340 is revised to read as follows:

Authority: 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

§ 340.3 [Amended]

■ 2. In § 340.3, paragraph (b)(4)(iii) is amended by adding the words ''or industrial'' immediately after the word ''pharmaceutical''.

§ 340.4 [Amended]

■ 3. Section 340.4 is amended by adding an OMB control number citation at the end of the section to read as follows: ''(Approved by the Office of Management and Budget under control number 0579–0216)''.

Done in Washington, DC, this 31st day of July 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–19877 Filed 8–5–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 993

[Docket No. FV03–993–4 IFR]

Dried Prunes Produced in California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule decreases the assessment rate established for the Prune Marketing Committee (Committee) under Marketing Order No. 993 for the 2003–04 and subsequent crop years from $2.60 to $2.00 per ton of salable dried prunes. The Committee locally administers the marketing order which regulates the handling of dried prunes grown in California. Authorization to assess dried prune handlers enables the Committee to incur expenses that are reasonable and necessary to administer the program. The crop year began August 1 and ends July 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: August 7, 2003. Comments received by October 6, 2003, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or E-mail: *moab.docketclerk@usda.gov.* Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.ams.usda.gov/fv/moab.html.*