# Supplemental Permit Conditions

## FOR RELEASE OF TRANSGENIC RICE
## USDA-APHIS-BRS Permit: 05-073-01r

**1) Compliance with Regulations**

Any regulated article introduced not in compliance with the requirements of 7 CFR Part 340 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.

This Permit (APHIS form 2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest 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 chemicals; and (4) 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.

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

The procedures, processes, and safeguards used to prevent escape, dissemination, and persistence of the transgenic plants 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.

**2) Distance to other rice**

To prevent cross-pollination of the transgenic rice with other rice, there must be at least ¼ mile between the transgenic rice and any other rice not included under this permit. This ¼ mile buffer includes a 50 foot fallow zone.

**3) Scouting for Weedy Rice**

Ventria will scout for any weedy red rice within the ¼ mile isolation zone. If found, APHIS shall be notified as soon as possible but not later than within 5 working days that it has been discovered and Ventria will take appropriate measures to destroy the plants.

**4) Weeds**

Weeds in the field test plot will be controlled by herbicide treatment or by hand rouging.

**5) Perimeter Fallow Zone**

To ensure that transgenic plants are not inadvertently commingled with plants to be used for food or feed, a perimeter fallow zone of at least 50 ft. must be maintained around the transgenic test site in which no crops are grown that will be harvested or used for food or feed. The perimeter fallow zone must start outside of any permitted border rows of non-transgenic plants that are the same as, or sexually-compatible with, the regulated article, and it shall be managed in such a way as to allow detection and destruction of volunteer plants that are the same as or sexually compatible with the transgenic plants.

**6) Dedicated Planting and Harvesting Equipment**

To ensure that regulated articles are not inadvertently removed from the site, planting and harvesting equipment must be dedicated to use in the permitted test site(s) from the time of planting through the end of harvesting. After this time, APHIS authorization will not be required for this equipment to be used on APHIS-permitted sites planted to the same types of transgenic crops as authorized under this permit (e.g. the same or different sites planted to the same crop with the same target protein(s) in subsequent growing seasons under an extension of this permit or a different permit), but authorization will be required from APHIS before this planting and harvesting equipment can be used on sites planted to crops not included under this permit. In the latter case, the permittee must notify APHIS, BRS and the PPQ Regional Biotechnologist and 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.

**7) Cleaning of Equipment**

To minimize the risk of seed movement and commingling, equipment used for planting 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 harvested material must also be cleaned prior to loading and after transportation to the authorized site in accordance with procedures submitted to and approved by APHIS. Seed cleaning and drying must also be performed in accordance with the procedures submitted to and

approved by APHIS so as to confine the plant material and minimize the risk of seed loss, spillage, or commingling.

**8) 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 these facilities are returned to general use, they must be cleaned in accordance with procedures submitted to and approved by APHIS. In this case, the permittee must notify APHIS, BRS, the PPQ Regional Biotechnologist and State Regulatory Official at least 21 calendar days in advance of cleaning facilities for return to general use so that APHIS may schedule an inspection to ensure that the facilities have been cleaned appropriately.

**9) Post Harvest**

As soon as physically possible following the fall harvest, the field must be burned and disked, and may be flooded during the off-season, to degrade the plant material. If weather does not permit burning, then the field must be disked as soon as possible. An attempt should be made to schedule the harvests so that rainy conditions do not prevent disking under the unharvested plant material.

**10) Post Harvest Monitoring**

For the cropping season following harvest of the transgenic lines, unless the fields will be planted back into transgenic lines of the same target molecule (with the appropriate APHIS permit), the field test site may be reflooded to promote growth of any rice seed which may have escaped harvest the previous year. The field test site and perimeter fallow zone must be monitored for volunteer rice plants monthly whenever weather conditions are favorable for seed germination **at least until November, 2006**, and volunteers must be eradicated by mechanical destruction or with a herbicide prior to flowering.

**11) 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.

**12) Reports and Confidential Business Information**

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 F.R. 38561-63.

**13) Pre-Planting Notification**

The permittee is required to notify the APHIS, BRS Permits office and the appropriate PPQ Regional Biotechnologist and State Regulatory Official(s) at least 7 calendar days before the anticipated planting date.

**14) Planting Report**

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

A. A detailed map of the planted site with sufficient information to locate it, that includes: the state, county, address, along with GPS coordinates (inclusive of the border rows of any sexually compatible plants); and
B. The location and the approximate number and/or acres of transgenic plants which were actually planted at the test site for the target protein.
C. The total acreage of the test plot (exclude border rows, if any).
D. The distance from the genetically engineered plants to the **nearest** plants of the same crop which will be used for food, feed, or seed production.
E. The actual planting date

Fax the planting report to the following APHIS personnel:

A. The Chief, Biotechnology Risk Assessment Staff at Area Code (301) 734-8669
B. The Compliance Staff at (301) 734-8669
C. The State Regulatory Official (CBI-Deleted copy only)

Provide APHIS with the contact information for each field test site, and indicate if planting and harvesting equipment will be moved between authorized field test sites.

Contact information for the State Regulatory officials is located at: http://www.aphis.usda.gov/brs/lt_sta.html.

**15) Termination Report**

At least 21 calendar days before the anticipated harvest/termination of the field test the permittee is required to notify the APHIS BRS Permits office, the appropriate BRS Compliance Staff and State Regulatory Official(s) (http://www.aphis.usda.gov/brs/lt_sta.html).

**16) Field Test Data Report**

Within 6 months after the end of the field test (final harvest or crop destruct), the permittee is required to submit a field test data report to the BRS Permits office. Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

**17) Monitoring Report**

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 and perimeter

fallow zone were inspected for volunteers, the number of volunteers observed, and the actions taken.

**18) Unauthorized Release**

APHIS shall be notified orally immediately upon discovery and in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.

For immediate oral notification, contact the following APHIS staff in the order indicated below.

APHIS BRS Compliance Staff at (301) 734-6363; (301) 734-6356; (301) 734-5612. You may leave a message. For emergencies, if you are unable to reach the Compliance Staff, you may call: (301) 734-7324, (301) 734-6331, or (301)734-0029 and indicate that you wish to report an unauthorized or accidental release of a regulated article. In the event that one of these persons cannot be reached, contact:

The appropriate APHIS PPQ Regional Biotechnologist.
http://www.aphis.usda.gov/brs/regbiot.html
The appropriate APHIS State Plant Health Director.
http://www.aphis.usda.gov/brs/regulatory.html.

Unless otherwise directed, written notification should be sent to:
Animal and Plant Health Inspection Service (APHIS)
BRS Compliance Branch, Rm. 5B52
4700 River Rd. Unit 147
Riverdale, MD 20737

**19) Inspections**

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 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.

**20) Additional Data Requirements**

A. Permittee must monitor for human serum albumin in the soil surrounding the plants mid way through the growing season and after the crop is harvested. These data must be submitted with the field data report.

B. Permittee must quantify the amount of human serum albumin in stem, leaves, roots and flower parts at flowering and the amount of serum albumin in stem, leaves, roots and seeds at harvest.