

3

Animal Product
Manual

Reference

Live Animals and Related Material

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Introduction

The *Live Animals and Related Material* section covers importations of living organisms and related material for which DHS-CBP has approval to take regulatory action. Examples include embryos, ova, and semen; organisms and vectors, including microorganisms (viruses, bacteria) imported for research purposes; antisera; diagnostic reagents; monoclonal antibodies; test kits; and antivenin.

Not covered in this section are the following live animal importations:

- ◆ Blood or a derivative of blood; regulate these by-products under ***Blood and Related By-Products***


- ◆ Eggs for hatching, including commercial importations of uncooked baluts. Contact the nearest VS office for further action. Consider eggs being imported for research as embryos; see [Table 3-8-20](#)
- ◆ Extracts or derivatives of animal organs or glands; regulate these by-products under [Organs](#)
- ◆ Human pharmaceuticals and human vaccines in final dosage form; see **Human Pharmaceuticals and Human Vaccines**
- ◆ Importations of live animals, except for laboratory animals (see [Animal Tissue](#) on **page 3-8-9**). Consult with local VS for notification and procedures for any live animal import **other than** those handled by the U.S. Public Health Service (PHS)
- ◆ Live animals found while clearing aircraft or vessels; see **Safeguarding Live Animals**
- ◆ African rodents, bats, cats, civets, dogs, and nonhuman primates; see PHS, and also refer nonhuman primates to FWS. The Centers for Disease Control and Prevention (CDC) has jurisdiction over the importation of African rodents, bats, cats, civets, dogs, and nonhuman primates. The importer should contact the CDC for import restrictions (phone 404/498-1600)
- ◆ Pet birds in passenger baggage and aboard vessels or yachts and pleasure vessels; see [Handling Pet Birds](#)
- ◆ Used semen and embryo containers; see [Empty Semen and Embryo Containers](#) for action to take
- ◆ Veterinary biologics such as bacterins, vaccines, toxins, toxoids, and test kits for the diagnosis of animal diseases. These animal products are authorized entry under a veterinary biological product permit issued by VS, Center for Veterinary Biologics; see [Requests for VS Permits Table 2-4-16](#)

When a VS permit authorizes entry of live animals, match the following information on the shipping documents with that on the permit:

- ◆ Current date
- ◆ Description of the material
- ◆ Shipper
- ◆ Consignee
- ◆ Conditions spelled out on the permit

Follow [Table 3-8-1](#) as you match the permit with the shipping documents.

TABLE 3-8-1 Validate Importation Authorized Entry by a VS Permit

If the shipping documents:	And the:	Then:
Match the permit		RELEASE or CONTROL as specified on the permit
Do not match the permit	Permit has expired	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. HAVE the consignee contact VS, TTSPS, IEAS, or CVB (see page 2-4-29) 3. SAFEGUARD the importation until you hear from VS, TTSPS
	Discrepancy is other than an expired permit	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

Locator

When a VS permit **does not** accompany an importation of live animals, use [Table 3-8-2](#) to determine the appropriate regulatory action to take.

TABLE 3-8-2 Where to Find Regulatory Action on Live Animals and Related Material Not Authorized By a VS Permit

If the importation is:	Then:
Amphibians	Go to Table 3-8-11
Aquatic animals (including fish, sharks, shellfish, and whales)	
Animal tissue	Go to Table 3-8-6
Cat (feline) materials	Go to Table 3-8-10
Dog (canine) materials	
Earthworms and Earthworm Manure (Castings)	GO to Table 3-8-3
Human materials	Go to Table 3-8-8
Laboratory mammals and their associated materials	GO to Table 3-8-7
Microorganisms (bacteria, viruses, fungi)	GO to Table 3-8-4
Organisms and vectors	GO to Table 3-8-12
Nonhuman primate materials	GO to Table 3-8-9
Ova and embryos	GO to Table 3-8-20
Reptiles	Go to Table 3-8-11
Semen from equine	GO to Table 3-8-18
Semen from other than equine	GO to Table 3-8-19
Used embryo, ova, or semen containers	GO to Empty Semen and Embryo Containers on page 2-2-13
Other than described above	CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

Earthworms and Earthworm Manure (Castings)

TABLE 3-8-3 Earthworms and Earthworm Manure (Castings)

If:	And the country or region of export is:	And the earthworms are:	And from:	And:	Then:
<ul style="list-style-type: none"> ◆ Live earthworms ◆ Freeze-dried earthworms ◆ Earthworms in any form other than pelletized, or in capsules 	Canada	In soil	<ul style="list-style-type: none"> ◆ Alberta: A farm unit and associated land located near the municipality of Fort Saskatchewan; or a farm unit and associated land located near the municipality of Spruce Grove ◆ British Columbia: That portion of the municipality of Central Saanich on Vancouver Island, east of West Saanich Road ◆ Newfoundland: The entire island ◆ Quebec: the municipality of Saint-Amble 	→	REFUSE ENTRY
			Part of Canada other than that described in the cell above	→	RELEASE ¹
			Not in soil	→	RELEASE ¹
	Other than Canada	In alcohol	→	RELEASE	
		Not in alcohol	→	Is accompanied by PPQ Form 526, Permit to Move Live Plant Pests ²	RELEASE ¹ or CONTROL as specified on the permit
			Lacks the permit	→	REFUSE ENTRY

