

3

Animal Product
Manual

Reference

Miscellaneous Products

Contents

Introduction	page 3-15-1
Locator	page 3-15-3
Birds' Nests	page 3-15-5
Fomites	page 3-15-6
Carriers Including Containers	page 3-15-7
Egg Cartons, Crates, Flats, or Liners	page 3-15-7
Used Farm Machinery	page 3-15-8
Footwear	page 3-15-9
Garbage	page 3-15-9
Semen and Embryo Containers	page 3-15-9
Straw, Hay, and Grass, and Canadian Origin Soil	page 3-15-10
Used Meat Covers and Scrap Bagging	page 3-15-12
Human Pharmaceuticals and Human Vaccines	page 3-15-12
Human Pharmaceuticals, Human Vaccines, Antivenom, Dietary Supplements, Organs and Their Derivatives, and Nutraceuticals Containing Animal-derived Components	page 3-15-13
Human Pharmaceuticals and Human Vaccines Containing Milk/Milk Products as the Only Animal Origin Ingredient	page 3-15-16
Dietary Supplements Containing Milk/Milk Products as the Only Animal-Origin Ingredient	page 3-15-17
Cosmetics	page 3-15-18
Asian Medicinal Products	page 3-15-21
Asian Medicinal Products of Equine, Ruminant or Swine Origin	page 3-15-22
Asian Medicinal Products of Bird or Poultry Origin	page 3-15-24
Chemically Synthesized, Biosynthesized, and Natural Products	page 3-15-26
Proteins/Peptides/Enzymes/Hormones of Microbial Origin Including Recombinants	page 3-15-28
Chemically Synthesized Proteins, Peptides, Enzymes, Hormones	page 3-15-29
Plasmids, Nucleic Acids (RNA, DNA), Primers, Probes	page 3-15-30
Salt Scrapings	page 3-15-32

Introduction

The *Miscellaneous Products* section covers products which **do not** fit appropriately under any other section in the *Reference* chapter. These products are listed as follows:

- ◆ Asian medicinal products
- ◆ Birds' nests
- ◆ Cosmetics
- ◆ Fomites

- ◆ Human pharmaceuticals that contain animal-derived components¹
- ◆ Human vaccines that contain animal-derived components¹
- ◆ Products of biotechnology
 - ❖ DNA
 - ❖ Plasmid
 - ❖ Probe
 - ❖ RNA
- ◆ Salt scrapings

These products are regulated because they are at risk of transmitting animal disease viruses. The products can transmit viruses by association with animals or by being made from animal by-products.

Also, listed in the locator ([Table 3-15-2](#)) are examples of miscellaneous products that are admissible and **do not** require a VS permit.


When a VS permit authorizes entry of the miscellaneous product, 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 3-15-1](#) as you match the permit with the shipping documents.

¹ If there are no animal-derived components, then the product is unrestricted.

TABLE 3-15-1 Action to Take on Miscellaneous Products Imported Under VS Permit

If:	And the shipping documents:	And the:	Then:
Miscellaneous products imported under VS Permit	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 for renewal (see Table 2-4-17) 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** authorize entry, use [Table 3-15-2](#) which directs you to the final regulatory action to take.

TABLE 3-15-2 Determine Where to Find the Regulatory Action on Miscellaneous Products Not Authorized by a Permit




If:	And the importation is:	Then:
Miscellaneous products that are not authorized by a permit	Animal products to be incorporated into cosmetics	GO to Table 3-15-13
	Antibiotics	RELEASE
	Asian medicinal products	GO to Table 3-15-14
	Birds' nests	GO to Table 3-15-3
	Cheese and yogurt starters ◆ <i>Lactobacillus</i> sp. ◆ <i>Streptococcus</i> sp. ◆ Fungi, including yeast	RELEASE
	Chemically synthesized, biosynthesized, and natural products	GO to Chemically Synthesized, Biosynthesized, and Natural Products on page 3-15-26
	Fomites (carriers, footwear, garbage, used farm machinery, meat covers, semen and embryo containers, hay or straw, egg cartons, crates, flats, or liners)	GO to Fomites on page 3-15-6
	Fungal cultures (non-pathogenic to livestock or avian)	RELEASE only if not a plant pest
	Human pharmaceuticals, including dietary supplements, and human vaccines	Go to Human Pharmaceuticals and Human Vaccines
	Tallow derivatives	GO to Table 3-15-23
Paraffin or resin embedded materials (non-livestock)	RELEASE	

Birds' Nests

Birds' nests are imported for both edible and inedible purposes. Edible birds' nests are the dried, glutinous secretion from salivary glands of Southern Asiatic swifts. These nests are used in making soup.

