SUPPLEMENTAL PERMIT CONDITIONS
Permit: 05-045-01r

[Note: Any regulated article introduced not in compliance with the requirements of 7 CFR Part 340 or of 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, and the responsible party may be subject to fines or penalties as authorized by the Plant Protection Act.]

1. The permittee is required to notify the State regulatory official and APHIS's Chief of Biotechnology Risk Assessment at least one week prior to planting any new sites for this permit. 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, EPA or State Regulatory Officials to participate in these inspections. Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 F.R. 38561-63.

2. The procedures, processes, and safeguards which will be used to prevent escape, dissemination, and persistence of the transgenic plant and its progeny at each of the intended destinations as described in the permit application and in these 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.

3. Within 28 calendar days after planting any new sites, submit a report that includes the following information for each field test site:

A. A planting map of the site, with sufficient information to locate it.
B. The total acreage of the test plot (exclude border rows, if any).

Fax the report to the following APHIS personnel:
1. The Chief, Biotechnology Risk Assessment Staff at Area Code (301) 734-8669
2. The PPQ Regional Biotechnologist (fax number enclosed)
3. The State Regulatory Official (CBI-Deleted copy only)

4. Consistent with standard permit conditions at 7 CFR 340.4(f) (9), **field test data reports must be submitted within 6 months after the end of the field test** (final harvest or crop destruct). In addition, a 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 was inspected for volunteers, the number of volunteers observed, and the actions taken. **Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permissions by APHIS for future field trials.**

5. This Permit (APHIS form 2000) does not eliminate the permittee's legal responsibility to obtain any and all other Federal and State approvals that might be required.

6. **Given the nature of the testing involved**, in addition to the procedures outlined in the permittee's application, **APHIS will also require** leaf tissue analysis (using appropriate statistical methods) approximately one month prior to anticipated leaf fall such that appropriate leaf collection procedures may be implemented if leaf mercury levels are found to be at or above EPA action levels. If the permittee's final experimental procedures include this testing, that will suffice.
Results of this testing should be submitted to BRS prior to leaf fall.

7. Consistent with standard permit conditions at 7 CFR 340.4(f) (10), APHIS shall be notified verbally immediately upon discovery and in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.

For immediate verbal notification, contact the following APHIS staff in the order indicated below.
1. APHIS BRS Deputy Administrator's office [phone numbers: (301) 734-7324; (301) 734-5745; (202) 720-4383)]. 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 Chief of either the BRS Biotechnology Permit Program Operations staff or the Biotechnology Risk Assessment staff, or the permit reviewer. In the event that one of these persons cannot be reached, contact:
2. The appropriate APHIS PPQ Regional Biotechnologist.
3. 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/lt_sta.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.

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.