SUPPLEMENTAL PERMIT CONDITIONS
FOR PERMIT # 04-061-01r

1. APHIS' Biotechnology Regulatory Services (BRS) or a Regional Biotechnologist may conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State Regulatory Official and the appropriate Regional Biotechnologist (see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by the Regional Biotechnologist. The permittee is required to notify the Regional Biotechnologist and the State Official at least 1-week before the termination of the experiment, i.e. before the plants are harvested.

3. Consistent with Section 13 f of the permit application, to minimize the potential for outcrossing or for transgenic volunteers to occur, during the course of field test, the permittee: 1) shall only plant transplants started from individual transgenic *Nicotiana tabacum* seeds; 2) shall confirm with the directors or field managers that no *Nicotiana*-related crops are being grown on the Fort Meade, Maryland site where the transgenic plots will be, nor within 1320 feet; 3) shall monitor the area within 40 meters of the transgenic test plot, and keep it free of all *Nicotiana* species until all of the plants are harvested; 4) shall have trained personnel monitor the plots; 5) shall harvest test plots of *N. tabacum* (both transgenic and nontransgenic) before the plants have initiated flowering; and 6) shall enclose the field plot area with fencing of sufficient size to keep animals such as deer from entering the plots, and keep the top of the fenced area covered with shade cloth to prevent birds from gaining entrance; 7) shall have trained staff monitor the site for a period of one year after the last harvest of the plants, removing and destroying all volunteers found; and 8) shall not allow any *N. tabacum* plants (both transgenic and nontransgenic) to produce seeds capable of germination. **Documentation that these conditions have been met shall be submitted with the field test report (see item 6, below).** The field site shall not be planted back to *Nicotiana* species or any plant species that would be used for food or feed for 1 year, during which time these areas shall be monitored for volunteer *Nicotiana* species, and any which are found shall be destroyed prior to flowering. In addition, all personnel handing transgenic plant material shall be trained by the permittee regarding these permit conditions and procedures to ensure that transgenic plant material is confined to the field test site and laboratory facilities and is not used for food or feed.

4. APHIS BRS should be notified of any proposed changes to the protocol referenced in the permit application.

5. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permitte'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 or feed use of genetically engineered crops harvested from the field experiment. (According to the permit application, all genetically engineered plants harvested from this experiment will be destroyed.)

6. Consistent with standard permit conditions at 7 CFR 340.4(f) (9), **field test data reports must be submitted within 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. **In addition, a post-harvest/post-season monitoring report must be submitted within 3 months after the end of the monitoring period** (as referenced in paragraph 3) that includes the dates the field site and perimeter fallow zone were inspected for *Nicotiana* volunteers,

the number of volunteers observed, and the actions taken. **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 Regulatory Division (2) Director, Rm. 5B54
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)
Chief, Biotechnology Permit Program Operations, Rm. 5B53
4700 River Rd. Unit 147
Riverdale, MD 20737.