TABLE 3-8-3 Earthworms and Earthworm Manure (Castings) (continued)

If:	And the country or region of export is:	And the earthworms are:	And from:	And:	Then:
Earthworm manure (earthworm castings) ³	Canada	→	<ul style="list-style-type: none"> ◆ Alberta: A farm unit and associated land located near the municipality of Fort Saskatchewan; or a farm unit and associated land located near the municipality of Spruce Grove ◆ British Columbia: That portion of the municipality of Central Saanich on Vancouver Island, east of West Saanich Road ◆ Newfoundland: The entire island ◆ Quebec: the municipality of Saint-Amble 	→	REFUSE ENTRY
			Part of Canada other than that described in the cell above	→	RELEASE
			Other than Canada	→	REFUSE ENTRY
Earthworms, pelletized, or in capsules and packaged for human consumption				→	RELEASE

- 1 Because live earthworms are perishable, expedite shipments that you are authorized to release.
- 2 Since earthworms may harbor plant pathogens in their guts, earthworms are regulated by 7CFR 330.200.
- 3 Earthworm manure is regulated as earthworm castings by USDA as soil

Microorganisms (Bacteria, Viruses, Fungi)

TABLE 3-8-4 Microorganisms

If:	And:	Then:
Recombinant microorganism	→	GO to Table 3-8-5
Recombinant microorganism that poses a threat to humans	→	CDC Permit required, CONTACT the Centers for Disease Control and Prevention at 404/498-1600
Nonrecombinant microorganism ¹	Is accompanied by shipper or producer's declaration ²	RELEASE
	Lacks the shipper or producer's declaration or statements ²	DO NOT RELEASE the HOLD until the importer provides the required documentation

- 1 Examples of nonrecombinant, nonpathogenic microorganisms are as follows: *Lactobacillus* (used to manufacture yogurt); *Micrococcus* (skin bacterium); *Penicillium* (used to produce penicillin, an antibiotic); and *Serratia* (soil microbe).

Examples of microorganisms requiring a permit to authorize entry are as follows: *Hemophilus influenzae*, *Actinobacillus equuli*, *Actinomyces bovis*, *Streptococcus bovis*, *Rhodococcus equi*, *Helicobacter pylori*, *Lawsonia intracellularis*, *Clostridium perfringens*, *Pasteurella multocida*, Bluetongue virus, Vesicular stomatitis virus, porcine parvovirus, and epizootic hemorrhagic disease virus.

- 2 A declaration which provides, in a clear and concise manner, the following information:
- ◆ Genus and species of the microorganism
 - ◆ Microorganism is **not** considered to be pathogenic to livestock or poultry

Recombinant Microorganisms

Recombinant microorganisms can be bacteria, viruses, or yeast. Recombinant technology involves the transfer of genes from one organism into another organism. Examples of transference include the following:

- ◆ Transferring insect or herbicide resistance to plants
- ◆ Transferring normal human genes to replace defective ones
- ◆ Transferring genes which manufacture hormones or enzymes to those that **do not**

The most common recombinant microorganisms are as follows:

- ◆ Bacteria, *Escherichia coli* and *Bacillus subtilis*
- ◆ Yeasts, *Streptomyces* and *Saccharomyces*
- ◆ Virus, *Vaccinia*

TABLE 3-8-5 Recombinant Microorganisms

If:	And the microorganism:	And the importation:	Then:
Recombinant microorganisms	Contains animal-derived additive or stabilizer, e.g., albumin	Is accompanied by shipper or producer's declaration ¹	RELEASE
		Lacks the shipper/producer's declaration ¹	REFUSE ENTRY
	Does not contain animal-derived additive or stabilizer	Is accompanied by shipper or producer's declaration ²	RELEASE
		Lacks the shipper/producer's declaration	REFUSE ENTRY

1 A declaration which provides, in a clear and concise manner, the following information:

- ◆ A detailed name or description of the microbe/recombinant product, including genetic insert
- ◆ Identification of additive or stabilizer
- ◆ Confirmation that the material is produced by recombinant microbial expression (vector **must not** be considered pathogenic for livestock or avian species)
- ◆ Confirmation that the organism **does not** contain genes or express antigens of livestock or poultry disease agents
- ◆ Confirmation that the product will be used **only** in vitro

2 A declaration which provides, in a clear and concise manner, the following information:

- ◆ A detailed name or description of the microbe/recombinant product, including genetic insert
- ◆ Confirmation that the preparation does not contain any animal-derived additives, such as albumin
- ◆ Confirmation that the material is produced by recombinant microbial expression (vector **must not** be considered pathogenic for livestock or avian species)
- ◆ Confirmation that the organism **does not** contain genes or express antigens of livestock or poultry disease agents

