SUPPLEMENTAL PERMIT CONDITIONS
For Release of Tobacco
USDA-APHIS- BRS Permit 06-037-01r

I. Compliance with Regulations

1. Any regulated article introduced not in compliance with the requirements of 7 Code of Federal Regulation Part 340 or any standard 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 such plant pests. The responsible party may be subject to fines or penalties as authorized by the Plant Protection Act (7 U.S.C. 7701-7772).

2. This Permit (APHIS form 2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (A) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (B) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (C) experimental use of unregistered chemicals; and (D) 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.

3. The procedures, processes, and safeguards used to prevent escape, dissemination, and persistence of the regulated article as described in the permit application, in APHIS-approved Standard Operating Procedures (SOPs) 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.

II. Reporting Unauthorized Releases and Unintended Effects

1. According to the regulation in 7 CFR § 340.4(f)(10)(i), APHIS shall be notified orally immediately upon discovery and notified in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.

   - For immediate oral notification, contact APHIS/BRS Compliance Staff at (301) 734-5690 and ask to speak to a Compliance and Inspection staff member.
   - In the event of an emergency and you are unable to reach the BRS Compliance Staff at the above number, you may call:

The APHIS/BRS Regional Biotechnology Coordinator assigned to the state, where the field test occurs

For Western Region, contact Ralph Stoaks by phone at (970) 494-7573 or e-mail ralph.d.stoaks@aphis.usda.gov

For Eastern Region, contact Ashima Sengupta by phone at (919) 855-7622 or e-mail Ashima.Sengupta@aphis.usda.gov

Or

The APHIS/PPQ Regional Biotechnology Coordinator assigned to the state where the field test occurs

For Western Region, contact Stacy Scott by phone at 970-494-7577 or e-mail Stacy.E.Scott@aphis.usda.gov

For Eastern Region, contact Susan Dublinski by phone at (919) 855-7324 or e-mail Susan.G.Dublinski@aphis.usda.gov

Or

The APHIS State Plant Health Director for the state where the field test occurs. The list of APHIS State Plant Health Director is available at http://ceris.purdue.edu/napis/names/sphdXstate.html

KY	Mike Madryga, Prospect	(502) 228-8224	(502) 228-6306	michael.b.madryga@aphis.usda.gov

2. According to the regulation in 7 CFR § 340.4(f)(10)(ii), APHIS shall be notified in writing as soon as possible but within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).

3. Written notification should be sent by one of the following means:

By e-mail:
BRSCompliance@aphis.usda.gov

By mail:
Biotechnology Regulatory Services (BRS)
Compliance and Inspection Branch
USDA/APHIS
4700 River Rd. Unit 147
Riverdale, MD 20737

III. Perimeter Fallow Zone

1. 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. (unless a variance is granted by APHIS) must be maintained around the transgenic test site in which no crops are grown to be harvested or used for food or feed.

2. The permitted border rows of non-transgenic plants that are the same as, or sexually-compatible with, the regulated article are considered part of the field test. The perimeter fallow zone shall start outside the border rows.

3. The perimeter fallow zone shall be managed in a way that allows detection and destruction of volunteer plants that are the same as, or sexually compatible with, the transgenic plants.

IV. Harvester Use and Cleaning

1. Harvesting equipment may be used on non-regulated research tobacco that are not used for food or feed (BRS Variance 05-001). APHIS/BRS and the State Regulatory Official must be notified at least 21 calendar days before return to general use.

2. APHIS/BRS should be notified at least 21 calendar days prior to the initial harvest, additional harvests may occur without notifying APHIS (BRS Variance 05-001).

V. Cleaning of Equipment

1. 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.

2. Equipment used to transport seeds or harvested material must be cleaned prior to loading and after transportation to the authorized site in accordance with procedures submitted to and approved by APHIS.

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

VI. Use of Dedicated Storage Facilities

1. 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.

2. Before returning these facilities to general use, they must be cleaned in accordance with procedures submitted to and approved by APHIS. **The permittee must notify** APHIS/BRS and the State Regulatory Official at least 21 calendar days in advance to allow for APHIS to schedule an inspection to ensure that the facilities have been cleaned appropriately.

VII. Post Harvest Monitoring

The field test site including the perimeter fallow zone must be monitored for the presence of volunteer **tobacco** plants for **one year** after termination of the field test. Viable plant material should not remain at the test site following termination.

