

IMPORTING ANIMALS AND ANIMAL PRODUCTS

Introduction

Federal authority for regulating the import of animals and animal products is split between several federal agencies. The particular agency with jurisdiction depends on the specific type of animal or animal product. Federal agencies that may have authority include:

- Food and Drug Administration (e.g., vaccines, feeds)
- Public Health Service (e.g., human vaccines and pharmaceuticals)
- Fish and Wildlife Service (e.g., fish, marine animals)
- Animal and Plant Health Inspection Service (animals and animal-derived materials)

Scope

This SOP is limited in scope to federal authority for international import permits issued by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), and Veterinary Services (VS). This SOP does not address:

- State of Nebraska Department of Agriculture regulations regarding the domestic import of certain animals into Nebraska. Refer to the Nebraska Department of Agriculture website <http://www.nda.nebraska.gov/regulations/animal/tilac.html>, for information about Nebraska requirements.
- Export regulations. The UNL Office of Research compliance is responsible for administering the UNL export compliance program. Export restrictions are beyond the scope of this SOP.
- Plant and plant related import and transfer requirements.

General Permit Requirements

An APHIS-VS permit is generally required for importing any animals, materials derived from animals, or materials exposed to animals. Detailed information regarding federal import requirements is available at http://www.aphis.usda.gov/import_export/index.shtml.

Exclusions

APHIS provides for several exclusions from the permit requirements. While excluded materials do not require an APHIS-VS import permit, they will be reviewed at the port of entry by USDA inspectors. In general, those materials excluded from APHIS-VS permit requirements must be accompanied with documentation to show why they are excluded (i.e., free of livestock or poultry disease agents). Furthermore, materials excluded from APHIS-VS permits may require permits from other federal agencies. Following is a

generic list of APHIS-VS exclusions. However, these exclusions are limited in scope and the reader is cautioned to consult the APHIS website for more detailed information.

- **Human Pharmaceuticals and Human Vaccines Containing Animal Components**
Including (Permit Not Required): Human vaccines and human pharmaceuticals in final dosage form approved by the Food and Drug Administration (FDA). The U.S. Food and Drug Administration and U.S. Public Health Service, have primary jurisdiction over human drugs and human vaccines.
Not Including (Permit Required): Antivenom, vaccines/pharmaceuticals for animal use, vaccines/pharmaceuticals containing live livestock or poultry viruses, dietary supplements and nutraceuticals, and insulin.
- **Human and Non-Human Primate Material (excluding cell culture)**
Including (Permit Not Required): Tissues, blood, extracts, proteins, DNA. The Centers for Disease Control (CDC) has jurisdiction over human and non-human primate material.
Not including (Permit Required): Cell cultures, tissues in culture, hybridomas, and their products.
- **Feline and Canine Material**
Including (Permit Not Required): Semen for research purposes, blood, tissues, serum, feces, extracts, fluids.
Not including (Permit Required): Semen for reproductive purposes, cell cultures, tissue cultures, cell culture products.
- **Live Laboratory Mammals and Their Materials (for Research Purposes)**
Including (Permit Not Required): Transgenic/knock-out mice and rats, hamsters, gerbils, guinea pigs, rabbits, ferrets, and their blood, tissue, DNA, extracts, antibodies, feces, sera, and antisera for research purposes. (blood, sera, antibodies, and antisera is limited to less than 1 liter). The Centers for Disease Control (CDC) has jurisdiction over live laboratory mammals and their material.
Not including (Permit Required): Primates, dogs, cats, livestock*, poultry, hedgehogs, tenrecs, minipigs, monoclonal antibodies, hybridomas, cell lines, and material for commercial purposes.
- **Amphibians, Fish, Reptiles, Shellfish, and Aquatic Species (including venom)**
Including (Permit Not Required): Blood, tissues, serum, feces, extracts, fluids, venom, urine, chondroitin, and glucosamine from these species. The US Fish and Wildlife Service has jurisdiction over the importation of marine mammals and fish.
Not including (Permit Required): Antivenom, oils, and meals (e.g. fish oil or fish meal).
- **Chemically Synthesized Materials**
Including (Permit Not Required): Biochemicals, materials not containing or derived from animal products including cell culture derived products.
- **Microbially Produced Materials**
Including (Permit Not Required): Enzymes, plasmids, proteins, antibiotics, hormones, extracts, phages, DNA, and microbes (usually E. coli or yeasts) that do not express material of an exotic livestock or poultry disease.
- **Recombinant Microbes and Their Products**
Including (Permit Not Required): Microbes (bacteria, viruses, yeasts/fungi), proteins, hormones, extracts, plasmids, DNA, RNA, and recombinant non-pathogenic bacteria/yeasts (such as E. coli & Saccharomyces cerevisiae) and their products that are not related to

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livestock or avian species or disease causing agents and that do not contain animal products such as albumin or serums.

Not including (Permit Required): Materials produced by cell culture techniques.

- **Non-Pathogenic Microorganisms**

Including (Permit Not Required): Non-pathogenic bacteria, viruses, algae, or yeast (fungi), including environmental or water organisms, such as algae. However, there may be USDA APHIS, Plant Protection and Quarantine (PPQ) permit requirements for environmental samples and algae.

Not including (Permit Required): Any microorganism that is known to cause infectious, contagious, or communicable diseases of livestock or poultry.

- **Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in Vitro Use)**

Including (Permit Not Required): Monoclonal antibodies, cell culture supernatants, ascitic fluid, cell extracts, hybridomas, cell cultures/lines which are not derived from livestock* or avian species and which: 1) are for in vitro use; 2) have not been exposed to livestock or avian disease agents exotic to the United States; 3) do not produce antigens or contain genes of livestock or avian disease agents or do not produce monoclonal antibodies directed against livestock or avian disease agents. In addition, monoclonal antibodies intended for in vivo human use do not require a permit.

Not including (Permit Required): Cell lines of livestock* or avian species origin and their products, microbial cultures and their products.

- **Test Kits**

Including (Permit Not Required): Pre-packaged kits and kit components (reagents, calibrators, controls) packaged for final use.

Not including (Permit Required): Kits used to diagnose infectious diseases of animals (excluding humans).

- **Animal Feeds, Feed Supplements, and Pre-Mixes**

Including (Permit Not Required): Animal feeds, feed supplements, and pre-mixes containing vitamins and/or minerals (including vitamins coated with porcine gelatin or sheep wool grease) as the only animal-origin ingredients. In this context, animal feeds may include livestock, poultry, bird, rodent, and aquaculture feeds, as well as pet treats. The U.S. Food and Drug Administration regulate the importation of animal feeds and ingredients intended for incorporation into animal feeds.

Obtaining APHIS Veterinary Permit

It is the responsibility of the Principal Investigator (PI) to make an application for and obtain required APHIS-VS permits and/or meet the requirements of the State of Nebraska Department of Agriculture animal importation regulations before engaging in the transport of regulated animals and animal products. APHIS permits can be downloaded at http://www.aphis.usda.gov/import_export/forms.shtml.

Research involving the use of live vertebrate animals is subject to requirements of UNL's IACUC.

*The term livestock includes any bovine, ovine, caprine, porcine, equine, cervid, fish and shellfish.