SUPPLEMENTAL PERMIT CONDITIONS
For Release of Tobacco
USDA-APHIS- BRS Permit 05-354-04r
June 22, 2006

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

CA	Helene Wright, Sacramento	(916) 930-5500	(916) 930-5518	helene.r.wright@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

Because the location of the experimental release is a paved surface in an industrial area and the regulated articles will be placed in pots, there are no requirements for post harvest land use.

IV. Dedicated Planting and Harvesting Equipment

Because the planting and harvesting will be by hand, there are no requirements for dedicated planting and harvesting equipment.

V. Cleaning of Equipment

To minimize the risk of seed movement and commingling, equipment used for planting and harvesting, as well as other equipment 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.

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. APHIS authorization should be received before facilities are returned to general use.

VII. Post Harvest Monitoring

Because the location of the experimental release is a paved surface and the regulated articles will be placed in pots, there are no requirements for post harvest land use.

VIII. Post Harvest Land Use Restrictions

Because the location of the experimental release is a paved surface and the regulated articles will be placed in pots, there are no requirements for post harvest land use.

IX. 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.

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

X. 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)

CA	Helene Wright, Sacramento	(916) 930-5500	(916) 930-5518	helene.r.wright@aphis.usda.gov

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 1320 feet.
   v. A list of the specific confinement option(s) selected at each site if your permit allows different confinement options (e.g. bagging flowers, border rows, or isolation distance.).
   vi. The actual planting date.

3. **Pre-Harvest/ Termination Notice**
   At least 21 calendar days prior to the anticipated 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. A list of the lines planted at each site
   vi. 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

Because the location of the experimental release is a paved surface and the regulated articles will be placed in pots, there are no requirements for monitoring.

XII. Isolation Distance:

The tobacco field test will be grown at an isolation distance of at least 1320 feet from the nearest tobacco.

XIII. Additional Data Requirements:

The applicant should provide the following additional data in the 6 month field test report.

1. Permittee should quantify the amount of antibody in pollen, nectar, stems, leaves and roots at midgrowth, and at harvest of lines that will be planted in future production phase field tests or field tests that will require an Environmental Assessment.

2. Permittee should document potential detrimental toxic affects on honey bees. This documentation may include evidence such as scientific literature references, honey bee feeding studies and field observations for presence of any dead honey bees.

3. Permittee should document the potential for the expressed protein to be present in honey. Based on APHIS discussions with Planet Biotechnology, the use of sterile hybrids in future field tests raises the possibility that the flowers will result in tobacco flowers that may produce substantial amounts of pollen that may contain the transgenes. If there is a potential for this protein to be in honey then this is a concern that needs to be adequately addressed in the Environmental Assessment. Please take this opportunity to examine the literature and plan field studies as needed to address this issue.

4. Provide positive controls for the pollination studies to ensure that conditions of the environmental release would support pollination. These may involve human-assisted pollination of control plants.