Apply plant regulations to all importations of birds' nests. They **must** be free from soil and prohibited plant material such as wheat (or related genera) straw, rice straw, corn (or related genera) straw, noxious weed propagules, or parasitic plants and their seeds.

TABLE 3-15-3 Birds' Nests

If the birds' nests are:	And the country or region of export is:	And the importation:	Then:
<ul style="list-style-type: none"> ◆ Edible ◆ Inedible 	Affected with HPAI (H5N1) only	Is accompanied by a VS permit	RELEASE  The importation may be subject to plant regulations.
		Lacks a VS permit	REFUSE ENTRY
	Affected with both HPAI (H5N1) and END	Is accompanied by a VS permit	RELEASE  The importation may be subject to plant regulations.
		Lacks a VS permit	REFUSE ENTRY
	Affected with END only	Is appropriately certified ¹	RELEASE
		Lacks certification ¹	REFUSE ENTRY
Free from both HPAI (H5N1) and END		RELEASE	

¹ An official government veterinary certificate stating the birds' nests were heated to a minimum internal temperature of 161°F (72°C).

Fomites

Fomites are inanimate objects that may be contaminated with animal disease viruses and could transmit those viruses into the United States. Fomites are those importations which are likely to have come in contact with animals or animal products, such as:

- ◆ Barn dirt
- ◆ Barn sand
- ◆ Barns (brick, adobe, wood)
- ◆ Carriers
- ◆ Clothing
- ◆ Containers
- ◆ Egg cartons, crates, flats, or liners
- ◆ Farm machinery, used
- ◆ Feed
- ◆ Feeders
- ◆ Feed utensils
- ◆ Footwear
- ◆ Garbage
- ◆ Garden soil
- ◆ Hair, livestock
- ◆ Hay
- ◆ Meat covers
- ◆ Pails
- ◆ Road sand
- ◆ Semen and embryo containers
- ◆ Soil
- ◆ Stalls
- ◆ Straw, hay, and grass
- ◆ Vehicles
- ◆ Walls, brick, and plaster
- ◆ Wood

Procedures for taking regulatory action on some of the fomites listed above occur in the *Manual for Agricultural Clearance (MAC)*, and are also regulated under the plant regulations and appear in the *Plant Import—Nonpropagative Volume of Manuals*.

Carriers Including Containers

Aircraft, ship, railroad car, and truck carriers and containers are considered a risk when found contaminated with evidence of blood, hay, straw, manure, or garbage. Procedures for taking action on trucks from Mexico that are found contaminated with animal material are covered under ***Trucks Transporting Livestock from Mexico*** on **page 2-2-12**. Procedures for taking action on other contaminated carriers are in *Manual for Agricultural Clearance (MAC)* and will **not** be repeated here.

Egg Cartons, Crates, Flats, or Liners

Egg cartons, crates, flats, or liners can be contaminated with blood, feathers, manure, shell, or egg. Go to **Table 3-15-4** for action to take.

TABLE 3-15-4 Egg Cartons, Crates, Flats, or Liners

If:	And upon inspection, the packing material is:	Then:
◆ Eggs cartons	Clean and uncontaminated	RELEASE
◆ Egg crates	Contaminated with blood, egg shell, egg breakage, feathers, or manure	REQUIRE the importer to REMOVE and DESTROY the packing material
◆ Egg flats		
◆ Egg liners		

Used Farm Machinery

Used farm machinery includes vehicles, equipment, and other implements used in agricultural and farming operations. Go to [Table 3-15-5](#) to regulate imported farm machinery that is used (**not** new).