Animal Tissue

TABLE 3-8-6 Action to Take on Animal Tissue

If the tissue originated from:	Then:
Amphibians, aquatic species, or reptiles	GO to Table 3-8-11
Canines (dogs)	GO to Table 3-8-10
Felines (cats)	
Humans	GO to Table 3-8-8
Live laboratory animals (including ferrets, gerbils, guinea pigs, hamsters, mice, rabbits, or rats)	GO to Table 3-8-7
Live laboratory animals regulated by CDC (including African rodents, bats, and civets)	GO to Table 3-8-7
Livestock (horses, ruminants, swine or avian species (birds and poultry)	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing the entry 3. PROVIDE the importer with the appropriate options, including applying for a VS permit issued by VS, TTSPS (see Table 2-4-16)
Nonhuman primates	GO to Table 3-8-9

Live Laboratory Mammals and Their Associated Materials for Research Purpose



Important

The Centers for Disease Control and Prevention (CDC) regulates the importation of African rodents, bats, cats, civets, dogs, and nonhuman primates; see [Table 3-8-7](#) on page 3-8-10 for African rodents, bats, and civets; see [Table 3-8-9](#) on page 3-8-13 for nonhuman primates; and see [Table 3-8-10](#) on page 3-8-14 on page for cats and dogs.

For the purposes of this section, laboratory mammals (and their products) include ferrets, gerbils, guinea pigs, hamsters, mice, rabbits, rats, transgenic rabbits, transgenic rats, and transgenic/knockout mice; see [Table 3-8-7](#) on page 3-8-10.





If the cages containing the animals also contain fruits or vegetables (used as a source for water), then have the importer or the importer's agent remove any prohibited material prior to being released to a consignee.

TABLE 3-8-7 Live Laboratory Mammals and Their Associated Materials for Research Purposes

If the importation is:	And is:	And is:	And is:	And:	Then:
Live laboratory mammals for research purposes	African rodents, bats, civets	→			CONTACT the Centers for Disease Control and Prevention which has jurisdiction over these items at 404/498-1600
	<ul style="list-style-type: none"> ◆ Ferrets, gerbils, guinea pigs, hamsters, mice, rabbits, rats, transgenic rabbits, transgenic/knockout rats, transgenic/knockout mice ◆ Other than listed above 	→		Is accompanied by VS-recommended documentation ¹	RELEASE; a USDA permit is not required
				Lacks the VS-recommended documentation ¹	CONTACT USDA-APHIS-VS National Center for Import and Export at 301/734-3277 to determine if a USDA permit is required

TABLE 3-8-7 Live Laboratory Mammals and Their Associated Materials for Research Purposes (continued)

If the importation is:	And is:	And is:	And is:	And:	Then:	
Laboratory mammal materials for research purposes		Blood fractions include albumin, antibodies, antisera, blood clotting factors, red or white blood cells, plasma, whole blood	Less than one (1) liter	Is accompanied by VS-recommended documentation ²	RELEASE; a USDA permit is not required	
				Lacks the VS-recommended documentation ²	CONTACT USDA-APHIS-VS National Center for Import and Export at 301/734-3277 to determine if USDA permit is required	
			One (1) liter or greater	Is accompanied by a USDA permit	RELEASE	
				Lacks a USDA permit	REFUSE ENTRY	
		DNA, Enzymes, Extracts, Feces, Fluids, Hormones, Peptides, RNA, Semen, Tissue, Other than listed above			Is accompanied by VS-recommended documentation ²	RELEASE; a USDA permit is not required
					Lacks the VS-recommended documentation ²	CONTACT USDA-APHIS-VS National Center for Import and Export at 301/734-3277 to determine if USDA permit is required

1 VS recommends the following documentation accompany each shipment: a written statement confirming that the live laboratory mammals:

- ◆ Have **not** been exposed to or inoculated with any livestock or poultry disease agents exotic to the United States
- ◆ **Do not** originate from a facility where work with exotic disease agents affecting livestock or poultry is conducted

2 VS recommends that the following documentation accompany each shipment; a written statement:

- ◆ Identifying the material and naming the animal species
- ◆ Confirming that the material was derived **only** from laboratory mammals that have **not** been inoculated with or exposed to any livestock or poultry disease agents exotic to the United States
- ◆ Confirming that the material was derived **only** from laboratory mammals that did **not** originate from a facility where work with exotic disease agents affecting livestock or avian species is conducted
- ◆ If applicable, identifying the immunogen for antibodies/antiserum

Human Materials

TABLE 3-8-8 Human Materials

If the importation is:	And is:	And:	Then:
Material collected from humans	<ul style="list-style-type: none"> ◆ Blood fractions¹ ◆ DNA ◆ Enzymes ◆ Extracts ◆ Feces ◆ Fluids ◆ Hormones ◆ Peptides ◆ RNA ◆ Semen ◆ Tissue ◆ Urine ◆ Other than listed above 	Is accompanied by VS-recommended documentation ²	1. RELEASE 2. CONTACT and REFER to the Centers for Disease Control and Prevention which has jurisdiction over these items, at 404/498-1600
		Lacks the VS-recommended documentation ²	1. A USDA permit may be required; CONTACT USDA-APHIS-VS-National Center for Import and Export at 301/734-3277 to determine if a USDA permit is required 2. CONTACT and REFER to the Centers for Disease Control and Prevention which has jurisdiction over these items at 404/498-1600

1 Blood fractions include albumin, antibodies, antisera, blood clotting factors, red or white blood cells, plasma, sera, whole blood.

