SUPPLEMENTAL PERMIT CONDITIONS
Permit: *04-114-01r*— Chlorogen–tobacco

1. APHIS's Biotechnology Regulatory Services (BRS) and/or an APHIS PPQ Regional Biotechnologist or State Plant Health Official may conduct inspections of the test site, facilities, and/or records at the beginning of the test, mid-season or during flowering, at and/or following harvest, and during the post-season monitoring period. The permittee is required to notify the appropriate State Regulatory Official(s) and the appropriate APHIS Regional Biotechnologist at least 1-week before the test begins and at least 1 week before the harvest/termination of the field test. Contact information for the APHIS PPQ Regional Biotechnologists are included on the attached map, and for the State Regulatory officials, this information is maintained at http://www.aphis.usda.gov/brs/lt_sta.html.

2. The proposed procedures, processes, and safeguards which will be used to prevent escape, dissemination, and persistence of the transgenic plant and its progeny at each of the intended destinations as described in the permit application, in APHIS-approved standard operating procedures, and in these permit conditions must be strictly followed. The permittee must maintain records sufficient to verify compliance with these procedures. These records are subject to audit by APHIS. **APHIS, BRS must be notified of any proposed changes to the protocol referenced in the permit application.**

In addition, the following conditions will apply for field tests with plants expressing pharmaceuticals or biologics, consistent with APHIS' Federal Register Notice on Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds (Docket No. 03-031-1):

A. To ensure that transgenic plants are not inadvertently commingled with plants to be used for food or feed, **a fallow perimeter zone of at least 50 ft. must be maintained** around the transgenic test site in which no crops are grown that will be used for food or feed. The fallow zone must start outside of any border rows of non-transgenic sexually-compatible plants.

B. **Authorization must be obtained from APHIS, BRS to grow crops for food or feed the following growing season(s) on the field test site and perimeter fallow zone, when there is a potential for volunteer plants to be inadvertently harvested with the crop**.

C. 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) for the duration of the test (the time of planting through the end of harvesting). **APHIS authorization will be required before this equipment is used elsewhere.** In addition, tractors and tillage attachments, such as disks, plows, harrows, and subsoilers, must be cleaned in accordance with the procedures submitted to and approved by APHIS before they are moved off of the test site. Seed cleaning and drying must be performed in accordance with the procedures submitted to and approved by APHIS that are designed to confine the plant material and minimize the risk of seed loss or spillage.

D. Dedicated facilities (locked or secured buildings, bins, or areas, restricted to authorized personnel only) must be used for storage of equipment and regulated articles for the duration of the field test. Facilities must be cleaned in accordance with the

procedures submitted to and approved by APHIS before they are returned to general use.

E. Within 4 weeks after planting, please **submit a report** that includes the following information for **each site**:

1. A map of the site **including the GPS coordinates for each corner of the plot (inclusive of the border rows of any sexually compatible plants).**

2. The number of transgenic plants which were actually planted at the test site

3. The total acreage of the test plot (exclude border rows, if any)

4. A report which indicates 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 chart below for any of these crop plants.

5. A list of the specific containment option(s) selected at **each** site if your permit allows different containment options (e.g. bagging flowers, border rows, or isolation distance).

Fax the report to:
1. The Biotechnologist who reviewed your application at Area Code (301) 734 8669
2. The Regional Biotechnologist (fax number enclosed)
3. The State official where the test is being performed
(see http://www.aphis.usda.gov/brs/lt_sta.html for fax numbers).

Crop	**Scouting Distance**
Maize	One mile
Barley	One-eighth mile
Wheat	One-eighth mile
Rice	One-eighth mile
Tobacco	One-half mile

5. This approved Biotechnology 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 chemical; 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.

6. Consistent with standard permit conditions at 7 CFR 340.4(f) (9), field test data reports must be submitted with 6 months after the end of the field test (final harvest or crop destruct). APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials. **Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 F.R. 38561-63.**

7. Consistent with standard permit conditions at 7 CFR 340.4(f) (10), 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.

1. 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:
2. The appropriate APHIS PPQ Regional Biotechnologist.
3. The appropriate APHIS State Plant Health Director.

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 Compliance Officer, Rm. 5B50
4700 River Rd. Unit 147
Riverdale, MD 20737.

When 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)
Tony Roman
Chief, Biotechnology Program Operations , Rm. 5B53
4700 River Rd. Unit 147
Riverdale, MD 20737.