

# 3

Animal Product  
Manual

## Reference

### *Live Animals and Related Material*

#### Contents

Introduction	page 3-8-1
Locator	page 3-8-4
Earthworms	page 3-8-5
Microorganisms (Bacteria, Viruses, Fungi)	page 3-8-6
Recombinant Microorganisms	page 3-8-6
Animal Tissue	page 3-8-8
Laboratory Mammals and Various Vertebrates and Invertebrates and Their Associated Materials	page 3-8-8
Centers for Disease Control and Prevention (CDC) Regulations Overlap	page 3-8-9
Live Laboratory Mammals and Their Associated Materials	page 3-8-10
Human Materials	page 3-8-11
Nonhuman Primate Materials	page 3-8-12
Canine (Dog) and Feline (Cat) Materials	page 3-8-13
Amphibian, Aquatic Animal, and Reptile Materials	page 3-8-14
List of Laboratories Working with Exotic Viruses, Including FMD	page 3-8-15
Organisms and Vectors	page 3-8-16
Organisms and Vectors for Research or Biological Use	page 3-8-17
Hybridoma Cells, Recombinant and Nonrecombinant Cell Lines, Cell and Tissue Cultures, and Their Products	page 3-8-18
Monoclonal Antibodies, Ascitic Fluid, and Tissue Culture Supernatants	page 3-8-21
Reagents	page 3-8-22
Test Kits and Kit Components	page 3-8-22
Semen, Ova, and Embryos	page 3-8-24

#### 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 imported for research purposes; organisms and vectors imported for research purposes, including microorganisms (viruses, bacteria), 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; refer to **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; refer to **Human Pharmaceuticals and Human Vaccines** on **page 3-15-11**
- ◆ Importations of live animals, except for laboratory animals (see **Animal Tissue** on **page 3-8-8**). 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; refer to **Safeguarding Live Animals** on **page 2-4-29**
- ◆ Nonhuman primates, dogs and cats; refer to PHS, and also refer nonhuman primates to FWS. The Centers for Disease Control and Prevention (CDC) has jurisdiction over the importation of dogs, cats, and nonhuman primates. The importer should contact the CDC for import restrictions (phone 404/639-3311)
- ◆ Pet birds in passenger baggage and aboard vessels or yachts and pleasure vessels; refer to **Handling Pet Birds** on **page 2-4-18**
- ◆ Used semen and embryo containers; refer to **Empty Semen and Embryo Containers** on **page 2-2-13** 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; refer to **Requests for VS Permits** on **page 2-4-25**

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 stated on the permit
<b>Do not</b> match the permit	Permit has expired	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. HAVE the consignee contact VS, TTSPS, IEAS, or CVB (see <a href="#">page 2-4-26</a>)</li> <li>3. SAFEGUARD the importation until you hear from VS, TTSPS</li> </ol>
	Discrepancy is <b>other than</b> an expired permit	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a>)</li> </ol>

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

## Earthworms

**TABLE 3-8-3 Regulatory Action to Take on Earthworms**

If from a country:	And from:	And:	And from:	And:	Then:	
Free from FMD	Canada	In soil	Newfoundland or that portion of the Municipality of Central Saanich on Vancouver Island in the Province of British Columbia east of West Saanich Road	→	REFUSE ENTRY	
			A part of Canada <b>other than</b> that described in the cell above	→	RELEASE	
		<b>Not</b> in soil	→			
	<b>Other than</b> Canada				Is accompanied by PPQ Form 526, Permit to Move Live Plant Pests <sup>1</sup>	RELEASE <sup>2</sup> or CONTROL as specified on the permit
					<b>Lacks</b> the permit	REFUSE ENTRY
Affected with FMD				Is accompanied by both: ◆ VS Permit ◆ PPQ Form 526, Permit to Move Live Plant Pests <sup>1</sup>	RELEASE <sup>2</sup> or CONTROL as specified on the permit	
				<b>Lacks</b> the permit	REFUSE entry	