TABLE 3-15-5 Imported, Used Farm Machinery

If:	And the country or region of export is:	And the importation:	And visual inspection reveals the machinery:	Then:
Imported, used farm machinery	Affected with FMD	Is appropriately certified ¹	Is clean	RELEASE
			Is dirty ²	1. COMPLETE PPQ Form 523, Emergency Action Notification 2. PROVIDE the importer with the appropriate options ❖ Re-export ❖ Clean and wash ³
		Lacks certification	→	REFUSE ENTRY
	Free from FMD		→	Is clean
Is dirty ²				1. COMPLETE PPQ Form 523, Emergency Action Notification (since dirty farm machinery is unrestricted from FMD-free countries, this is to take care of plant pests) 2. REQUIRE that the equipment be cleaned and washed prior to entry

1 A government certificate signed by an official representative of the national health service of the region or area of origin. The certificate **must** carry an official seal and a statement declaring that, "The used farm equipment indicated on this certificate has been steam cleaned and is free of all dirt and particulate matter." In addition, the certificate **must** also supply the following information:

- ◆ Date of issue of the certificate
- ◆ Name and address of the applicant
- ◆ Name and address of the consignor
- ◆ Name and address of the consignee
- ◆ Date the equipment was cleaned
- ◆ Container number or marks
- ◆ Serial number of each piece of equipment
- ◆ Name of vessel or carrier
- ◆ Bill of lading number
- ◆ Description of the piece of equipment

The Vietnamese regulatory agency for issuing and certifying certificates of steam cleaning for used farm equipment is "The Vietnam Pesticide Company/Termite Control & Fumigation Company."

2 If a coating of road film is the **only** visible dirt found, and **no** other organic matter is present, RELEASE the machinery.

- 3 Used farm machinery that is dirty may be allowed entry if the machinery is cleaned at a port which has a cleaning facility. If the port of entry **does not** have a cleaning facility, then the importer or the importer's agent may choose to send the machinery directly to a port with a cleaning facility. However, **never** allow overland transport. If the cleaning option is **not** selected, the importer or the importer's agent **must** re-export the machinery within 48 hours. If workable, take digital photographs of the equipment and the certificate and submit to the local AQI VMO for follow-up with the country or region that supplied the certification (for AQI VMO contact information see [Figure H-1-2](#)).

Footwear

Shoes or boots which have been used on a farm or ranch that has livestock or poultry and is located in a country with diseases of concern, may be contaminated. Procedures for taking action on footwear are under ***Articles That Require Cleaning and Disinfection*** on page 2-4-13.

Garbage

Garbage includes all waste material derived from fruit, vegetables, meat, or other plant or animal (including poultry) parts; any refuse associated with the waste material on board a carrier, including food scraps, table refuse, galley refuse, food wrappers, or packaging material; other waste material from stores, food preparation areas, passengers' or crews' quarters, dining rooms, or any other area on a carrier. Garbage also means food and meals that were available for consumption by passengers and crew on a carrier, but were **not** consumed. Procedures for controlling garbage are in the *Manual for Agricultural Clearance* (MAC) and will **not** be repeated here.

Semen and Embryo Containers

All containers that have been previously used to transport semen or embryos present a risk of introducing animal diseases. These containers may be manifested as nitrogen containers. First, you **must** ensure that the semen or embryo containers are empty. Then you can take the appropriate action based on the country of origin and animal class of the semen or embryo. The procedures for handling empty semen or embryo containers are under the *Procedures* section, ***Clearing Regulated Cargo***.

Straw, Hay, and Grass, and Canadian Origin Soil

Straw, hay, and grass can be contaminated by animal diseases through association with animals. Such plant material may also harbor ticks. Therefore, straw, hay, and grass imported as animal feed, as animal bedding, as packing material, or for manufacturing is regulated under animal regulations.

The following straw, hay, or grass materials are **not** subject to animal regulations:

- ◆ Manufactured items such as mats, hats, souvenirs, jackets, brooms, and naturally dried flowers
- ◆ Straw, hay, or grass obviously selected, processed, and packed for sale or distribution as decorative material
- ◆ Related plant products such as broomcorn, sugarcane, corn, silage soybeans, soybean meal, and flax

Note that these previously bulleted importations may be subject to plant regulations and appear in the *Plant Import: Nonpropagative Volume of Manuals*.

Importations of Canadian origin soil are **unrestricted** due to animal health concerns. Importations of straw, hay and grass from Canada, New Zealand, and Norway are **unrestricted** since these countries are free from fever ticks and FMD; however, importations from all countries may be subject to plant regulations.

