Regulatory Procedures for Transgenic Insects

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Research related to transgenic arthropods and insects is mostly in early stages of development. There is research underway with a variety of organisms to develop appropriate transformation methods and have focused on transposable elements such as *piggyBac* and paratransgenesis. Selectable markers such as enhanced green and red fluorescent proteins (EGFP and DsRed) are being used to evaluate transformation efficiency. Arthropods have been genetically engineered to be resistant to pests and disease (e.g., honey bees), produce pharmaceuticals (e.g., silkworms), prevent transmission of plant diseases (e.g., glassy-winged sharpshooters, planthoppers), prevent the spread of human and animal diseases (e.g., mosquitoes, kissing bugs, sand flies, tse tse flies, house flies, blowflies, stable flies), with autocidal traits (e.g., pink bollworms and medflies), and as biological control organisms (e.g., mites).

There are several laws that provide regulatory authority for transgenic insects most of which fall under USDA/APHIS. The Plant Protection Act (PPA) (2000) provides regulatory authority to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Exotic organisms such as insects imported for use as biological control organisms are regulated under the PPA. Transgenic arthropods that are plant pests (e.g., pink bollworm or medfly) or indirectly affect plant pests (e.g., biological control organisms) are regulated under the PPA. The Animal Health Protection Act focuses on the prevention, detection, control, and eradication of diseases and pests of animals. Genetically engineered (GE) arthropod pests of humans and animals such as mosquitoes that are made incapable of vectoring disease are regulated under the Animal Health Protection Act. The Virus-Serum-Toxin Act (VSTA) is intended to assure the safe and effective supply of animal vaccines and other biological products. Arthropods such as mosquitoes that have been genetically engineered to vector disease vaccines would be regulated under the VSTA as well as the AHPA. The Honey Bee Act gives APHIS authority to regulate importation and propagation of honey bees. Additional authority for transgenic insects falls to the Food and Drug Administration (FDA) which regulates new animal drugs under the Federal Food Drug and Cosmetic Act (FFDCA). The Environmental Protection Agency may regulate environmental releases of arthropods with a symbiotic relationship with a genetically engineered microbe under the Toxic Substances Control Act (TSCA) or the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

An APHIS permit is required for the importation, movement or environmental release of transgenic insects. Appropriate containment or confinement of the transformed organism is required whether the organism is released, imported or moved interstate. A permit for environmental release will require a risk assessment, a formal NEPA analysis (in some cases by preparation of an Environmental Assessment (EA)) that is shared with the public, publication of the availability of the EA in the Federal Register, a public comment period, final deliberations, and then if appropriate, an issuance of a Finding of No Significant Impact (FONSI) and approval of the permit

(http://www.aphis.usda.gov/brs/arthropod_discuss.html). Permits have been issued by BRS for caged and open-field releases of transgenic pink bollworms and predatory mites (http://www.aphis.usda.gov/brs/arthropod_release.html).

When an application is received, it is evaluated for completeness for the purpose of doing a risk assessment. If it is found deficient, the applicant is informed what information is needed and time is allowed to provide the information. The main purpose of the risk assessment is to determine if genetic alteration changes ecological or environmental properties of the organism. Such potential risks associated with the release of a transgenic arthropod or other invertebrate could include displacement of native populations, change in host or prey utilization, change in distribution, effects on endangered or threatened species, transfer of DNA to other organisms, or, if one of the characteristics of the transgenic arthropod was increased resistance to herbicides or pesticides (http://www.aphis.usda.gov/brs/arthropod_discuss.html).

A confined field trial is where the candidate arthropod is prevented from becoming established and spreading. Confinement may be by physical barriers such as screen cages, pesticides, cultural control, and biological measures such as induced sterility or pheromone traps. Confined field tests can provide important information before unconfined release is requested and may be useful to observe changes in biology, ecology, and behavior of the transgenic form compared to the parental form (http://www.aphis.usda.gov/brs/arthropod_discuss.html).