2 VS recommends the following documentation accompany each shipment: a written statement

- ◆ Identifying the material and naming the species
- ◆ Confirming that the material was **not** obtained from humans or non-human primates that have been inoculated with or exposed to any livestock or poultry disease agent exotic to the United States
- ◆ Confirming that the material is **not** of tissue culture origin
- ◆ Confirming that the material is **not** zoonotic

Nonhuman Primate Materials

TABLE 3-8-9 Nonhuman Primate Materials

If the importation is:	And is:	And:	Then:
Material collected from nonhuman primates	<ul style="list-style-type: none"> ◆ Blood fractions¹ ◆ DNA ◆ Enzymes ◆ Extracts ◆ Feces ◆ Fluids ◆ Hormones ◆ Peptides ◆ RNA ◆ Semen ◆ Tissue ◆ Urine ◆ Other than listed above 	Is accompanied by VS-recommended documentation ²	<ol style="list-style-type: none"> 1. A USDA permit is not required 2. CONTACT and REFER to the Centers for Disease Control and Prevention which has jurisdiction over these items, at 404/498-1600
		Lacks the VS-recommended documentation ²	<ol style="list-style-type: none"> 1. CONTACT USDA-APHIS-VS-National Center for Import and Export at 301/734-3277 to determine if a USDA permit is required 2. CONTACT and REFER to the Centers for Disease Control and Prevention which has jurisdiction over these items, at 404/498-1600

- 1 Blood fractions include albumin, antibodies, antisera, blood clotting factors, red or white blood cells, plasma, whole blood.
- 2 VS recommends the following documentation accompany each shipment; a written statement:
 - ◆ Identifying the material and naming the animal species
 - ◆ Confirming that the material was **not** obtained from humans or non-human primates that have been inoculated with or exposed to any livestock or poultry disease agent exotic to the United States
 - ◆ Confirming that the material is **not** of tissue culture origin
 - ◆ Confirming that the material is **not** zoonotic

Canine (Dog) and Feline (Cat) Materials


TABLE 3-8-10 Canine (Dog) and Feline (Cat) Materials

If the importation is:	And is:	And:	Then:
Material collected from either: ◆ Canines (dogs) ◆ Felines (cats)	◆ Blood fractions ¹ ◆ DNA ◆ Enzymes ◆ Extracts ◆ Feces ◆ Fluids ◆ Hormones ◆ Peptides ◆ RNA ◆ Semen ² ◆ Serum ◆ Tissue ◆ Urine ◆ Venom ◆ Other than listed above	Is accompanied by VS-recommended documentation ³	1. RELEASE; a USDA permit is not required 2. If you have a question regarding live canine (dog) or feline (cat) animals, contact the Centers for Disease Control and Prevention at 404/498-1600
		Lacks the VS-recommended documentation ³	1. CONTACT USDA-APHIS-VS-National Center for Import and Export at 301/734-3277 to determine if a USDA permit is required 2. If you have a question regarding live canine (dog) or feline (cat) animals, contact the Centers for Disease Control and Prevention which has jurisdiction over these items at 404/498-1600

- 1 Blood fractions include albumin, antibodies, antisera, blood clotting factors, red or white blood cells, plasma, whole blood.
- 2 If dog semen is to be used for reproductive purposes and **not** research, then the semen is unrestricted as long as the species is confirmed.
- 3 VS recommends the following documentation accompany each shipment: a written statement:
 - ◆ Identifying the material and naming the animal species
 - ◆ Confirming that the material does **not** contain any other animal-derived material (i.e., does **not** contain any livestock or poultry origin material)
 - ◆ Confirming that the material was **not** derived from feline or canine species which were inoculated with or exposed to any infectious agents of USDA agricultural concern

Amphibian, Aquatic Animal, and Reptile Materials

TABLE 3-8-11 Materials Derived from Amphibians, Aquatic Animals, and Reptiles

If the imported material is from:	And is:	And:	Then:
<ul style="list-style-type: none"> ◆ Amphibians ◆ Aquatic animals (including fish, sharks, shellfish, whales) ◆ Reptiles 	<ul style="list-style-type: none"> ◆ Blood fractions¹ ◆ DNA ◆ Enzymes ◆ Extracts ◆ Feces ◆ Fluids ◆ Hormones ◆ Peptides ◆ RNA ◆ Semen ◆ Tissue ◆ Urine 	Is accompanied by the shipper or producer's declaration ²	RELEASE
		Lacks the shipper/producer's declaration or statements ²	REFUSE ENTRY
Other than one listed above			1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

1 Blood fractions include albumin, antibodies, antisera, blood clotting factors, red or white blood cells, plasma, whole blood.