1 Regulated by 7CFR 330.200, since earthworms may harbor plant pathogens in their guts.

2 Because live earthworms are perishable, expedite shipment that you are authorized to release.

## Microorganisms (Bacteria, Viruses, Fungi)

**TABLE 3-8-4 Regulatory Action to Take on Microorganisms**

If the microorganism is:	And:	Then:
Recombinant	→	GO to <a href="#">Table 3-8-5</a>
Nonrecombinant <sup>1</sup>	Is accompanied by shipper/producer letterhead documentation stating: <ul style="list-style-type: none"> <li>◆ Genus and species of the microorganism</li> <li>◆ Microorganism is <b>not</b> considered to be pathogenic<sup>2</sup> to livestock or poultry</li> </ul>	RELEASE
	<b>Lacks</b> the documentation described above	<b>DO NOT RELEASE</b> 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 Pathogenic—capable of causing disease.

### 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 Regulatory Action to Take on Recombinant Microorganisms**

If the microorganism:	And the importation:	Then:
Contains animal-derived additive or stabilizer, e.g., albumin	Is accompanied by shipper/producer letterhead documentation indicating <b>all</b> of the following: <ul style="list-style-type: none"> <li>◆ Genus and species of the microorganism</li> <li>◆ Additive or stabilizer</li> <li>◆ Intended use of the microorganism (e.g., in vitro versus in vivo)</li> </ul>	RELEASE
	<b>Lacks</b> the documentation described above	<b>DO NOT RELEASE</b> the HOLD until the importer provides the required documentation
<b>Does not</b> contain animal-derived additive or stabilizer	Is accompanied by shipper/producer letterhead documentation indicating <b>all</b> of the following: <ul style="list-style-type: none"> <li>◆ Genus and species of the microorganism</li> <li>◆ Microorganism <b>does not</b> contain an animal-derived additive or stabilizer</li> <li>◆ Microorganism <b>does not</b> contain genes or express antigens of livestock or poultry disease agents</li> </ul>	RELEASE
	<b>Lacks</b> the documentation described above	<b>DO NOT RELEASE</b> the HOLD until the importer provides the required documentation

## Animal Tissue

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

If the tissue originated from:	Then:
Amphibians, aquatic species, or reptiles	GO to <a href="#">Table 3-8-11</a>
Canines (dogs)	GO to <a href="#">Table 3-8-10</a>
Felines (cats)	
Humans	GO to <a href="#">Table 3-8-8</a>
Laboratory animals (including gerbils, guinea pigs, hamsters, mice, rabbits, or rats)	GO to <a href="#">Table 3-8-7</a>
Livestock (horses, ruminants, swine or avian species (birds and poultry))	<ol style="list-style-type: none"><li>1. <b>DO NOT</b> RELEASE the HOLD</li><li>2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing the entry</li><li>3. PROVIDE the importer with the appropriate options, including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-25</a>)</li></ol>
Nonhuman primates	GO to <a href="#">Table 3-8-9</a>

## Laboratory Mammals and Various Vertebrates and Invertebrates and Their Associated Materials



This section **does not** include cats, dogs, and nonhuman primates.

For the purposes of this section, laboratory mammals (and their products) include gerbils, guinea pigs, hamsters, mice, rabbits, transgenic rabbits, rats, transgenic rats, and transgenic/knockout mice. To be admissible, these animals **must** meet the following criteria:

- ◆ Animals **must not** have been in the wild **nor** inoculated with exotic livestock disease agents, and **must not** have been exposed to livestock or poultry diseases

- ◆ Animals **must not** have been shipped from a laboratory working with the FMD virus and other exotic viruses; refer to the [List of Laboratories Working with Exotic Viruses, Including FMD](#) on **page 3-8-15**

### Centers for Disease Control and Prevention (CDC) Regulations Overlap


The Centers for Disease Control and Prevention (CDC) regulates the importation of cats, dogs, live laboratory animals, and nonhuman primates.



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.

