SUPPLEMENTAL PERMIT CONDITIONS
For Release of *Populus tremula x P. alba*

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) 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.

(2) 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).

(3) 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.

(4) APHIS/BRS and/or an APHIS/PPQ personnel may conduct inspections of the test location, facilities, and/or records. APHIS may invite State Regulatory Officials to participate in these inspections. Inspections will include examination of records that verify compliance with regulations.

(5) 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.

(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) 734-5690 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
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:

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)
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

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

(8) 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. Annual Report

Within 30 days after the anniversary date (one year increments from the effective date) an Annual Report must be submitted to APHIS. If the permit has been amended, the Annual Report is due 30 days from the anniversary date (one year increments from the effective date) of the ORIGINAL permit. 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 (include acreage of border rows if appropriate);
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.

b. Pre-harvest/ Termination Notice
At least 21 calendar days prior to the anticipated harvest or termination, the applicant must submit a Notice to BRS indicating the planned date of harvest/termination and the contact information for the test site.
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 regulated article planted;
iv. Total acreage of any border rows planted;
vi. The methods of observation;
vii. 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.
viii. 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.

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 applicant has described devitalization of all plant material and removal of all soil from the test beds in his permit application. Viable plant material should not remain at the test

site following termination. When this has been demonstrated to BRS and assessed by an APHIS inspector, no post trial monitoring will be required.

(9) **Post Harvest Land Use Restrictions**

When permit condition 8.d. has been satisfied, no post harvest land use restrictions will be required.

10) **Other notes specific for this permit:**

A. A perimeter 50 ft. fallow zone is NOT required. Applicant must, however, manage the perimeter surrounding the test beds to control excessive weed growth.
B. Dedicated planting and harvesting equipment is not required.
C. Specific SOPs describing equipment cleaning are not required.
D. Dedicated storage facilities are not required.