2 A declaration which provides, in a clear and concise manner, the following information:

- ◆ Identification of the material and species of origin
- ◆ Material **does not** contain any avian, equine, ruminant, or swine species products (such as in transport media or stabilizers)

List of Laboratories Working with Exotic Viruses, Including FMD

Country	Laboratory
Australia	CSIRO, Division of Animal Health Geelong, Victoria
Brazil	Centro Panamericano de Fiebre Aftosa Rio de Janeiro
Botswana	Botswana Vaccine Institute Department of Animal Health and Production Gaborone
Canada	Animal Disease Research Institute, Virology Section Nepean, Ontario
France	CNEVA Lyon, Laboratoire de pathologie bovine Lyon, Cedex CIRAD, Department d'élevage et de médecine vétérinaire
Germany	Hannover Veterinary School, Institute of Virology Bunteweg 17, Hanannover Institut für Geflügelkrankheiten der Justus-Liebig Giessen
Iran	Razi Vaccine and Serum Institute, Tehran
Italy	Instituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia "B Ubertini" Brescia National Centre for Exotic Diseases Teramo
Japan	National Institute for Animal Health Ibaraki
Kenya	Organisation for African Unity/ Interafrican Bureau for Animal Resources, Nairobi Kenya Agricultural Research Institute Nat'l Veterinary Research Centre, Kikuyu
Poland	National Veterinary Research Institute Pulawy
Portugal	Laboratorio Nacional de Veterinaria Lisbon
Republic of South Africa	Onderstepoort Institute for Exotic Diseases Onderstepoort Veterinary Institute Onderstepoort
Russia	All-Russian Research Institute for Animal Health Vladimir
Spain	Centro de Investigacion en Sanidad Animal Valdeolmos 28130 Madrid Laboratorio de Sanidad y Produccion Animalde Madrid 28110 Algete, Madrid
United Kingdom	Institute for Animal Health, Pirbright Laboratory Working Surrey, CVL Weybridge, Addlestone Surrey

FIGURE 3-8-1 List of Laboratories Working with Exotic Viruses, Including FMD

Organisms and Vectors

Organisms are living cultures or collections of animals or their derivatives which may introduce or disseminate any contagious or infectious disease of animals, including poultry. Importations regulated as organisms include the following:

- ◆ Bacterial cultures
- ◆ Culture medium
- ◆ Excretions
- ◆ Fungi (including yeast)
- ◆ Ticks, mites, sand flies, mosquitoes
- ◆ Tissues of livestock and birds
- ◆ Viruses

A vector can be an animal (to include arthropods [which include insects]), or an organism that: (1) has been exposed to or inoculated with any contagious, infectious, or communicable disease agent of livestock or poultry; and (2) is capable of transmitting this agent to livestock or poultry.

EXAMPLE

Examples of animals that can serve as vectors include chickens and other avian species, ferrets, horses, ruminants (cattle, sheep, goats), or swine.

Examples of arthropods that can serve as vectors include ticks, mites, sand flies, and mosquitoes.

Refer live animals, excluding laboratory animals, to the nearest VS office. Refer arthropods (including insects), and other biting/blood sucking organisms, either whole or parts thereof, that can serve as vectors to VS, TTSPS. at 301-734-3277.

When a VS permit **does not** authorize entry to the importation of organisms or vectors, use [Table 3-8-12](#) which directs you to the final regulatory action to take.

TABLE 3-8-12 Regulatory Action to Take on Organisms and Vectors

And the product is:	And the importation is:	And the importation is for:	And:	Then:
Veterinary biologic used for the diagnosis, treatment, or prevention of animal diseases including bacterins and vaccines	In final dosage form	—————→		1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)
	Not in final dosage form	Research or biological use	Is accompanied by a VS permit	RELEASE
			Lacks a VS permit	REFUSE ENTRY
Other than a veterinary biologic	—————→			GO to Table 3-8-13
Bulk shipments to be used as drugs, medicine, nutritional supplements, or in test kits	—————→	Pharmaceutical Use	—————→	1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see Table 2-4-16)
In final dosage form	—————→			GO to Human Pharmaceuticals and Human Vaccines on page 3-15-12

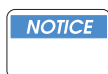
Organisms and Vectors for Research or Biological Use

Organisms and vectors may be imported for scientific studies. They include such materials as microorganisms (bacteria, viruses, fungi), sera, cell lines and their products, antitoxins, and proteins such as hormones and enzymes. They are used to diagnose, treat, or prevent human and animal diseases.