## Live Laboratory Mammals and Their Associated Materials


**TABLE 3-8-7 Regulatory Action to Take on Live Laboratory Mammals and Their Associated Materials**

If the shipment consists of:	And the shipment:	Then:
Live laboratory mammals <sup>1</sup>	Is accompanied by both: <ul style="list-style-type: none"> <li>◆ Health certificate that states the mammals are clinically healthy</li> <li>◆ Statement on shipper/producer letterhead that indicates the mammals: (a) have <b>not</b> been exposed to <b>nor</b> inoculated with any livestock or poultry disease agents that are exotic to the United States; and (b) <b>did not</b> originate from a facility where work with exotic disease agents affecting livestock or poultry is conducted<sup>2</sup></li> </ul>	RELEASE
	<b>Lacks</b> the documentation described in the cell above	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required documentation
Live laboratory mammal materials: <ul style="list-style-type: none"> <li>◆ Blood fractions<sup>3</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen</li> <li>◆ Tissue</li> <li>◆ Urine</li> </ul>	Is accompanied by shipper/producer letterhead documentation that: <ul style="list-style-type: none"> <li>◆ Identifies the material and the species collected from</li> <li>◆ States that the mammals from which the material was derived: (a) have <b>not</b> been exposed to <b>nor</b> inoculated with any livestock or poultry disease agents that are exotic to the United States; (b) <b>did not</b> originate from a facility where work with exotic disease agents affecting livestock or poultry is conducted; and (c) identifies the immunogen (for antisera)</li> </ul>	RELEASE
	<b>Lacks</b> the statements described in the cell immediately above	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required documentation
<b>Other than</b> one listed in the cells above		1. <b>DO NOT</b> RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

- 1 Laboratory mammals include gerbils, guinea pigs, hamsters, mice, rabbits, rats, transgenic rats, and transgenic/knockout mice.
- 2 For a list of these laboratories, see [List of Laboratories Working with Exotic Viruses, Including FMD](#) on page 3-8-15.
- 3 Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

## Human Materials


**TABLE 3-8-8 Regulatory Action to Take on Human Materials**

If the imported material is:	And was collected from:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Blood fractions<sup>1</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen</li> <li>◆ Tissue</li> <li>◆ Urine</li> </ul>	Humans	Is accompanied by a declaration on shipper/producer letterhead documentation that: <ul style="list-style-type: none"> <li>◆ Provides a detailed, accurate description of the product and species identification</li> <li>◆ If the product <b>does not</b> contain an animal product, states "Human product containing no animal product"</li> <li>◆ If the preparation does contain animal-derived additives, states the "[<i>type of additive</i>]" and that the product will be used <b>only</b> in vitro</li> <li>◆ States that the product is <b>not</b> of tissue culture origin</li> <li>◆ States that the material is <b>not</b> zootic</li> </ul>	RELEASE
		<p style="text-align: center;"><b>Lacks</b> the declaration or statements described above</p>	<p style="text-align: center;"><b>DO NOT</b> RELEASE the HOLD until the producer or shipper provides the required statements</p>
<p><b>Other than</b> one listed above</p>			<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a>)</li> </ol>

1 Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

## Nonhuman Primate Materials


**TABLE 3-8-9 Action to Take on Nonhuman Primate Materials**

If the imported material is:	And was collected from:	And:	Then:
<ul style="list-style-type: none"> <li>◆ Blood fractions<sup>1</sup></li> <li>◆ DNA</li> <li>◆ Enzymes</li> <li>◆ Extracts</li> <li>◆ Feces</li> <li>◆ Fluids</li> <li>◆ Hormones</li> <li>◆ Peptides</li> <li>◆ RNA</li> <li>◆ Semen</li> <li>◆ Tissue</li> <li>◆ Urine</li> </ul>	Nonhuman primates	Is accompanied by a declaration on shipper/producer letterhead that: <ul style="list-style-type: none"> <li>◆ Provides detailed, accurate description of the product and species identification</li> <li>◆ States "Nonhuman primate product containing no other nonhuman primate product"</li> <li>◆ States that the product is <b>not</b> of tissue culture origin</li> <li>◆ States that the material is <b>not</b> zootic</li> </ul>	RELEASE
		<b>Lacks</b> the declaration or statements described above	<b>DO NOT</b> RELEASE the HOLD until the producer or shipper provides the required statements
Other than one listed above			1. <b>DO NOT</b> RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