TABLE 3-15-6 Straw, Hay and Grass

If:	And the country or region of export is:	And:	And:	Then:
◆ Grass ◆ Hay ◆ Straw	Canada, New Zealand or Norway	—————→		1. RELEASE for animal health concerns 2. APPLY plant quarantines as appropriate
	Mexico	The State of Chihuahua, or Sonora, or the Mexicale region of Baja California Norte	Certified ¹	REFUSE ENTRY
		State other than Chihuahua or Sonora or the Mexicale region of Baja California Norte	—————→	
	Other than Canada, New Zealand or Norway	—————→		GO to Table 3-15-7

¹ Certified by a salaried, federal veterinarian of the Mexican government as originating from the State of Chihuahua or Sonora or the Mexicale region of Baja California Norte.

TABLE 3-15-7 Straw, Hay and Grass from Countries Other Than Canada, Mexico, New Zealand, or Norway

If:	And the country or region of export is:	And is the importation is to be used for:	And the importation is:	Then:	
<ul style="list-style-type: none"> ◆ Grass ◆ Hay ◆ Straw 	<p>Other than Canada, Mexico, New Zealand, or Norway</p>	Animal feed or bedding	→	<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 Figure H-1-2) 3. If released for animal health concerns, apply plant quarantines as appropriate 	
		Manufacturing	Consigned to an approved establishment		AUTHORIZE shipment under seal with a VS Form 16-78 (see Appendix K to complete the form)
			Not consigned to an approved establishment		<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
		Packing material		→	<ol style="list-style-type: none"> 1. ALLOW importer to remove if practicable; otherwise REFUSE ENTRY 2. REQUIRE that the packing material be destroyed 3. GO to Disinfection on page 2-4-13¹
		Samples for research	Accompanied by a VS permit		RELEASE
			Lacks a VS permit		REFUSE ENTRY
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 Figure H-1-2) 3. If released for animal health concerns, apply plant quarantines as appropriate 		

1 To disinfect whatever the packing material was in contact with.

Used Meat Covers and Scrap Bagging

Meat covers are burlap or cloth covers that were previously used to wrap fresh or frozen meat. Also regulated are mixed importations of scrap bagging with one or more pieces of material identified as being used to cover meat.



Important

Used burlap bags and covers which have been used for plant products are regulated under the plant regulations. Refer to the *Plant Import: Nonpropagative Volume of Manuals*.

TABLE 3-15-8 Used Meat Covers and Scrap Bagging

If the importation is:	And the country or region of export is:	Then:
◆ Used meat covers	Free from ASF, CSF, SVD, and FMD	RELEASE
◆ Scrap bagging	Affected with ASF, CSF, SVD, or FMD	REFUSE ENTRY

Human Pharmaceuticals and Human Vaccines

To regulate imported pharmaceuticals, first read the label or accompanying data sheet, fact sheet, or information sheet. The label and sheets are your main source for information about the product's ingredients. The label should identify any animal-derived components that are present in the product. Continue to [Table 3-15-9](#).



Important

Read the label first (and any accompanying data, fact, or information sheets) to ascertain if the product contains any animal-derived components.

TABLE 3-15-9 Human Pharmaceuticals and Human Vaccines

If:	And after reading the label, you verify that there are:	Then:
◆ Human pharmaceuticals	No animal-derived components in the product	RELEASE
◆ Human vaccines	Animal-derived components in the product	GO to Table 3-15-10

Human Pharmaceuticals, Human Vaccines, Antivenom, Dietary Supplements, Organs and Their Derivatives, and Nutraceuticals Containing Animal-derived Components

TABLE 3-15-10 Human Pharmaceuticals, Human Vaccines, Antivenom, Dietary Supplements, Organs and Their Derivatives, and Nutraceuticals Containing Animal-derived Components

If:	And the product is:	And:	And the importation:	And:	Then:
<ul style="list-style-type: none"> ◆ Human pharmaceuticals containing animal- derived components ◆ Human vaccines containing animal- derived components 	Other than antivenom, dietary supplements, organs and their derivatives, or nutraceuticals (including chondroitin sulfate and glucosamine)	Is in final dosage form	Is accompanied by VS recommended documentation ¹	→	A USDA permit is not required. RELEASE
			Lacks the VS recommended document ¹	→	1. A USDA permit is not required. 2. CONTACT and REFER to the Food and Drug Administration
		Is not in final dosage form	Contains milk/milk products as the only animal-origin ingredient	→	GO TO Table 3-15-11
			Contains animal-origin ingredients other than milk/milk products or animal origin ingredients in combination with milk/milk products	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS Permit		REFUSE ENTRY
Antivenom	→			Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS Permit		REFUSE ENTRY