Some examples of organisms and vectors which are regulated for research or biological use follow:

- ◆ Antitoxins and antivenoms
- ◆ Ascitic fluid from mouse or rat
- ◆ Cell and tissue cultures
- ◆ Cell line
- ◆ Culture media
- ◆ Enzymes
- ◆ Hybridoma cells
- ◆ Microorganisms (bacteria, fungi, protozoans, and viruses)

- ◆ Monoclonal antibodies
- ◆ Reagents
- ◆ Tissue samples



Some biological products are highly perishable. Therefore, expedite an importation when you are authorized to release the importation. If you **cannot** release the HOLD, then allow the importer to apply dry ice or refrigerate the by-product.

When a VS permit **does not** authorize entry to the importation of organisms or vectors, use **Table 3-8-13** that directs you to the final regulatory action to take.

TABLE 3-8-13 Where to Find Regulatory Action on Organisms and Vectors Imported for Research or Biological Use

If the importation is:	Then:
Amphibians, fish, reptiles, shellfish	GO to Table 3-8-11
Canines (dogs) or felines (cats)	GO to Table 3-8-10
Cell and tissue cultures, hybridoma cells, recombinant and nonrecombinant cell lines, and their products	GO to Table 3-8-14
Live laboratory animals	GO to Table 3-8-7
Microorganisms (bacteria, fungi, protozoans, and viruses)	GO to Table 3-8-4
Monoclonal antibodies, ascitic fluid, and tissue culture supernatants	GO to Table 3-8-16
Test kits and kit components	GO to Table 3-8-17
Organisms and vectors not listed above	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

Hybridoma Cells, Recombinant and Nonrecombinant Cell Lines, Cell and Tissue Cultures, and Their Products

Recombinant cell lines are those which have foreign genetic material inserted into their genetic material. The purpose is to produce many copies of a specific product, such as a human viral gene, in a system which is capable of replicating rapidly or expressing a desired protein. Some examples of cell lines which are often recombinant are NSO, Chinese hamster ovary (CHO), human stromal cell line containing genes for SV40, and mouse embryonic stem cell line transfected with human 2 virus gene.

Nonrecombinant cell lines have **not** had their genetic material manipulated. Many of the recombinant cell lines can also be nonrecombinant. CHO, NSO, COS-1, *Spodoptera frugiperda* (SF9), and mouse embryonic stem cells (HM1) are sometimes non-recombinant.



Some biological products are highly perishable. Therefore, expedite an importation when you are authorized to release the importation. If you **cannot** release the hold, allow the importer to apply dry ice or refrigerate the by-product.


When a VS permit **does not** authorize entry to the importation the following products, then use [Table 3-8-14](#) that directs you to the final regulatory action to take:

- ◆ Ascitic fluid
- ◆ Cell and tissue cultures
- ◆ Cell lines
- ◆ Hybridoma cells
- ◆ Monoclonal antibodies
- ◆ Tissue culture supernatant

TABLE 3-8-14 Hybridoma Cells, Recombinant and Nonrecombinant Cell Lines, Cell and Tissue Cultures, and Their Products

If the importation is:	And is of:	And is for:	Then:
Cell lines	<ul style="list-style-type: none"> ◆ Avian origin ◆ Equine origin ◆ Ruminant origin ◆ Swine origin 	In vivo use or in vitro use	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see Table 2-4-16)
<ul style="list-style-type: none"> ◆ Hybridomas ◆ Recombinant cell lines ◆ Nonrecombinant cell lines ◆ Rodent cell lines 	Other than avian, equine, ruminant, or swine origin	→	GO to Table 3-8-15
<ul style="list-style-type: none"> ◆ Ascitic fluids ◆ Monoclonal antibodies ◆ Tissue culture supernatants 	Other than avian, equine, ruminant, or swine origin	→	GO to Table 3-8-16

TABLE 3-8-15 Hybridoma, Recombinant and Nonrecombinant Cell Lines, and Rodent Cell Lines Not of Avian or Livestock Origin


If:	And is of:	And is for:	And:	Then:
<ul style="list-style-type: none"> ◆ Hybridoma ◆ Recombinant cell lines ◆ Nonrecombinant cell lines ◆ Rodent cell lines 	Other than avian origin or livestock origin	In vivo use		1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see Table 2-4-16)
		In vitro use	Is accompanied by the proper certification ¹	RELEASE
			Lacks the required certification	REFUSE ENTRY

1 A declaration which provides, in a clear and concise manner, the following information:

- ◆ Identifies the materials as a cell line or product of a cell line
- ◆ States that the material is for in-vitro use or in-vivo use in humans
- ◆ States that the material **did not** originate from a facility where work with exotic viruses affecting livestock and avian species is conducted
- ◆ States that the material is **not** recombinant, **or** if recombinant, contains **no** genes and expresses **no** products of exotic livestock or poultry disease agents

Monoclonal Antibodies, Ascitic Fluid, and Tissue Culture Supernatants

TABLE 3-8-16 Monoclonal Antibodies, Ascitic Fluid, Tissue Culture Supernatants

If:	And:	And:	Then:
<ul style="list-style-type: none"> ◆ Ascitic fluid ◆ Monoclonal antibodies ◆ Tissue culture supernatants 	<ul style="list-style-type: none"> ◆ In vitro use ◆ In vivo use in humans 	Is accompanied by the producer's or shipper's declaration ¹	RELEASE
		Lacks the producer's/shipper's declaration	REFUSE ENTRY
	Not for use in humans		