1 Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

## Canine (Dog) and Feline (Cat) Materials


**TABLE 3-8-10 Regulatory Action to Take on Canine (Dog) and Feline (Cat) Materials**

If the imported material is:	And:	Then:
Canines (dog) or felines (cat): ◆ Blood fractions <sup>1</sup> ◆ DNA ◆ Enzymes ◆ Extracts ◆ Feces ◆ Fluids ◆ Hormones ◆ Peptides ◆ RNA ◆ Semen <sup>2</sup> ◆ Serum ◆ Tissue ◆ Urine ◆ Venom	Is accompanied by a declaration on shipper/producer letterhead that:  ◆ Identifies the material as canine or feline  ◆ States that the material <b>does not</b> contain any other animal-derived material from livestock or poultry  ◆ States that the material was <b>not</b> derived from cats or dogs which were inoculated with or exposed to any infectious agents of agricultural concern	RELEASE
	<b>Lacks</b> the statements or declarations described in the cell immediately above	<b>DO NOT RELEASE</b> the HOLD until the producer or shipper provides the required statement
<b>Other than</b> one listed above		1. <b>DO NOT RELEASE</b> the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

- 1 Blood fractions include albumin, antibodies, antiserum, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.
- 2 If dog semen is for reproductive purposes and **not** research, then it is unrestricted.

## Amphibian, Aquatic Animal, and Reptile Materials

**TABLE 3-8-11 Regulatory Action to Take on Materials Derived from Amphibians, Aquatic Animals, and Reptiles**

If the imported material is from:	And:	Then:
Amphibians, aquatic animals (including fish, sharks, shellfish, whales), or reptiles ◆ Blood fractions <sup>1</sup> ◆ DNA ◆ Enzymes ◆ Extracts ◆ Feces ◆ Fluids ◆ Hormones ◆ Peptides ◆ RNA ◆ Semen ◆ Tissue ◆ Urine	Is accompanied by a declaration shipper/producer letterhead that: ◆ Describes the material and the species of origin ◆ States that the material <b>does not</b> contain any equine, ruminant, swine, or avian species products (such as in transport media or stabilizers)	RELEASE
	<b>Lacks</b> the declaration or statements described above	<b>DO NOT RELEASE</b> the HOLD until the producer or shipper provides the required statement
<b>Other than</b> one listed above		1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <a href="#">Appendix H</a> )

1 Blood fractions include albumin, antibodies, blood clotting factors, leukocytes (white blood cells), plasma, red blood cells, and whole blood.

## 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, an insect, 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 insects 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 that can serve as vectors to VS, TTSPS.

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**

<b>If the importation is for:</b>	<b>And the product is:</b>	<b>Then:</b>
Research or biological use	A veterinary biologic used for the diagnosis, treatment, or prevention of animal diseases including bacterins and vaccines	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer of the HOLD because the importation requires a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options, including applying for a veterinary biological product permit issued by VS, CVB (see <a href="#">page 2-4-25</a>)</li> </ol>
	<b>Other than</b> a veterinary biologic	GO to <a href="#">Table 3-8-13</a>
Pharmaceutical use	A bulk shipment to be used as drugs, medicine, nutritional supplements, or in test kits	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-25</a>)</li> </ol>
	In final dosage form	GO to <a href="#">Human Pharmaceuticals and Human Vaccines</a> on <a href="#">page 3-15-11</a>

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

**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 it. 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 Regulatory Action for Hybridoma Cells, Recombinant and Nonrecombinant Cell Lines, Cell and Tissue Cultures, and Their Products**


If the importation is:	And:	Then:
Cell line of avian or livestock (equine, ruminant, or swine) origin	Is for in vivo <b>or</b> in vitro use	1. <b>DO NOT</b> 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 <a href="#">page 2-4-25</a> )
<b>Neither</b> of avian nor livestock origin	Consists of hybridomas, recombinant and nonrecombinant cell lines, or rodent cell lines	GO to <a href="#">Table 3-8-15</a>
	Consists of monoclonal antibodies, ascitic fluid, or tissue culture supernatant	GO to <a href="#">Table 3-8-16</a>

**TABLE 3-8-15 Regulatory Action for Hybridoma, Recombinant and Nonrecombinant Cell Lines, and Rodent Cell Lines Not of Livestock Origin**