TABLE 3-15-10 Human Pharmaceuticals, Human Vaccines, Antivenom, Dietary Supplements, Organs and Their Derivatives, and Nutraceuticals Containing Animal-derived Components (continued)

If:	And the product is:	And:	And the importation:	And:	Then:
Dietary supplements, nutraceuticals, homeopathic medicines			Contains milk/milk products as the only animal-origin ingredient	→	GO TO Table 3-15-12
			Contains porcine gelatin as the only animal origin ingredient	Is appropriately certified ²	RELEASE
				Lacks the required certification ²	REFUSE ENTRY
			Contains tallow derivatives as the only animal origin ingredient	→	RELEASE
			Contains marine origin chondroitin sulfate or marine origin glucosamine as the only animal origin ingredients	Is accompanied by a shipper's or producer's declaration ³	RELEASE
				Lacks a shipper's or producer's declaration ³	REFUSE ENTRY
			Contains oils, meals, or other rendered marine origin ingredients	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
				Lacks a VS Permit	REFUSE ENTRY
			Contains animal-origin ingredients other than listed above	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
Lacks a VS Permit	REFUSE ENTRY				
Contains only plant origin ingredients	→	REFER to the Plant Import NonPropagative Volume of Manuals			
Contains no plant or animal origin ingredients	→	RELEASE			
Organs and their derivatives (examples include but are not limited to: insulin, heparin, bile, oxytocin, etc.)	Excretions, secretions, extracts, and derivatives of organs and glands	→	GO TO Organs and Their Derivatives for Research or Pharmaceutical Use		

- 1 VS recommends the following documentation accompany each shipment: a written statement
 - Providing a detailed and accurate description of the material
 - Confirming that the vaccine/pharmaceutical material is intended for human use only
 - Confirming that the material **does not** contain live livestock or poultry viral agents
 - Confirming that the material is prepared, packaged, and physically labeled in final dosage form ready for sale to the consumer
- 2 An official certificate issued by a veterinarian employed by the national government region of origin stating that the gelatin was derived from pigs.
- 3 A declaration which provides, in a clear and concise manner, the following information:
 - Identification of the material and species of origin
 - The material **does not** include any avian, equine, ruminant, or swine species or their materials (such as media or stabilizers)

Human Pharmaceuticals and Human Vaccines Containing Milk/Milk Products as the Only Animal Origin Ingredient




TABLE 3-15-11 Human Pharmaceuticals and Human Vaccines Containing Milk/Milk Products as the Only Animal Origin Ingredient

If the product is:	And the country or region of export is:	And:	And:	And:	Then:
Human pharmaceuticals or human vaccines containing milk/milk products as the only animal origin ingredient ¹	Canada			Is appropriately certified ²	RELEASE
				Lacks the required certification ²	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer the opportunity to obtain the appropriate certification
	Other than Canada	Milk/milk products originated in a FMD-free region	Human pharmaceutical or human vaccine was processed in a FMD-free region	Is appropriately certified ³	RELEASE
				Lacks the required certificate ³	REFUSE ENTRY
		Milk/milk products originated in an FMD-affected region	Human pharmaceutical or human vaccine was processed in a FMD-affected region	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
				Lacks a VS Permit	REFUSE ENTRY
Milk/milk products originated in an FMD-affected region	Human pharmaceutical or human vaccine was processed in a FMD-affected region	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit		
		Lacks a VS Permit	REFUSE ENTRY		

- 1 Applies to both commercial shipments and personal use shipments in passenger baggage/mail shipments
- 2 Any one of the following is sufficient proof of Canadian origin:
 - ◆ Original certificate signed by a Canadian Food Inspection Agency (CFIA) official, and stating the product originated in Canada or was legally imported into Canada (may be quarterly certificate)
 - ◆ North American Free Trade Agreement (NAFTA) certificate of origin (also known as Customs Form 434, available at: http://forms.cbp.gov/pdf/CBP_Form_434.pdf This form is also acceptable if produced on company letterhead or Canadian letterhead)
 - ◆ Invoice listing a Canadian vendor
 - ◆ Labels, commercially printed, that indicate the material is a product of Canada
- 3 Certification, endorsed by the Veterinary Service of the originating country or region, that has the following statement: The milk/milk product was processed in [name of country], a region listed in 9CFR§94.1(a)(2) as free of foot-and-mouth disease and rinderpest, from milk produced in [name of country], a region listed in 9CFR§94.1(a)(2) as free of foot-and-mouth disease and rinderpest. The milk/milk product has never been in any region where foot-and-mouth disease and rinderpest exists, except when moving under seal as described in 9CFR§94.16(c).

