SUPPLEMENTAL PERMIT CONDITIONS

For Release of Tobacco Mosaic Virus

(1) Please note that transportation of all test and plant materials to and from the field test site must be done in accordance with APHIS/USDA regulations outlined in "Container requirements for the movement of regulated articles", 7 CFR 340.8 unless a shipping container variance has been approved by APHIS/BRS

(2) BRS should be notified in writing of any proposed changes to the permit application (or approved permit) including for example confinement protocols, transgenic lines or constructs, release sites, acreage, etc. Changes usually require amendments to the permit and must be pre-approved by BRS. Requests should be directed to Regulatory Permit Specialist, USDA/APHIS/BRS, Biotechnology Permit Services, 4700 River Road, Unit 91, Riverdale, Maryland 20737.

(3) Any regulated article introduced not in compliance with the requirements of 7 CFR 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).

(4) This Permit does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including for the use of: (A) 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.

(5) 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.

(6) Inspections:

APHIS/BRS and/or an APHIS/PPQ personnel 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.

(7) Reporting an Unauthorized or Accidental Release

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 verbal notification, contact APHIS/BRS Compliance Staff at (301) 734-5690 and ask to speak to a

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Compliance and Inspection staff member. Leave a verbal report on voicemail if the phone is not answered by a Compliance Officer.
- In addition, in the event of an emergency in which you need to speak immediately to APHIS personnel regarding the situation, you may call:

The APHIS/BRS Regional Biotechnologist assigned in the region where the field test occurs:
For Western Region, contact the Western Region Biotechnologist at (970) 494-7513
or e-mail: BRSWRBT@aphis.usda.gov
For Eastern Region, contact the Eastern Region Biotechnologist at (919) 855-7622 or e-mail:
BRSERBT@aphis.usda.gov

Or

The APHIS State Plant Health Director for the state where the unauthorized release occurred. The list of APHIS State Plant Health Directors is available at:
http://www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml.
or
http://pest.ceris.purdue.edu/stateselect.html

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

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

By mail:
Biotechnology Regulatory Services (BRS)
Regulatory Operations Program
USDA/APHIS
4700 River Rd. Unit 91
Riverdale, MD 20737

3. Additional instructions for reporting compliance incidents may be found at
http://www.aphis.usda.gov/biotechnology/compliance_incident.shtml

(8) Reporting Unintended Effects:

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).

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

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

By mail:
Biotechnology Regulatory Services (BRS)
Regulatory Operations Program
USDA/APHIS
4700 River Rd. Unit 91
Riverdale, MD 20737

(9) Perimeter Fallow Zone:

To ensure that genetically modified TMV is not spread to TMV-susceptible 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 test site in which no crops are grown to be harvested or used for food or feed.

The perimeter fallow zone shall be managed in a way that allows detection and destruction of volunteer plants.

(10) Dedicated Planting and Harvesting:

To ensure that the regulated article is not inadvertently removed from the site, inoculation, chemical application, and harvesting equipment must be dedicated for use in the permitted test site(s) from the time of planting through the end of harvesting for each trial.

After harvest, you will not be required to obtain APHIS authorization to use this equipment on APHIS -permitted sites (same sites or different sites) containing plants inoculated with the same genetically modified virus with the target protein(s) authorized under this permit, in subsequent growing seasons under an extension of this permit or a different permit.

Authorization is required from APHIS before this inoculation, spraying, and harvesting equipment can be used on sites planted to crops not included under this permit. The permittee must notify APHIS/BRS and the 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.

(11) Cleaning of Equipment:

To minimize the risk of spread of TMV and TMV-infected material, equipment used for inoculation, chemical spraying, 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 virus inoculum or infected 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.

(12) 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 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.

(13) 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.

(14) 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.

