

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. 03–031–1]

Field Testing of Plants Engineered To Produce Pharmaceutical and Industrial Compounds

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Request for comments.

SUMMARY: The Animal and Plant Health Inspection Service is providing information to the public on technical aspects of its biotechnology regulatory program as it relates to permit conditions for field testing plants that have been genetically engineered. The Agency is also seeking public comment on ways to improve specific aspects of its program. The specific topics on which we are seeking comment include permit confinement measures, procedures to verify compliance, and ways to enhance the transparency of the permitting system.

DATES: We will consider all comments that we receive on or before May 9, 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. 03–031–1, 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. 03–031–1. 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. 03–031–1” 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, is available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

The Coordinated Framework for Regulation of Biotechnology, issued by the Office of Science and Technology Policy in 1986 (51 FR 23302), describes the authorities the Federal Government uses to ensure that the development, testing, and use of the products of biotechnology occur in a manner that is safe for plant and animal health, human health, and the environment. The statutes include those administered by the Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency.

Under the Plant Protection Act (7 U.S.C. 7701–7772), the Secretary of Agriculture may prohibit or restrict the importation, entry, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or the dissemination of a plant pest into the United States. The Secretary's authority under the Plant Protection Act has been delegated to the Administrator of APHIS.

Under that authority, APHIS administers 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.” Part 340 (referred to below as the regulations) governs 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, or any organism that is unclassified and/or whose classification is unknown. The regulations refer to such organisms as “regulated articles.”

With certain limited exceptions, the importation or interstate movement of any regulated article is prohibited unless that movement is authorized by a permit issued by APHIS. Similarly, the release into the environment of any regulated article is likewise prohibited unless the release is authorized by a permit or, for specific classes of regulated articles, the Administrator has been notified of the release in accordance with § 340.3 of the regulations, which provides for the use, under certain circumstances, of a streamlined permitting procedure called notification.

Field test permits include detailed descriptions of the conditions under which the permit is issued. These conditions address movement of the regulated articles to the field test site, conduct of the field test, and then any movement of the regulated articles to facilities where the compounds of interest are extracted. Section 340.8 of the regulations provides specific container requirements for the movement of regulated articles. Other conditions are designed to confine the regulated articles to the test site during the test and ensure that they do not persist in the environment beyond the conclusion of the field test. APHIS will continue to require, on a case-by-case basis, that applicants submit additional protocols for review and approval when such protocols are deemed to be pertinent to the applicant's compliance with the regulations. Permit conditions also cover the period after harvest when the test site is monitored for any volunteer plants (plants originating from seeds of the crop planted the previous season). APHIS officers inspect field test sites, audit records, and review field data reports to verify compliance.