United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147 Riverdale, Maryland 20737-1236

SUPPLEMENTAL PERMIT CONDITIONS

FOR FIELD TESTS OF PLANTS ENGINEERED TO PRODUCE PHARMACEUTICALS OR INDUSTRIAL PRODUCTS.

Permit: 04-121-02r, ProdiGene, corn

1) Compliance with Regulations

Any regulated article introduced not in compliance with the requirements of 7 CFR Part 340 or supplemental permit conditions, shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary, to prevent the introduction of a plant pest. The responsible party may be subject to fines or penalties as authorized by the Plant Protection Act.

This Permit (APHIS Form 2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemicals; and (4) food, feed, pharmacological, biologic or industrial use of regulated articles or their products and co-mingled plant material. In the latter case, depending on the use, reviews by APHIS, the U.S. Food and Drug Administration, or the U.S. Environmental Protection Agency may be necessary.

If the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application or suffers an unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms), APHIS shall be notified as soon as possible but no later than within 5 working days. In such cases, notice should be sent to:

Animal and Plant Health Inspection Service (APHIS)
Chief, Biotechnology Permit Program Operations, Rm. 5B53
4700 River Road, Unit 147
Riverdale, MD 20737.

The procedures, processes and safeguards used to prevent escape, dissemination and persistence of the transgenic plant as described in the permit application, in APHIS-approved Standard Operating Procedures (SOP) and in the supplemental permit conditions must be strictly followed. The permittee must maintain records sufficient to verify compliance with these procedures, including information regarding who performed the activity. Persons performing such activities shall have received training as described in a training program submitted to and approved by APHIS. These records are subject to examination by APHIS. APHIS/BRS must be notified of any proposed changes to the protocol referenced in the permit application.

2) Distance to Other Corn Plants
Permittee must ensure that any corn from previous seasons is harvested and removed in a radius of 0.25 mile of the transgenic corn plot, before the transgenic corn is sown. No corn can be grown within 1 mile (5,280 feet) of the field test site throughout the duration of any field test which involves open-pollinated corn. When pollen flow is controlled by placing bags around the corn tassels or by the use of male sterile plants and detasseling, there will be no other corn with 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. When pollen flow is controlled by the use of male sterile plants and detasseling, detasseling must performed at least every 48 hours during the period of time of tassel emergence. Test plots will be monitored as stated in the permit application to ensure that plants are not flowering.

3) Weeds
Weeds in the field test plot will be controlled by herbicide treatment or by hand rouging.

4) Perimeter Fallow Zone
To ensure that transgenic plants are not inadvertently commingled with plants to be used for food or feed, a perimeter fallow zone of at least 50 ft. must be maintained around the transgenic test site in which no crops are grown that will be harvested or used for food or feed. The perimeter fallow zone must start outside of any permitted border rows of non-transgenic plants that are the same as, or sexually-compatible with, the regulated article, and it shall be managed in such a way as to allow detection and destruction of volunteer plants that are the same as or sexually compatible with the transgenic plants.

5) Dedicated Planting and Harvesting Equipment
To ensure that regulated articles are not inadvertently removed from the site, planting and harvesting equipment must be dedicated to use in the permitted test site(s) from the time of planting through the end of harvesting. After this time, APHIS authorization will not be required for this equipment to be used on APHIS-permitted sites planted to the same types of transgenic crops as authorized under this permit (*e.g.* the same or different sites planted to the same crop with the same target protein(s) in subsequent growing seasons under an extension of this permit or a different permit), but authorization will be required from APHIS before this planting and harvesting equipment can be used on sites planted to crops not included under this permit. In the latter case, the permittee must notify APHIS/BRS and the PPQ Regional Biotechnologist and State Regulatory Official at least 21 calendar days in advance of cleaning this equipment for this purpose so that APHIS may schedule an inspection to ensure that the equipment has been cleaned appropriately.

6) Cleaning of Equipment
To minimize the risk of seed movement and commingling, equipment used for planting and harvesting, as well as other field equipment (e.g. tractors and tillage attachments, such as disks, plows, harrows and subsoilers) used at any time from the time of planting through the post-harvest monitoring period must be cleaned in accordance with procedures submitted to and approved by APHIS before they are moved off of the test site. Equipment used to transport harvested material must also be cleaned prior to loading and after transportation to

the authorized site in accordance with procedures submitted to and approved by APHIS. Seed cleaning and drying must also be performed in accordance with the procedures submitted to and approved by APHIS so as to confine the plant material and minimize the risk of seed loss, spillage or commingling.

7) Use of Dedicated Storage Facilities

Dedicated facilities (locked or secured buildings, bins or areas, posted as restricted to authorized personnel only) must be used for storage of equipment and regulated articles for the duration of the field test. Before these facilities are returned to general use, they must be cleaned in accordance with procedures submitted to and approved by APHIS. In this case, the permittee must notify APHIS/BRS, the PPQ Regional Biotechnologist and State Regulatory Official at least 21 calendar days in advance of cleaning facilities for return to general use so that APHIS may schedule an inspection to ensure that the facilities have been cleaned appropriately.

