## Guide for Movements and Imports of Disarmed Agrobacterium species and Drosophila melanogaster Developed using Genetic Engineering

The Animal and Plant Health Inspection Service (APHIS) regulates introductions of certain organisms developed using genetic engineering (modified organisms) which are, or have the potential to be, plant pests. Biotechnology Regulatory Services (BRS) issues Letter of No Permit Required (LONPR) for certain modified organisms that are exempt from the requirement for permits for import and interstate movement upon request to facilitate their movement, which might otherwise be impeded by the organism's similarity to regulated organisms.

Modified and disarmed *Agrobacterium* species, including *Agrobacterium tumefaciens* (synonyms include: *A. radiobacter* and *Rhizobium radiobacter*), *A. rhizogenes* (synonym include: *R. rhizogenes*) and *A. vitis*, do not require a BRS permit for their movement when the modified genetic material is stably integrated into the genome and does not include the complete infeciotus genome of a plant pest, and are specifically exempted under 7 CFR § 340.5(d), which states:

(d) Exemption for GE disarmed *Agrobacterium* species. A permit for importation or interstate movement is not required for any GE disarmed *Agrobacterium* species, provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the genome, and the modified material does not include the complete infectious genome of a plant pest.

Modified *Drosophila melanogaster* developed for research purposes that do not contain genetic material designed to propagate through a population by biasing the inheritence rate do not require a BRS permit for their movement and are specifically exempted under 7 CFR § 340.5(e), which states:

(e) Exemption for Drosophila melanogaster. A permit for importation or interstate movement is not required for modified Drosophila melanogaster, provided that it is moved as a secure shipment and that any introduced genetic material is not designed to propagate through a population by biasing the population inheritance rate.

## How to Request a LONPR for the Importation of Modified *Agrobacterium* species (disarmed) and *Drosophila melanogaster*

Make a request via email to BRSNoPermitRequired@usda.gov with the following information: {Applicant's Name} {Applicant's Institution} {Applicant's Full Mailing Address} {Applicant's phone number} {Applicant's email}

The requestor should certify that the organism(s) in the request meets the criteria for exemption from the requirement for a permit and that any supporting information provided in the request and any attachments is complete and accurate to the best of their knowledge.

## Note:

A Letter of No Permit Required **does not expire**. Once it has been issued, additional requests from the applicant are not necessary, and it can be used indefinitely for future movements of modified disarmed *Agrobacterium* species and *D. melanogaster* that meet the exemptions listed above.

Wild-type *D. melanogaster*, other *Drosophila and Agrobacterium* species may require a permit from USDA-APHIS Plant Protection Quarantine.

## When a BRS Permit is Needed for the Movement and Importation of modified *Agrobacterium* species and *D. melanogaster:*

The movement of modified Agrobacterium species and D. melanogaster needs a BRS permit if it:

- Contains an introduced genetic sequence from plant pests and the introduced genetic sequences are capable of producing an infectious agent that causes plant disease, or encoding a compound that causes plant disease,
- Contains an introduced genetic sequence that produces a biological agent or toxin that is on the select agents and toxins list.
- Is used for biocontrol of plant pests and could pose a plant pest risk, or
- For *D. melanogaster*, contains a sequence capable of influencing biased inheritance rate (e.g., any gene drive that influences biased inheritance rates).

A BRS permit can be obtained from APHIS e-File.