SUPPLEMENTAL PERMIT CONDITIONS

For Release of Tobacco Mosaic Virus (TMV)

(1) 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.

(2) 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).

(3) 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.

(4) 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.

(5) 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.

(6) 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) 851-3935 and ask to speak to a 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

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(7) 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

(8) Perimeter Fallow Zone:

To ensure that inoculated Nicotiana excelsiana plants are not inadvertently commingled with plants to be used for food or feed, a perimeter fallow zone of at least 20 ft. must be maintained around the transgenic test site in which no crops are grown to be harvested or used for food or feed.

(9) Dedicated Harvesting:

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

After harvest, you will not be required to obtain APHIS authorization to use this equipment on APHIS -permitted sites (same sites or different sites) planted with same transgenic crop, 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 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.

(10) Cleaning of Equipment:

Equipment used for inoculation 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 inoculation 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.

(11) 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.

(12) 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 to plants that are resistant to TMV (such as corn, etc.).

(13) Reports and Notices:

Submit all reports and notices via ePermits using the link under "My Reports and Notices."
A link to instructions for submitting via ePermits is located here:
https://epermits.aphis.usda.gov/epermits/xml_schema/BRS_Reports_and_Notices_User_Guide.pdf

Other options are to submit reports and notices via email or paper, however, we strongly encourage submission via ePermits. If submitting using any other method, both CBI and CBI-deleted or non-CBI copies should be submitted via:

BRS E-mail:
BRSCompliance@aphis.usda.gov

BRS Mail:
Animal and Plant Health Inspection Service (APHIS)
Biotechnology Regulatory Services (BRS)
Regulatory Operations Program
4700 River Rd. Unit 91
Riverdale, MD 20737

a. Pre-Inoculation Notice

At least 7 calendar days before inoculation, submit a Pre-Inoculation notice that includes the following information for each field test site:

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- Provide APHIS with the contact information for each field test site.
- Indicate if inoculation and harvesting equipment will be moved between authorized field test sites.
- A map that clearly identifies the site location to facilitate any inspections by USDA personnel.
- The planned number of acres for each gene construct.
- The planned inoculation date.

b. Release Report

Release reports must be submitted to BRS by the 15th of the month following the month in which the environmental release was started and must include the following data:

- Permit number
- Regulated article
- State
- County
- Location Name (Unique ID)
- GPS coordinates of the release site
- Field Release Unique ID
- Inoculation Start Date
- Total acreage of the regulated article released
- List of all constructs released

(This list is optional in the release report but must be included in the Field Test Report)

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 six 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 must include:

- Permit number
- State
- County
- Location Name(s)
- Location Unique ID(s)
- Any inoculaton that occurred at each location
- GPS coordinates for each location
- Size of the release (in acres) at each location
- Phenotypic designations (all constructs that were released)
- Indicate if any of the regulated material was destroyed before harvest

If so provide the Pre-Harvest destruction completion date and describe how the pre-harvested material was destroyed

- Indicate if any of the inoculated material was harvested

If so provide the harvest completion date

- Describe how the harvested material was destroyed
- If the material was destroyed in the field and not removed from the field, provide the date the field test was completely terminated and describe the method of termination
- If material was removed from the field and destroyed off site describe how it was disposed of and provide the date of destruction.
- If material was removed from the field and placed in storage, provide the amount of material that was stored and provide a description of the storage location
- Describe any other disposition methods that may be applicable
- Describe any deleterious effects on plants, non target organisms, or the environment
- Describe methods of observations and resulting data and analyses
- Indicate if you have submitted any of the following:

1. A report on the accidental or unauthorized release of the regulated article;
2. A report that characteristics of the permitted species are substantially different from those listed in the application; or
3. A report of any unusual occurrence

We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of non-regulated status for their regulated article. APHIS considers 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.

e. 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.

(14) ***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.

(15) After the final harvest, the field trial and 20 ft. border area will be tilled by disking to chop up the remaining plant material.

(16) After the plants are inoculated with TMV and through the final harvest, the known TMV weedy host plants will be checked weekly for TMV symptoms. Any weedy hosts showing TMV symptoms will be devitalized by removal from the ground or chopping them up.

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United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

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 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 340.5.

Rev. 3/2003

Permit Number: 12-032-107r

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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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