SUPPLEMENTAL PERMIT CONDITIONS

For Release of Populus tremula x P. alba and P. nigra x P. maximowiczii

Please note that the regulated article must be shipped in containers as specified in 7 CFR 340.8 and should be handled as specified by the regulation 7 CFR 340.7 and/or the conditions described in the permit application unless a variance request has been reviewed and approved by APHIS-BRS.

(1) The applicant will work with appropriate state and federal EPA regulatory agencies to ensure that the poplar trees are disposed of appropriately.

(2) Trees are not allowed to flower under this permit.
An additional data requirement for this permit is a detailed report on any flowering that might occur while under the field test and how flowers were terminated before maturation if they occur. See details under the Annual Report and Field Test Report sections.

(3) All material must be disposed of after it is devitalized according to any and all pertinent state and federal EPA regulations. It is at incumbent upon the permit applicant to contact the appropriate state and federal EPA authorities to determine appropriate disposal of the devitalized material.

(4) After termination of the field trial, the site will be monitored for volunteer plants. Eastern Cottonwood trees are the only poplar native to this region, but it can be easily differentiated from the transgenic trees by differences in leaf type. Eastern Cottonwood has very leathery, flat, shiny deltoid-shaped leaf with crenate (round to blunt teeth) leaf edges. The transgenic hybrids have leaves that are thinner, more papery leaves that lack luster, are lighter green and have an attenuated tip with a wavy margin. Any non-transgenic poplar genotype that is planted on this site after the transgenic field trial is terminated will be clearly distinguishable from the transgenics based on leaf morphology.

(5) Volunteer Monitoring
The test sites and adjacent land within 100 meters shall be monitored for any volunteer Populus plants every 6 months during the field test and for two years after completion of the field test, during which time any volunteer plants will be destroyed before they flower. During the monitoring period following completion of the test, the site will not be planted with poplars, so that any volunteer seedlings that emerge can be easily identified. If volunteers (sucker shoots) are still emerging during the second year, a third year will be added to the monitoring period to ensure no that no shoots are continuing to be produced.

(6) Please note that transportation of all test and plant materials to and from the field test location must be done in accordance with APHIS/USDA regulations outlined in "Container requirements for the movement of regulated articles", 7CFR340.8(b)(I & ii) unless a shipping container variance has been approved by APHIS-BRS.

(7) 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 locations, 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 147, Riverdale, Maryland 20737.

(8) 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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(9) This Permit does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including for the use of: (1) any non-genetically engineered plant pests 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.

(10) APHIS/BRS and/or an APHIS/PPQ personnel may conduct inspections of the test location, facilities, and/or records at any time.

(11) Harvested plant material may not be used for food or animal feed unless it is first devitalized and approved for such use by the U.S. Food and Drug Administration; and for plant-incorporated protectants, a tolerance for the pesticide must first be established by the U.S. Environmental Protection Agency.

(12) 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)
Compliance and Inspection Branch
USDA/APHIS
4700 River Rd. Unit 147
Riverdale, MD 20737

(13) 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:
Animal and Plant Health Inspection Service (APHIS)
Biotechnology Regulatory Services (BRS)
Compliance and Inspection Branch
4700 River Rd. Unit 147
Riverdale, MD 20737

BRS Fax:
Compliance and Inspection Branch
(301) 734-8669

a. Planting Report

Within 28 calendar days after planting, submit a report, in paper format or electronically, that includes the following

information for each field test location:
i. Permit number;
ii. Regulated article;
iii. Release location [provide state, county, internal identification number (if available), and either a single GPS coordinate as a reference point (center of plot or specify corner) or specific address];
iv. Approximate number of seeds or plants or acres planted per transformed line (event) for each construct (transformation code);
v. Total acreage of regulated articles planted and border rows;
vi. The actual planting date(s)

If multiple plantings occur that are separated in time by more than a month, then a planting report is required within 28 days of each planting.

b. Annual Report

Within 30 days after the anniversary date (one year increments from the effective date) an Annual Report must be submitted to APHIS. FAILURE TO SUBMIT ANNUAL REPORTS MAY RESULT IN REVOCATION OF THE PERMIT. The Annual Report shall reflect the current status and observations to date for each location. It shall include the information submitted in the Planting Report, plus the following:

i. An accounting of the acreage or number of plants per line (event) for each construct that remain in the ground
ii. A detailed map of the plantings.
iii. Total remaining acreage.
iv. The methods of observation;
v. 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.
vi. If any material was harvested, removed, or terminated or otherwise destroyed, a disposition table with the following information for each line (event) released should be provided::
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 is or was to be taken to a contained facility; and what was done to devitalize residual and/or harvested material at the location,.
vi. A DETAILED ACCOUNTING OF ANY FLOWERING THAT OCCURED AND HOW THE FLOWERS WERE HANDLED. THIS SHOULD INCLUDE THE NUMBER OF FLOWERS OBSERVED AND HOW THEY WERE TERMINATED.

c. Field Test Report

Within 6 months after the expiration date of the permit, the permittee is required to submit a Field Test Report. NOTE: If a new application is approved to continue the field test past its scheduled expiration date, an annual report should continue to be submitted until the final expiration date, at which point the Field Test Report will be due after 6 months. Field Test Reports provide the final status and observations at each location and shall include:
i. List of all constructs and specific transformed lines (event) planted;
ii. Planting date(s), and harvest dates if any material was harvested;
iii. Total acreage of the test;
iv. The methods of observation;
v. 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.
vi. A disposition table with the following information:

Site name (or GPS), crop, 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.
vii. A DETAILED ACCOUNTING OF ANY FLOWERING THAT OCCURED AND HOW THE FLOWERS WERE HANDLED. THIS SHOULD INCLUDE THE NUMBER OF FLOWERS OBSERVED AND HOW THEY WERE TERMINATED.

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.

d. Monitoring Report

The final monitoring report is due no later than 2 months from the end of the volunteer monitoring period.

The report must include:
i. Dates when the field location and perimeter fallow zone were inspected for volunteer plants;
ii. Number of volunteers observed;
iii. Any actions taken to remove or destroy volunteers.

(14) 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 Compliance and Inspection staff member.
- In the event of an emergency and you are unable to reach the BRS Compliance Staff at the above number, you may call:

The APHIS/BRS Regional Biotechnologist assigned to the state, where the field test occurs:
For Western Region, contact the Western Region Biotechnologist at (970) 494-7573 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/PPQ Regional Biotechnology Coordinator assigned to the state where the unauthorized release occurred.
For Western Region, contact Stacy Scott by phone at (970) 494-7577 or e-mail Stacy.E.Scott@aphis.usda.gov
For Eastern Region, contact Susan Dublinski by phone at (919) 855-7324 or e-mail Susan.G.Dublinski@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://ceris.purdue.edu/napis/names/sphdXstate.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)
Compliance and Inspection Branch
USDA/APHIS
4700 River Rd. Unit 147
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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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) Permit Conditions: A person who 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:

(2) 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.

(3) 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.

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

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

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

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

(8) 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.

(9) 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.

(10) A person who has been issued a permit 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.

(11) 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 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 the listed in he application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect non-target organism).

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(12) 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.

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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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