(15) 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)
Regulatory Operations Program
USDA/APHIS
4700 River Rd. Unit 91
Riverdale, MD 20737

BRS Fax:
Regulatory Operations Program
(301) 734-7487

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

Contact information for State Officials
http://www.nationalplantboard.org/member/index.html

a. Pre-Inoculation Notice

At least 7 calendar days before inoculating, submit a Pre-inoculation 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 inoculating, chemical spraying, 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 release of genetically modified TMV.
v. The planned inoculation date.

b. Planting and Inoculation Report

Within 28 calendar days after inoculation, 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;
ii. The location and the approximate number and/or acres of inoculated plants at the test site for each of the target proteins;

iii. List of all constructs inoculated;
iv. The total acreage of the test;
v. Total acreage of any border rows planted;
vi. The distance between the infected plants and 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;
vii. 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);
viii. The actual planting and inoculation date.

c. 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.

d. Field Test Report

Within 6 months after the expiration date of the permit, the permittee is required to submit a Field Test Report. Field Test Reports provide the final status and observations at each location and shall include:
i. The number and/or acres of plants inoculated with the genetically modified virus at the test site for each of the target proteins;
ii. List of all viral constructs used for inoculation;
iii. The total acreage of the test;
iv. Planting and harvest dates;
v. The methods of observation;
vi. The resulting data and analysis regarding all deleterious effects on plants, non-target organisms, or the environment. This should include, but not be limited to, data on insect damage, disease susceptibility, gross morphology and any indications of weediness or infection of weeds with TMV;
vii. A final disposition table with the following information for viral construct and plants inoculated:

Site name (or GPS), crop, gene(s), harvest date(s), and disposition of harvested material. Date(s) of harvest, removal, and/or termination; a formal record of how the regulated material was removed from the environment; what material and how much was harvested or removed and where it was transported, stored and further processed up to the time it was taken to a contained facility; and what was done to devitalize residual and/or harvested material at the location. APHIS must be notified if any regulated article is stored on a production site. In these cases the storage location, viral construct, crop, event, and quantity of each regulated article should be included in the disposition table.

e. 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.

f. Storage Report
In cases where a regulated article is stored on a production site, a report must be filed with APHIS each year the regulated article remains in storage at the production site. The report, which must include the permit number, storage location, crop, event, and quantity of each regulated article, must be filed prior to the anniversary of the expiration date of the permit under which the regulated article was produced.

(16) ^^^Important^^^

Interstate movement, release/movement, and release permits may also be subject to PPQ domestic permit and/or quarantine requirements. Please call PPQ @ (877) 770-5990 for additional assistance in regards to their requirements

(17) Treatment of protective wear

Protective wear such as boots and gloves that come in contact with the genetically engineered TMV must be discarded (autoclaved) or bleach-treated to inactivate the virus.

(18) Bee Monitoring

Permittee shall monitor every 5 days for the presence and any mortality of bees during pollen shed. Prior to and during this monitoring period, the permittee must also record all pesticide applications including type of pesticides applied and rate applied. The monitoring results must be submitted at the time of the field test reports.

(19) Soil sampling for presence of the recombinant proteins or genetically engineered TMV

Permittee must collect soil samples prior to first inoculation and after final harvest and analyze for the presence of the recombinant proteins (and/or presence of virus containing the insert) in soil samples. The results must be submitted at the time of the field test reports.

(20) Recombinant protein accumulation levels in various parts of the plants

Permittee must quantify the levels of accumulation of the recombinant proteins in stems, leaves, roots, and flower parts. This report must be included in the field test reports.

(21) Weed monitoring

The field will be monitored 3 times between inoculation and harvest for each inoculation for the presence of potential weeds and if they are infected with TMV.

(22) Other effects

Since this is the first time these recombinant proteins are being produced using this strategy, applicant intends to test the toxicological consequences on foraging animals and insects in the current year permit along with non-target organism monitoring if needed. Results of these tests should be provided in the field test reports.

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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 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 within 24 hours in the event of any accidental or unauthorized 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 characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect non-target organism).

(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

Permit Number: 09-344-105r

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Any regulated article introduced not in compliance with the requirements of 7 CFR 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. 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).

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