SUPPLEMENTAL PERMIT CONDITIONS
FOR RELEASE OF TRANSGENIC-TMV AND TRANSGENIC-TMV INOCULATED TOBACCO
USDA-APHIS-BRS Permit: 04-044-02r

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 such plant pests. 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.

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.

The procedures, processes, and safeguards used to prevent escape, dissemination, and persistence of the transgenic virus 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.

2) Distance to TMV Susceptible Plants

No plants susceptible to TMV will grown within 100 feet of the test site.

3) Weeds

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

The test site will be monitored for potential weed hosts. Any weedy host plants showing TMV-like symptoms will be harvested for analysis. The permittee must screen for the presence of TMV in these weed hosts including probe (s) that would identify both wild type and engineered viruses. If any of the weeds test positive for TMV, the material should be tested for the presence of sequences from the engineered vectors. The location of each weed sample collected should be identified on a field test map. All data resulting from weed tests must be submitted with the Field Test Data Report.

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.

All equipment that comes in contact with the regulated article will be washed with 10% bleach to inactivate the TMV.

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 tobacco plants for one year after termination of the field test (when the tobacco plants are disked into the soil). All tobacco plants recovered 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 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. 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. APHIS must approve the TMV resistant crop before planting after site termination.

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.

11) Planting Report

Within 28 calendar days after planting, 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); and
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 TMV susceptible host plants.

Fax the planting report to the following APHIS personnel:

A. The Chief, Biotechnology Risk Assessment Staff at Area Code (301) 734-8669
B. The PPQ Regional Biotechnologist (fax number enclosed)
C. The State Regulatory Official (CBI-Deleted copy only)

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 are included on the attached map and for the State Regulatory officials at http://www.aphis.usda.gov/ppq/biotech/lt_sta.html.

12) Inoculation Report
At least 7 calendar days before the anticipated inoculation date, the permittee is required to notify the APHIS, BRS Permits office and the appropriate PPQ Regional Biotechnologist and State Regulatory Official(s). Include in the inoculation report, a map that clearly identifies the site location to facilitate any inspections by USDA personnel, number of acres for each gene construct.

13) Field Test Data 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 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.

14) 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).

15) 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.

16) 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 numbers: (301) 734-7324; (301) 734-6331; (301)734-0029]. 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 BRS Chief of Permits or BRS Chief of Risk Assessment, or the permit reviewer. In the event that one of these persons cannot be reached, contact:
The appropriate APHIS PPQ Regional Biotechnologist.
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.

17) 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, 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.

18) Additional Data Requirements

A. Permittee must monitor daily for the presence and any mortality of bees during pollen shed. Permittee must also during prior to and during this monitoring period record all pesticide applications including type of pesticide applied and rate applied. This information must be submitted at the time of field data report.

B. Prior to any additional field tests under new permit at this site, permittee must develop an assay for aprotinin levels in the soil. Permittee must collect and preserve soil samples from these site prior to and after harvesting for future assaying.

C. Permittee must quantify the amount of aprotinin in stem, leaves, flower parts and roots at flowering and at first and regrowth harvest, stem, leaves, and roots.

Standard Permit Conditions For the Introduction of a Regulated Article (7 CFR 340.4 (f))

Permit Conditions: A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packaging material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.

(4) The regulated article shall be maintained only in areas and premises specified in the permit.

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.

(7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the administrator to be necessary to prevent the spread of plant pests.

(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing and within 24 hours in the event of any accidental or unauthroized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristcs substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

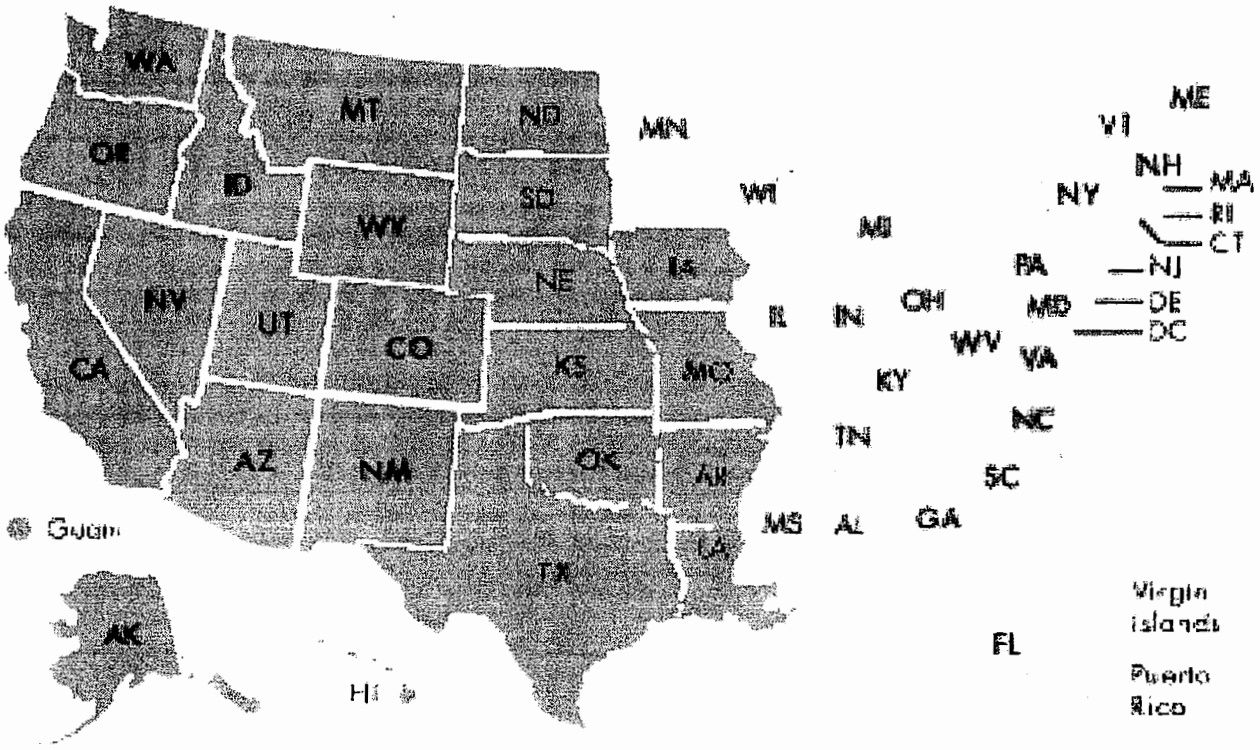
(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14 (b);

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, or its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose: and

(iii) Mark and identify the regulated article in accordance with 7 CFR 340.7.

Rev. 3/2003

AQI Ports in the United States



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Western Region

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The western region includes the states shaded in yellow plus: Alaska, American Samoa, Guam, Hawaii, Mariana Islands, Marshall Islands, Micronesia, and Palau.

Eastern Region

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The eastern region includes the states shaded in blue plus: Virgin Islands and Puerto Rico.