Proposed Rules

Federal Register
Vol. 68, No. 46
Monday, March 10, 2003

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: Rebecca Bech, Acting Director, Regulatory Policy Division, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–7324.

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.

The APHIS Biotechnology Permitting Program is a flexible system that allows the Agency to tailor permit conditions to address new information, technical innovations, and experience gained from compliance monitoring, as well as feedback from the public. This flexibility enables the Agency to address new advances in science that affect current and future uses of the technology with genetically engineered plants.

In the past, most field testing has been done with plants engineered to achieve agronomic improvements, such as resistance to diseases and pests or tolerance to specific herbicides. Recently, however, a small number of field tests have been authorized for plants engineered to produce compounds that are intended for pharmaceutical uses. APHIS authorized over 1,000 field tests during 2002, of which fewer than 20 were for field tests of plants engineered to produce pharmaceutical compounds. In 2002, approximately 130 acres of pharmaceutical producing plants were planted in experimental field tests at 34 sites. Most of these test sites were less than 5 acres. It is anticipated, however, that the number of requests for permits for field tests, and the scale of production, will increase significantly over the next few years.

Very few permits have been issued to date for plants in which the modification was made for the expressed intent of producing an industrial compound. However, as with plants engineered to produce pharmaceutical compounds, we anticipate an increase in requests for field tests of these types of plants. "Industrial" plants include those genetically engineered plants that are not intended for use as food or feed, but rather are intended to produce compounds that will be extracted for industrial uses. The range of potential uses of such substances includes, for example, applications in detergent manufacturing, paper production, mineral recovery, or in purely experimental research.

II. Changes in the Permit Conditions for 2003

APHIS is modifying its permit conditions and administrative procedures from those APHIS used in 2002. An example of a complete permit, with all conditions, can be viewed on the Internet at *http://www.aphis.usda.gov/ppq/biotech/pdf/sample_permit.pdf*. Some of the changes are related to scientific issues to achieve confinement, whereas other changes are related to ways APHIS administers the program. For all of the conditions described below, APHIS will consider variances proposed by applicants if they are appropriate for the specific case.

1. APHIS will institute the following changes in conditions for all plant species engineered to produce pharmaceutical and/or industrial compounds field tested under permit.

A. APHIS will increase the size of the perimeter fallow zone (not in production) around the field test site from 25 to 50 feet. This measure is designed to ensure that test plants are not inadvertently commingled with plants to be used for food or feed. APHIS currently prohibits the use of the field test site and its perimeter fallow zone to be used to produce food or feed crops during the tests. APHIS is increasing the size of the perimeter fallow zone around the test site to allow farm machinery to move around the site and yet still prevent physical mixing of the regulated plants with surrounding plants that may be used for food or feed.

B. APHIS will restrict the production of food and feed crops at the field test site and perimeter fallow zone in the following season in cases where there is a potential for volunteer plants to be inadvertently harvested with the following crop.

C. APHIS will require that planters and harvesters be dedicated to use in the permitted test site(s) for the duration of the tests. In addition, while tractors and tillage attachments, such as disks, plows, harrows, and subsoilers, do not have to be dedicated, they must be cleaned in accordance with protocols approved by APHIS (*see* item II.1.E below). To ensure the regulated articles are not inadvertently removed from the site, APHIS authorization will be required before the machinery is used elsewhere.

D. APHIS will require the use of dedicated facilities for the storage of equipment and regulated articles for the duration of the field test. Facilities must be cleaned according to APHIS-approved protocols prior to general use of the facilities.

E. APHIS will require cleaning procedures to be submitted and approved to minimize the risk of seed movement by field operations or equipment (movement of seed on tires of tractors, etc.) from the authorized test site.

F. APHIS will require procedures to be submitted and approved for seed cleaning and drying in order to confine the plant material and minimize the risk of seed loss or spillage.

G. APHIS will require the permittee to implement an approved training program to ensure that personnel are prepared to successfully implement and comply with permit conditions.

2. APHIS will institute the following changes in field test permit conditions for pharmaceutical corn.

A. APHIS will require that there will be no corn grown within 1 mile (5,280 feet) of the field test site throughout the duration of any field test which involves open-pollinated corn. This establishes a physical isolation distance that is eightfold greater than the isolation distance required for the production of foundation seed (660 feet). When pollen flow is controlled by placing bags around the corn tassels, there will be no other corn within 2,640 feet of the field test site, and the pharmaceutical corn must be planted no less than 28 days before or 28 days after any corn growing in a zone extending from 2,640 to 5,280 feet from the field test site, ensuring there is no overlap in anthesis.