If the material is for:	And:	Then:
In vivo use		<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer of the HOLD because the importation may require a VS permit authorizing its entry</li> <li>3. PROVIDE the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-25</a>)</li> </ol>
In vitro use	<p>Is accompanied by a declaration on shipper/producer letterhead that:</p> <ul style="list-style-type: none"> <li>◆ Identifies the materials as a cell line or product of a cell line</li> <li>◆ States that the material is for in-vitro use or in-vivo use in humans</li> <li>◆ States that the material <b>did not</b> originate from a facility where work with exotic viruses affecting livestock and avian species is conducted</li> <li>◆ States that the material is <b>not</b> recombinant, <b>or</b> if recombinant, contains <b>no</b> genes and expresses <b>no</b> products of exotic livestock or poultry disease agents</li> </ul>	RELEASE
	<b>Lacks</b> any of the required statements identified in the cell immediately above	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required statement(s)

## Monoclonal Antibodies, Ascitic Fluid, and Tissue Culture Supernatants

**TABLE 3-8-16 Regulatory Action to Take on Monoclonal Antibodies, Ascitic Fluid, Tissue Culture Supernatants**

If the monoclonal antibodies are for:	And:	Then:
In vitro use or in vivo use in humans	<p>Is accompanied by a declaration on shipper/producer letterhead that:</p> <ul style="list-style-type: none"> <li>◆ Identifies the material as a monoclonal antibody</li> <li>◆ Identifies the name of the immunogen</li> <li>◆ States the antibodies are for in vivo use, or if applicable, in vivo use in humans</li> <li>◆ States that the material <b>did not</b> originate from a facility where work with exotic viruses affecting livestock and avian species is conducted</li> <li>◆ States that the material is <b>not</b> recombinant, or if recombinant, states that the material contains <b>no</b> genes and expresses <b>no</b> products of exotic livestock or poultry disease agents</li> </ul>	RELEASE
	<b>Lacks</b> the statement described in the cell above	<b>DO NOT RELEASE</b> the HOLD until the importer provides the required statement
<b>Not</b> for use in humans		<ol style="list-style-type: none"> <li>1. <b>DO NOT RELEASE</b> the HOLD</li> <li>2. <b>ADVISE</b> the importer of the hold because the importation may require a VS permit authorizing its entry</li> <li>3. <b>PROVIDE</b> the importer with the appropriate options including applying for a VS permit issued by VS, TTSPS (see <a href="#">page 2-4-25</a>)</li> </ol>

## 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. Refer to [Processing Importations Authorized Entry by a VS Permit](#) on **page 2-4-27** 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**

<b>If the test kits and/or kit components are for:</b>	<b>And the importation:</b>	<b>Then:</b>
Diagnosis of human conditions or general laboratory uses unrelated to the diagnosis of human conditions	Is accompanied by a statement on shipper/producer letterhead indicating that the test kit and/or kit components are:  ◆ <b>Not</b> intended to diagnose infectious animal diseases  ◆ Prepackaged and ready for use	RELEASE
	Lacks the statement described above	<b>DO NOT</b> RELEASE the HOLD until the importer provides the required statement
Diagnosis of animal diseases		1. <b>DO NOT</b> RELEASE the HOLD 2. ADVISE the importer of the hold because the importation requires a VS permit authorizing its entry 3. PROVIDE the importer with the appropriate options including applying for a veterinary biological product permit issued by VS, CVB (see <a href="#">page 2-4-25</a> )
Animal-derived, in bulk, and <b>not</b> packaged for final use		1. <b>DO NOT</b> 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 <a href="#">page 2-4-25</a> )

## 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 it. 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.

**TABLE 3-8-18 Regulatory Action on Equine Semen**

If the equine <sup>1</sup> semen is from:	And imported for the purpose of:	And:	Then:
Canada <sup>2</sup>		→	RELEASE <sup>2</sup>
Other than Canada	Reproduction	→	1. CONSIDER it a live animal importation regulated by VS, IEAS 2. <b>DO NOT</b> RELEASE the HOLD 3. ADVISE the importer that the importation requires a VS permit authorizing its entry 4. HAVE the consignee contact VS, IEAS 5. SAFEGUARD the importation until you hear from IEAS (see <a href="#">page 2-1-3</a> )
	Diagnosis or research	Is accompanied by a VS-issued permit	RELEASE or CONTROL as stated on the permit
		Lacks a VS-issued permit	1. <b>DO NOT</b> 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 <a href="#">page 2-4-25</a> )

- Equine includes animals like asses, burros, donkeys, horses, or zebras.
- You **must** be able to confirm that the semen is equine semen and that the semen originated in Canada. If you **cannot** verify origin or species, then contact the local VS Port Veterinarian or the AVIC.