8) Post Harvest Monitoring

The field test site which includes the perimeter fallow zone must be monitored for the presence of corn plants for one year after termination of the field test. All volunteer corn plants will be rendered non-viable by turning into the soil or by herbicide treatment and then turning into the soil.

9) Post Harvest Land Use Restrictions

Production of any food or feed crop not specifically designated in the permit at the field test site and the perimeter fallow zone is restricted during the growing season that follows harvest or termination of the field test.

10) Reports and Confidential Business Information

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 F.R. 38561-63.

Planting Report

Within 28 calendar days after planting, the permittee must submit a planting report that includes the following information for each field test site:

A. A map of the site, with sufficient information to locate it, that includes: the GPS coordinates for each corner of the plot (inclusive of the border rows of any sexually compatible plants).
B. The location and the approximate number and/or acres of transgenic plants which were actually planted at the test site for each of the target proteins.
C. The total acreage of the test plot (exclude border rows, if any).
D. The distance from the genetically engineered plants to the nearest corn plants.

Fax the planting report to the following APHIS personnel:

A. The Chief, Biotechnology Risk Assessment Staff, Mr. Juan Roman, (301) 734-8669
B. The PPQ Regional Biotechnologist (Dr. Ralph Stoaks,(970)-494-7576
C. The State Regulatory Official, State of Texas (CBI-Deleted copy only), Mr. Robert Crocker, (512)-463-8225.

Provide APHIS with the contact information for each field test site and indicate if planting and harvesting equipment will be moved between authorized field test sites.

Contact information for the APHIS PPQ Regional Biotechnologists is included on the attached map and for the APHIS State Plant Health Director at http://www.aphis.usda.gov/travel/aqi.html.

11) Termination Report

At least 21 calendar days before the anticipated harvest/termination of the field test. The permittee is required to notify the APHIS/BRS Permits office and the appropriate PPQ Regional Biotechnologist and State Regulatory Official(s) (http://www.aphis.usda.gov/brs/regbiot.html).

12) Field Test Data Report

Within 6 months after the end of the field test (final harvest or crop destruction), the permittee is required to submit a field test data report to the BRS Permits office. Field test reports shall include: methods of observation, resulting data and analysis regarding all deleterious effects on plants, nontarget organisms or the environment.

13) Monitoring Report

Post-harvest/post-season monitoring report must be submitted within 3 months after the end of the monitoring period that includes the dates the field site and perimeter fallow zone were inspected for volunteers, the number of volunteers observed and the actions taken.

14) Unauthorized Release

APHIS shall be notified orally immediately upon discovery and in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.

For immediate oral notification, contact the following APHIS staff in the order indicated below.

APHIS BRS Deputy Administrator's office [phone number: (301) 734-7324]. Indicate that you wish to report an unauthorized or accidental release of a regulated article to the BRS Regulatory Division Director; or in that person's absence, to the Chief of either the BRS Biotechnology Permit Program Operations staff or the Biotechnology Risk Assessment staff, or the permit reviewer. In the event that one of these persons cannot be reached, contact:

The appropriate APHIS PPQ Regional Biotechnologist: Dr. Ralph Stoaks, (970)-494-7500.

The appropriate APHIS State Plant Health Director: Mr. Robert Crocker, Coordinator for Pest Management and Citrus Programs, Texas Department of Agriculture, Stephen F. Austin Building, 1700 N Congress, Austin, TX 78701. Tel: (512) 463-6332, Fax: (512) 463-8225

Contact information is maintained at the APHIS Biotechnology Regulatory Services website at http://www.aphis.usda.gov/brs/regulatory.html

Unless otherwise directed, written notification should be sent to:

Animal and Plant Health Inspection Service (APHIS)
BRS Regulatory Division (2) Director, Rm. 5B54
4700 River Rd. Unit 147
Riverdale, MD 20737

15) Inspections
APHIS/Biotechnology Regulatory Services (BRS) and/or an APHIS/PPQ Regional Biotechnologist or APHIS State Plant Health Director may conduct inspections of the test site, facilities and/or records at any time. APHIS may invite the FDA or State Regulatory Officials to participate in these inspections. Inspections will likely correspond to the beginning of the field test, mid-season or during flowering, at and/or following harvest, and during the post-harvest monitoring period. Inspections will include examination of records that verify compliance with regulations and SOPs.

16) Inspections
APHIS's Biotechnology Regulatory Services (BRS) and/or an APHIS/PPQ Regional Biotechnologist or APHIS State Plant Health Director may conduct inspections of the test site, facilities and/or records at any time. APHIS may invite the FDA or State Regulatory Officials to participate in these inspections. Inspections will likely correspond to the beginning of the field test, mid-season or during flowering, harvest and/or following harvest, and during the post-harvest monitoring period. Inspections will include examination of records that verify compliance with regulations and SOPs.