

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