**TABLE 3-8-19 Regulatory Action on Semen from Other Than Equine**

If the semen is from:	And imported for the purpose of:	And:	Then:
Ruminant (animals like cattle, deer, goats, or sheep)	Reproduction	→	<ol style="list-style-type: none"> <li>1. CONSIDER it a live animal importation regulated by VS, IEAS</li> <li>2. <b>DO NOT</b> RELEASE the HOLD</li> <li>3. ADVISE the importer that the importation requires a VS permit authorizing its entry</li> <li>4. HAVE the consignee contact VS, IEAS</li> <li>5. SAFEGUARD the importation until you hear from IEAS (see <a href="#">page 2-1-3</a>)</li> </ol>
	Diagnosis	Is accompanied by a VS issued permit	RELEASE or CONTROL as stated on the permit
		Lacks a VS issued permit	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer that the importation may require a VS permit authorizing its entry</li> <li>3. HAVE the importer contact VS, TTSPS (see <a href="#">page 2-4-25</a>)</li> </ol>
Dogs <sup>1</sup>	Reproduction	→	RELEASE
	Diagnosis or research	→	GO to <a href="#">Table 3-8-10 on page 3-8-13</a>
Insects (including honey bees)		→	RELEASE
Any <b>other</b> animal		→	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer that the importation may require a VS permit authorizing its entry</li> <li>3. HAVE the importer contact VS, TTSPS (see <a href="#">page 2-4-25</a>)</li> </ol>

1 You **must** be able to confirm that the semen is dog semen. Outside labeling indicating that the semen is dog semen is acceptable.

**TABLE 3-8-20 Regulatory Action on Embryos and Ova**

If the embryo <sup>1</sup> or ova was harvested from:	And is for the purpose of:	And:	
<ul style="list-style-type: none"> <li>◆ Equine (animals like ass, burro, donkey, horse, zebra)</li> <li>◆ Ruminant (animals like cattle, deer, goats, or sheep)</li> <li>◆ Swine (pigs and their relatives)</li> </ul>	Reproduction	→	<ol style="list-style-type: none"> <li>1. CONSIDER it a live animal importation regulated by VS, IEAS</li> <li>2. <b>DO NOT</b> RELEASE the HOLD</li> <li>3. ADVISE the importer that the importation requires a VS permit authorizing its entry</li> <li>4. HAVE the consignee contact VS, IEAS</li> <li>5. SAFEGUARD the importation until you hear from IEAS (see <a href="#">page 2-1-3</a>)</li> </ol>
	Diagnosis or research	Is accompanied by a VS-issued permit	RELEASE or CONTROL as stated on the permit
		<b>Lacks</b> a VS-issued permit	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer that the importation may require a VS permit authorizing its entry</li> <li>3. HAVE the importer contact VS, TTSPS (see <a href="#">page 2-4-25</a>)</li> </ol>
Insect	→	Is accompanied by PPQ Form 526, Permit to Move Live Plant Pests	RELEASE or CONTROL as stated on the permit
	→	<b>Lacks</b> PPQ Form 526, Permit to Move Live Plant Pests	REFUSE ENTRY
Any animal <b>other</b> than one listed in the cells above	→	→	<ol style="list-style-type: none"> <li>1. <b>DO NOT</b> RELEASE the HOLD</li> <li>2. ADVISE the importer that the importation may require a VS permit authorizing its entry</li> <li>3. HAVE the importer contact VS, TTSPS (see <a href="#">page 2-4-25</a>)</li> </ol>

1 If it is a used, empty embryo or ova container, then GO to [Empty Semen and Embryo Containers](#) on [page 2-2-13](#)