B. With the establishment of isolation distances of 1 mile for open-pollinated corn and one-half mile for controlled pollination corn field tests, APHIS will not allow the use of border rows to reduce these isolation distances. APHIS believes that other methods are available and do not pose the difficulties inherent in using border rows. For example, by eliminating the use of border rows/buffer strips, there will be a reduction in the amount of plant material that must be disposed of after the field test is terminated (border rows are handled the same as the regulated article, as their proximity to the plots make them possible pollen recipients). This should reduce the possibility of inadvertent mixing of regulated articles with nonregulated plant material.

III. Compliance

In order to ensure compliance with the regulations, as well as all permit conditions, APHIS will increase the number of field site inspections during the upcoming growing season to correspond with critical times relevant to the confinement measures. Examples might include inspection at the pre-planting stage to evaluate the site location; at the planting stage to verify site coordinates and adequate cleaning of planting equipment; at midseason to verify reproduction isolation protocols and distances; at harvest to verify cleaning of equipment and appropriate storage; at post-harvest to verify cleanup at the field site; and for the following growing season, inspections will be timed to ensure that regulated articles

do not persist in the environment. For example, a field test may have five inspections during the growing season and two additional inspections post-harvest; however APHIS may inspect more frequently in some cases.

The permittee must, as always, maintain records of activities related to meeting the permitting conditions. APHIS will increase the auditing of the permittee's records to verify that required permit conditions were accomplished. APHIS will continue to require permittees to regularly inspect sites and maintain accurate records that will be available for APHIS auditing. The permittee will be required to record all efforts undertaken to meet the confinement protocols and other permit conditions. Some of this information will be related to agronomic information (*i.e.*, detasselling, pollination time of test crop, pollination time of surrounding crops, etc.). Frequent APHIS audits will enable the Agency to identify any discrepancies and mitigate any potential adverse effects.

IV. Information to the Public—Transparency

Transparency of the regulatory system and information about its effectiveness are essential ingredients for informed dialogue with the public. APHIS believes that effective communication and dialogue with interested parties and the public are necessary to enable continued refinement of its regulatory system and help instill confidence in the safety of field testing.

APHIS recognizes the need to provide relevant and timely information to the public on all aspects of the regulations, including information on APHIS authorizations for field testing. APHIS is responding to the increased public interest in the types of genetically engineered plants that are being developed for potential use in medical, veterinary, food processing, and other applications in addition to the more traditional uses in plant variety development for growers.

For example, APHIS provides information on its website on field tests the Agency has authorized and also those pending authorization. In light of increased public interest in the types of confinement standards APHIS uses for field tests of plants engineered to produce pharmaceutical compounds, the Agency posted a letter to potential permit applicants regarding such standards on its website (*http://www.aphis.usda.gov/ppq/biotech/pdf/pharma_2000.pdf*).

In addition, FDA, in collaboration with APHIS's Biotechnology Regulatory Services and Center for Veterinary Biologics, recently published draft guidance for scientific questions and information to be considered during development of a protein pharmaceutical in a genetically engineered crop (*see* 67 FR 57828, published September 12, 2002). The document outlines manufacturing and pre-clinical considerations for such products in addition to the stringent procedures for drug and biologic approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*). In the coming months, the agencies will respond to comments received regarding the notice.

This **Federal Register** notice is a step in our program to increase awareness and establish effective dialogue about APHIS' regulatory program and the permit system. APHIS anticipates providing further opportunities for public involvement in coming months as the Agency continues to evaluate its regulatory program.

V. Issues for Comment

1. As explained above, APHIS is taking steps to increase transparency of its regulatory approach to plants engineered to produce pharmaceutical and industrial compounds. APHIS seeks comment on additional measures that the Agency can take or employ to increase transparency and to enhance the flow of information to interested parties and the public.

2. APHIS seeks comment on alternative procedures, and the scientific data or technical rationale on which they are based, for ensuring adequate confinement for field tests.

3. APHIS seeks comment on appropriate training standards, the use of third party auditors, standard-setting organizations, or other quality control mechanisms to monitor and ensure compliance. In addition, commenters are asked to provide information on other measures or approaches that APHIS might use to verify compliance.

VI. Conclusion

We welcome all comments on the scope and approach of the actions outlined above and encourage the submission of ideas on any associated topics or other suggestions. APHIS will consider all comments and recommendations in developing additional guidance.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements associated with the application of the procedures described in this notice were submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0579–0216 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503; and (2) 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 comments refer to Docket No. 03–031–1 and send your comments within 60 days of publication of this notice.

The changes in permit conditions described in this notice will result in additional recordkeeping and reporting.

We are soliciting comments from the public (as well as affected agencies) concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 7.4444 hours per response.

Respondents: Universities and pharmaceutical companies.

Estimated annual number of respondents: 12.

Estimated annual number of responses per respondent: 9.

Estimated annual number of responses: 108.

Estimated total annual burden on respondents: 804 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

Authority: 7 U.S.C. 166, 1622n, 7756, and 7761–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 4th day of March 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–5427 Filed 3–7–03; 8:45 am]

BILLING CODE 3410–34–P