VIII. Post Harvest Land Use Restrictions

1. Production of food and feed crops 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.

2. Permission must be obtained from APHIS/BRS prior to planting any food or feed crop at the field test site and perimeter fallow zone during the post-harvest monitoring period. Requests for such permission are not encouraged and will not be granted in cases where there is a reasonable potential for plant material derived from, or originating from, the regulated articles to become mixed with the proposed food or feed crop during harvesting.

Inspections

1. APHIS Biotechnology Regulatory Services (BRS) and/or an APHIS/PPQ Regional Biotechnologist, APHIS/BRS Regional Biotechnology Coordinator or APHIS State Plant Health Director may conduct inspections of the test site, facilities, and/or records at any time.

2. APHIS may invite the FDA or State Regulatory Officials to participate in these inspections.

3. 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.

4. Inspections will include examination of records that verify compliance with regulations and SOPs.

IX. Reports and Notices

Send notices and all reports (CBI and CBI deleted or non CBI copies) to BRS by e-mail, mail, or fax.

BRS E-mail:
BRSCompliance@aphis.usda.gov

BRS Mail:
Biotechnology Regulatory Services (BRS)
Compliance and Inspection Branch
USDA/APHIS
4700 River Rd. Unit 147
Riverdale, MD 20737

BRS Fax:
Compliance and Inspection Branch
(301) 734-8669

In addition, fax the CBI deleted or non CBI version of the pre-planting and pre-harvest (termination) notices to the State Regulatory Official(s)

KY	Mike Madryga, Prospect	(502) 228-8224	(502) 228-6306	michael.b.madryga@aphis.usda.gov

Contact information for State Officials
http://www.aphis.usda.gov/brs/lt_sta.html

1. **Pre-Planting Notice**
At least 7 calendar days before planting, submit a Pre-Planting notice that includes the following information for each field test site:
   i. Provide APHIS with the contact information for each field test site.
   ii. Indicate if planting and harvesting equipment will be moved between authorized field test sites.
   iii. A map that clearly identifies the site location to facilitate any inspections by USDA personnel.
   iv. The planned number of acres for each gene construct.
   v. The planned planting date

2. **Planting Report**
Within 28 calendar days after planting, submit a planting report that includes the following information for each field test site:
   i. A map of the site, with sufficient information to locate it, that includes: the state, county, address, GPS coordinates for each corner of the plot (inclusive of the border rows of any sexually compatible plants);

ii. 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;
iii. The total acreage of the test plot (exclude border rows, if any);
iv. The distance from the genetically engineered plants to the nearest plants of the same crop which will be used for food, feed, or seed production. A survey should be done within the distance specified in the permit.
v. The actual planting date.

3. Pre-Harvest/ Termination Notice

At least 21 calendar days prior to the anticipated first harvest or termination, submit a Notice indicating the planned date of harvest **or** termination and the contact information for each field test site. For multiple harvests, submit the notice prior to the initial harvest.

4. Field Test Report

Within 6 months after the end of the field test (final harvest or crop destruct), the permittee is required to submit a field test report. Field test reports shall include:

i. APHIS reference number
ii. Methods of observation.
iii. Resulting data.
iv. Analysis of all deleterious effects on plants, non-target organisms, or the environment.
v. Disposition table

The disposition table should contain the following information: site name (or GPS), crop, gene, harvest date, and disposition of harvested material.

The disposition table is a formal record of how the regulated material was removed from the environment. An accounting of the harvested material should be provided with regards to what material is harvested, how much material is harvested per site, what is done to devitalize residual and harvested material at the site, where the harvested material is transported, stored and further processed up to the time it is taken to a contained facility.

5. Monitoring Report

Within 3 months after the end of the monitoring period, submit a volunteer monitoring report. The report must include:

i. Dates when the field site and perimeter fallow zone were inspected for volunteers.
ii. Number of volunteers observed.
iii. Any actions taken to remove or destroy volunteers.

XII. Isolation Distance:

The tobacco field test will be grown at an isolation distance of at least 1320 feet from non-regulated tobacco. The closest tobacco that will be allowed to openly flower and produce seed is over 1 mile from the field test.

XIII. Additional Data Requirements:

The applicant should provide the following additional field data:

Permitee must quantify the amount of antibody binding activity in pollen, nectar, stems, leaves and roots at midgrowth, and at harvest.

XIV. Flower Removal:

The field will be surveyed to remove flowers prior to pollen release five days a week. It is possible that on occasion that a very small amount of mature pollen will be produced. However, the applicant will apply due diligence to remove flowers prior to pollen release. A log book needs to be maintained to demonstrate this activity is being performed.