1 A declaration which provides, in a clear and concise manner, the following information:

- ◆ Identifies the material as a monoclonal antibody
- ◆ Identifies the name of the immunogen
- ◆ States the antibodies are for in vitro use, or if applicable, in vivo use in humans
- ◆ States that the material **did not** originate from a facility where work with exotic viruses affecting livestock and avian species is conducted
- ◆ States that the material is **not** recombinant, or if recombinant, states that the material contains **no** genes and expresses **no** products of exotic livestock or poultry disease agents

Reagents

Reagents are used to detect the presence of substances by the chemical reactions or biological activity they cause. Reagents may be of animal origin or chemically synthesized and are usually imported for biological use. Reagents of animal origin can be regulated under different animal by-products. Some of these are monoclonal antibodies, bovine serum albumin, ruminant and porcine enzymes, collagen, heparin, rabbit antibodies, and cholesterol. When a VS permit **does not** authorize entry to the importation of the reagent, use the index to find the specific reagent and see that page.

Test Kits and Kit Components



Test kits manufactured to diagnose human conditions (e.g., diseases, metabolic imbalances, pregnancy, etc.) or for general laboratory uses unrelated to the diagnosis of human conditions (e.g., DNA sequencing) **do not** require a VS permit, regardless of any animal-derived component in the kits. These test kits **must** be prepackaged, labeled, and ready for use.

Individual kit components that are packaged for final use (e.g., vials of bovine enzyme, goat antiserum, albumin) **do not** require a VS permit.

What does require a VS permit are animal-derived kit components that are imported in bulk (e.g., drum of powdered bovine enzyme) and are **not** packaged for final use.

Test kits which are manufactured to diagnose animal diseases require APHIS Form 2006, United States Veterinary Biological Product Permit. This permit is issued by the Center of Veterinary Biologics. See [Processing Importations Authorized Entry by a VS Permit](#) on page **2-4-32** for processing animal products and by-products imported under permit. See [Table 3-8-17](#) that directs you to the final regulatory action to take.

TABLE 3-8-17 Test Kits and Kit Components

If:	And is:	And is for:	And the importation:	Then:
<ul style="list-style-type: none"> ◆ Test kits ◆ Test kit components 		◆ Diagnosis of human conditions	Is accompanied by the producer's or shipper's declaration ¹	RELEASE
		◆ General laboratory uses unrelated to the diagnosis of human conditions	Lacks the shipper's/producer's declaration or statements ¹	REFUSE ENTRY
		◆ Diagnosis of animal diseases	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	REFUSE PERMIT
	Animal-derived, in bulk, and not packaged for final use		Is covered by an applicable guideline	FOLLOW the applicable guidelines
			Is not covered by an applicable guideline	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. ADVISE the importer of the hold because the importation may require a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see Table 2-4-16)

1 A declaration which provides, in a clear and concise manner, the following information:

- ◆ Test kits and/or kit components are **not** intended to diagnose infectious animal diseases
- ◆ Test kits and/or kit components are prepackaged and ready for use

Semen, Ova, and Embryos

Semen is live animal sperm. Ova are live animal eggs. Embryos are live, fertilized eggs. Semen, ova, and embryos are imported either for reproductive (i.e. breeding), or research purposes.



Some biological products are highly perishable. Therefore, expedite an importation when you are authorized to release the importation. If you **cannot** release the hold, allow the importer to apply dry ice or refrigerate the by-product.

When a VS permit **does not** authorize entry for the importation of equine semen, use [Table 3-8-18](#); for semen other than from equine, use [Table 3-8-19](#); and for ova, or embryos, use [Table 3-8-20](#) which directs you to the final regulatory action to take.

Semen Originating from Canada

TABLE 3-8-18 Semen Originating from Canada

If the country of origin is:	And the semen is:	And the semen is imported for:	And is presented at:	And:	Then:	
Canada	Equine ¹		→	Origin and species can be confirmed ²	RELEASE	
				Origin and species cannot be confirmed	REFER the shipment to the VS Port Veterinarian	
	<ul style="list-style-type: none"> ◆ Ruminants, other than sheep and goats ◆ Poultry ◆ Swine 	Reproduction ³	Canadian land border port designated for this import ⁴		REFER the shipment to the VS Port Veterinarian	
				Port cited in 9CFR§98.33(a) or §98.33(d)	Is accompanied by a VS permit (VS Form 17-135)	<ol style="list-style-type: none"> 1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian
					Lacks a VS permit (VS Form 17-135)	REFUSE ENTRY
	Ruminants, sheep and goats only	Reproduction ³	→		<ol style="list-style-type: none"> 1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian 	
				Lacks a VS permit (VS Form 17-135)	REFUSE ENTRY	

TABLE 3-8-18 Semen Originating from Canada (continued)

