



Biotechnology Regulatory Services 4700 River Road, Unit 147 Riverdale, Maryland 20737-1236

## SUPPLEMENTAL PERMIT CONDITIONS

## For Release of Plutella xylostella

(1) All persons working with the genetically-engineered (GE) diamondback moth must be informed of these permit conditions. Anyone working with these insects must agree to and sign/ initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/ APHIS but must be readily accessible in the event of an inspection and presented upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized organisms and life stages, release locations, and authorization statement all appear on the document with the permit number. The residency condition does not need to be signed. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

- (2) Modifications to the containment of these organisms must be approved prior to making changes by applying for an amendment in ePermits.
- (3) This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agricultural Select Agent Program (ASAP) immediately by phone at 301-851-3300, and within seven (7) days submit APHIS/CDC Form 4 (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, ASAP; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: http://www.aphis.usda.gov/programs/ag\_selectagent/index.shtml). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of
- (4) If organisms that are not authorized in this permit are received, the permit holder must take all prudent measures to contain the organism(s) and notify the BRS Compliance Staff by contacting a compliance officer immediately (that is, within one business day) by calling 301-851-3935 or by e-mail to BRSCompliance@aphis.usda.gov. The permit holder must immediately notify the permit unit of the destruction of regulated organisms received under this permit, as above. Similarly, the permit holder must immediately notify the permit unit if facilities are destroyed or decommissioned for any reason.
- (5) The permit holder must maintain an official permanent work assignment at the address identified on this permit. If the permit holder ceases assignment/affiliation at the address identified on this permit, or personnel circumstances change in any way, then a compliance officer must be notified at the BRS Compliance Staff immediately (that is, within one business day) by either (a) email to BRS Compliance@aphis.usda.gov, (b) verbal communication at 301-851-3935, or (c) conventional mail to BRS Compliance Staff, 4700 River Road, Riverdale, Unit 91, MD 20737. The permit holder must destroy all regulated organisms prior to departure unless the permit holder either (a) requests cancellation of this permit and complies with all permit-specific termination conditions, (b) applies for and receives a permit to move the organisms to a new facility, or (c) relinquishes control of the regulated organisms to a qualified individual who obtained a permit for the continued use of these regulated organisms prior to this permit holder's departure.
- (6) All laboratories and growth chambers where this genetically engineered insect is employed will be locked with limited access by authorized personnel. In each area where a regulated genetically engineered organism is used, at least one sign must be posted stating that a regulated genetically engineered organism is being used.
- (7) Upon completion of research all engineered insects (except those retained for future research), will be disposed of by freezing at -20 for 24 hours/or autoclaving.
- (8) There is to be no further distribution of these genetically engineered insects under this permit without prior approval from State (intrastate movement) and Federal regulatory officials.
- (9) THIS AUTHORIZATION IS VALID FOR THE RELEASE INTO THE ENVIRONMENT OF THIS GENETICALLY ENGINEERED INSECT ONLY IN THE AREAS DESCRIBED IN THE APPLICATION.
- (10) THIS IS A CROP DESTRUCT TRIAL. Brassicas will be destroyed at the end of the research field trial. No plants of produce shall be used for food or feed. Upon completion of the experiment, the insecticide shall be sprayed on the plants and surrounding area within a 100 m radius of treated fields to kill remaining diamondback moth larvae.
- (11) Without prior notice and during reasonable hours authorized Plant Protection and Quarantine and State regulatory officials shall be allowed to inspect the conditions under which this genetically engineered insect is being kept.
- (12) Reporting an Unauthorized or Accidental Release
  - a. 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.

http://pest.ceris.purdue.edu/stateselect.html

b. Written notification should be sent by one of the following means:

By e-mail:

BRSCompliance@aphis.usda.gov

By mail:

Biotechnology Regulatory Services (BRS)

Permit Number: 13-297-102r

| THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING BRS OFFICIAL VIA EPERMITS |                   |
|---|-------------------|
| SIGNATURE OF BRS OFFICIAL   | DATE              |
| John Turner   | November 10, 2014 |