Animal and Plant Health Inspection Service

Veterinary Services

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Animal and Plant Health Inspection Service
Framework for the Regulation of Genetically Engineered Animals and Insects Pursuant to the Animal Health Protection Act

Rapid technological advancements have been made in genetic engineering (GE) of animals and other organisms that can affect animal health. Genetic engineering is the use of recombinant DNA (rDNA) or other modern molecular biology techniques to introduce new traits into plants, animals, or other organisms. These techniques are used to develop new traits to produce healthier food, organs for transplantation into humans, and animals with less environmental impact, for example, the emission of environmental contaminants.

Examples of some GE animals include

- Goats and chickens that produce human drugs or biologics
- Ornamental fish that fluoresce and are intended for aquarium use
- Large animal models of human disease (e.g., miniswine that are models of human hyperlipidemic disease)
- Atlantic salmon that reach a growth marker important to the aquaculture industry more rapidly than non-GE Atlantic salmon, and
- Mosquitoes whose offspring do not reach viable adulthood, resulting in suppression of the local wild-type mosquito population

GE animals, animal disease vectors, and animal pests have also become important model systems for research in pathology and developmental biology, and provide scientists a better understanding of how genetics contribute to the overall health of humans, livestock, and other animals. There are regulations in place for assessing the impact of GE insects that affect plant health. https://www.aphis.usda.gov/aphis/ourfocus/biotechnology This APHIS Framework specifically addresses the current regulatory posture for addressing the interstate and importation requirements of GE animals and insects which may be vectors of animal disease agents of concern.

Regulations for GE Animals and Insects Pursuant to the AHPA

The Animal Health Protection Act (AHPA) provides broad authority for regulating animals or insects that pose a risk to animal health. The AHPA gives the Secretary of Agriculture authority to prohibit or restrict imports or entry of any animal, article, or means of conveyance into the United States if the Secretary determines this is necessary to prevent the introduction or dissemination of any pest or disease of livestock. The Secretary delegates this responsibility to the Animal and Plant Health Inspection Service (APHIS).

GE Insects

For insects that serve as vectors for animal disease agents of concern, the AHPA defines a pest as “any of the following that can directly or indirectly injure, cause

damage to, or cause disease in livestock: a protozoan, plant, bacteria, fungus, virus or viroid, infectious agent or other pathogen, arthropod, parasite, prion, vector, animal, and any organism similar to or allied with any of the organisms described…."

APHIS implements this authority through regulations codified at Title 9 of the Code of Federal Regulations, Part 122 (9 CFR part 122). Regulations at 9 CFR part 122 establish permit-based procedures for the importation and interstate movement of organisms and vectors that could cause or transmit animal disease. The terms "organisms" and "vectors" are included in the definition of animal pest under the AHPA. The regulations do not differentiate whether such organisms and vectors are GE or non-GE and thus apply to both. The regulations in 9 CFR part 122 allow APHIS to issue permits for organisms and vectors that are imported into the United States or moved interstate. Section 122.1. As specified in 9 CFR, section 122.2, the Secretary may issue a permit at his discretion.

APHIS in its review process of such requests collaborates with other agencies such as the Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) to obtain scientific input on the review of an application, and to minimize duplication and avoid gaps in the regulatory review of such products. In the event where the regulatory pathway is not clear, extensive consultations occur among agencies in order to determine the need for regulatory action, processes to reach resolution for the request, and scope of scientific assessments needed in order to inform resolution of the request.

GE Animals

The regulations in 9 CFR, Part 93 define conditions for the importation of animals, and Part 71 defines rules for interstate movement of animals infected with certain diseases. These regulations are limited in scope to animals that are considered livestock, such as horses, cattle, bison, cervids, camelids, sheep, goats, swine, and other farm-raised animals. When considering the appropriate regulatory posture for APHIS, the same standards of review would be applied to GE animals as are applied to non-GE animals, that is, what is the animal health risk, and what mitigations, if any, could be applied to mitigate the animal health risk of an importation. It should be noted that farmed fish are regulated under the AHPA as it pertains to the importation and interstate movement of certain species capable of transmitting certain diseases. These specific requirements are found in 9 CFR Part 93. A specific example is the requirement for an importation permit and health certification for carp, koi and goldfish, which are susceptible to the disease Spring Viremia of Carp, which does not occur in the U.S.

APHIS participates in the National Aquatic Animal Health Plan which was developed to facilitate the legal movement of all aquatic animals, their eggs, and products in interstate and international commerce, protect the health and thereby improve the quality and productivity of farmed and wild aquatic animals, ensure the availability of diagnostic, inspection, and certification services; and minimize the impacts of diseases when they occur in farmed or wild aquatic animals. The plan provides the outline of how industry,

regional organizations, state, local, Tribal governments, and Federal agencies will communicate in order to identify strategies and issues that impact aquatic animal health. The FDA is identified in this plan as having authority over fish for consumption as food for humans or animals, while APHIS, Department of Commerce, and Department of Interior have various authorities on aquaculture from aquatic health and management to marketing, importation, interstate movement, and disease control and eradication activities. Regulation of genetically engineered fish or other aquatic species would occur within the context of this plan.

The FDA administers the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA regulates GE animals under the new animal drug provisions of the FD&C Act, as described in Guidance for Industry 187: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs (GFI 187). See FDA website for additional information:
http://www.fda.gov/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/

Application Process for Importation or Interstate Movement of GE Animal Pests and Disease Vectors

APHIS evaluates requests and issues permits for importing organisms that are animal pests, animal disease agents, or vectors of animal disease agents. All importations and interstate movements of these materials which pose a risk for dissemination of infectious diseases of animals require a permit from APHIS. Requests are evaluated on a case-by-case basis by reviewing the specifics of the study protocol, which describes the genetic modification, the organism in question, and the proposed work and supporting scientific literature from the importer. Part 122 of 9 CFR does not address the environmental release of these organisms. However, APHIS may conduct an environmental assessment and further evaluation if the request poses an adverse animal health risk.

After review of the study protocol and other scientific supporting literature, APHIS will determine the regulatory action needed on a case-by-case basis. The regulatory action may be issuance of a permit with specific restrictions, further assessment for risk or environmental impacts, or upon determination of no animal health impact, issuance of a letter of no jurisdiction. Requests for importation or interstate movement of GE animal pests must be made by application to APHIS, Veterinary Services, National Import Export Services. Applications will be evaluated individually to determine the appropriate regulatory requirements and assessments needed for each intended use of GE animal pests.

Electronic applications may be submitted through APHIS' e-Permits system at http://www.aphis.usda.gov/permits/login_epermits.shtml . VS Form 17-129 "Application for Import or In Transit Permit Animals, Animal Semen, Animal Embryos, Birds, Poultry, or Hatching Eggs" and VS Form 16-3 "Application for Permit to Import or Transport Controlled Material or Organisms or Vectors" are both available for

submission on the e-Permits system. Applications may also be requested by email at VS.Live.Animals.Import.Permits@aphis.usda.gov .

Additional Regulatory Requirements

After thorough review of pertinent regulations and research, APHIS has determined that no additional regulatory requirements are currently needed specifically for GE animals. However, we will continue to monitor and evaluate GE laboratory and field developments to assess the need for additional rulemaking.