If the country of origin is:	And the semen is:	And the semen is imported for:	And is presented at:	And:	Then:
Canada	<ul style="list-style-type: none"> ◆ Ruminants, including sheep and goats ◆ Poultry ◆ Swine 	Diagnosis or research (in vitro use only)	→	Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit
				Lacks a VS permit (VS Form 16-6A)	REFUSE ENTRY
	Dogs ⁵	Reproduction ⁶	→	Origin and species can be confirmed ²	RELEASE
				Origin and species cannot be confirmed	REFER the shipment to the VS Port Veterinarian
		Diagnosis or research	→		GO to Table 3-8-10 on page 3-8-14
	Bees		→	Is accompanied by a CFIA certificate verifying Canadian origin	RELEASE
Lacks the appropriate CFIA certificate				REFUSE ENTRY	
Animal other than listed above		→		<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. ADVISE the importer that the importation may require a VS permit authorizing entry 3. HAVE the importer contact VS, TTSPS (see Table 2-4-16) 	

- 1 Equine includes animals like asses, burros, donkeys, horses, or zebras.
- 2 Outside labeling indicating species and origin is acceptable.
- 3 Consider semen for reproduction to be a live animal importation regulated by VS.
- 4 Canadian border ports are listed in 9CFR§98.33(b).
- 5 You **must** be able to confirm that the semen is dog semen.
- 6 If dog semen is to be used for reproductive purposes and **not** research, then the semen is unrestricted as long as the species is confirmed.

Semen Originating from Countries Other Than Canada

TABLE 3-8-19 Semen from Countries Other Than Canada

If the country of origin is:	And the semen is from:	And is imported for:	And is from:	And:	Then:
Other than Canada	<ul style="list-style-type: none"> ◆ Equine¹ ◆ Poultry ◆ Ruminants ◆ Swine 	Reproduction ²	→	Is accompanied by a VS permit (VS Form 17-135)	1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian
				Lacks a VS permit (VS Form 17-135)	REFUSE ENTRY
		Diagnosis or research (in vitro use only)	→	Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit
				Lacks a VS permit (VS Form 16-6A)	REFUSE ENTRY
	Dogs ³	Reproduction ⁴	→	Species can be confirmed ³	RELEASE
				Species cannot be confirmed ³	REFER the shipment to the VS Port Veterinarian
		Diagnosis or research	→		GO to Table 3-8-10 on page 3-8-14
	Bees	→	Australia, Bermuda, Canada, France, Great Britain, or Sweden	Is accompanied by a government certificate verifying the country of origin	RELEASE
				Lacks the appropriate certificate	REFUSE ENTRY
			Country other than listed above	→	REFUSE ENTRY
Animal other than listed above	→			<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. ADVISE the importer that the importation may require a VS permit authorizing its entry 3. HAVE the importer contact VS, TTSPS (see Table 2-4-16) 	

1 Equine includes animals like asses, burros, donkeys, horses, or zebras.

2 Consider semen for reproduction to be a live animal importation regulated by VS.

- 3 You **must** be able to confirm that the semen is dog semen. Outside labeling indicating species and origin is acceptable.
- 4 If dog semen is to be used for reproductive purposes and **not** research, then the semen is unrestricted as long as the species is confirmed.

Embryos and Ova

TABLE 3-8-20 Embryos and Ova

If:	And harvested from:	And is imported for:	And:	And the importation:		
Embryos or ova ¹	<ul style="list-style-type: none"> ◆ Equine² ◆ Ruminants ◆ Swine 	Reproduction ³	→	Is accompanied by a VS permit (VS Form 17-135)	1. CONTROL as specified on the permit 2. REFER the shipment to the VS Port Veterinarian	
				Lacks a VS permit (VS Form 17-135)	REFUSE ENTRY	
		Diagnosis or research	→	Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit	
				Lacks a VS-issued permit (VS Form 16-6A)	REFUSE ENTRY	
	Bees		→	From Australia, Bermuda, Canada, Great Britain, or Sweden	Is accompanied by a government certificate verifying the country of origin	RELEASE or CONTROL as specified on the permit
				Lacks the appropriate certificate	REFUSE ENTRY	
			From other than a country listed above	→	REFUSE ENTRY	
Insects		→	Labeled with PPQ Form 599	→	RELEASE	
			Not labeled with PPQ Form 599	→	REFUSE ENTRY	
Mosquitoes		→		Is accompanied by a VS permit (VS Form 16-6A)	RELEASE or CONTROL as specified on the permit	
			Lacks a VS permit (VS Form 16-6A)	REFUSE ENTRY		
Animal other than listed in the cells above			→		1. DO NOT RELEASE the HOLD 2. ADVISE the importer that the importation may require a VS permit authorizing its entry 3. HAVE the importer contact VS, TTSPS (see Table 2-4-16)	

- 1 Used, empty embryo or ova containers are regulated under [Empty Semen and Embryo Containers](#) on [page 2-2-13](#).
- 2 Equine includes animals like asses, burros, donkeys, horses, or zebras.
- 3 Consider semen for reproduction to be a live animal importation regulated by VS.