Dietary Supplements Containing Milk/Milk Products as the Only Animal-Origin Ingredient

TABLE 3-15-12 Dietary Supplements Containing Milk/Milk Products as the Only Animal-Origin Ingredient

If the product is:	And the country or region of export is:	And:	And:	And:	Then:
Dietary supplements, including nutraceuticals or homeopathic medicines containing milk/milk products as the only animal-origin ingredient ¹	Canada			Is appropriately certified ²	RELEASE
				Lacks the required certification ²	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer the opportunity to obtain the certification
	Other than Canada	Milk/milk Products originated in a FMD-free region	Dietary supplement (nutraceutical or homeopathic medicine) was processed in a FMD-free region	Is appropriately certified ³	RELEASE
				Lacks the required certificate ³	REFUSE ENTRY
		Milk/milk Products originated in an FMD-affected region		Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
				Lacks a VS Permit	REFUSE ENTRY
Milk/milk Products originated in an FMD-affected region		Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit		
		Lacks a VS Permit	REFUSE ENTRY		

1 Applies to both commercial shipments and personal use passenger baggage and mail shipments.

2 Any one of the following is sufficient proof of Canadian origin:

- ◆ Original certificate signed by a Canadian Food Inspection Agency (CFIA) official, and stating the product originated in Canada or was legally imported into Canada (may be a quarterly certificate)
- ◆ North American Free Trade Agreement (NAFTA) certificate of origin (also known as Customs Form 434, available at: http://forms.cbp.gov/pdf/CBP_Form_434.pdf This form is also acceptable if produced on company letterhead or Canadian letterhead
- ◆ Invoice listing a Canadian vendor
- ◆ Labels, commercially-printed, that indicate the material is a product of Canada

3 Certification, endorsed by the Veterinary Service of the originating country or region, that has the following statement:

The milk/milk product was processed in [name of country], a region listed in 9CFR§94.1(a)(2) as free of foot-and-mouth disease and rinderpest, from milk produced in [name of country], a region listed in 9CFR§94.1(a)(2) as free of foot-and-mouth disease and rinderpest. The milk/milk product has never been in any region where foot-and-mouth disease or rinderpest exists, except when moving under seal as described in 9CFR§94.16(c).

Cosmetics

Cosmetics may have several ingredients of animal origin; however, if those cosmetics are packaged and ready for sale, then they are unrestricted. **Only** bulk components of animal products **other than** tallow derivatives or animal origin components covered by a veterinary services guideline, to be incorporated into cosmetics, may be regulated.

TABLE 3-15-13 Cosmetics Containing Animal Products

If:	And the cosmetics are:	And are:	And the importation:	Then:
Cosmetics containing animal products	Shipped In final, finished packaging and ready for sale	—————→		RELEASE
	Animal origin components not listed below and are regulated in other sections of the Animal Product Manual	—————→		Go to the applicable section in the Animal Product Manual and regulate accordingly.
	Animal origin components not regulated in other sections of the Animal Product Manual	Shipped as bulk components of animal origin ¹ , other than tallow derivatives or animal origin components covered by a Veterinary Services guideline ² , to be incorporated into cosmetics	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	REFUSE ENTRY
		Shipped as bulk components of animal origin ¹ , other than tallow derivatives or animal origin components covered by a Veterinary Services guideline ² , to be repackaged into final, finished form and ready for sale	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	REFUSE ENTRY
	Tallow derivatives (e.g., tallow derived: linoleic acid, stearic acid, glycein, etc.)	—————→		RELEASE
	Animal origin components covered by a Veterinary Services guideline ²	Is accompanied by applicable Veterinary Services guideline documentation ²	RELEASE	
Lacks applicable Veterinary Services guideline documentation ²		REFUSE ENTRY		

1 Components of animal origin except for tallow derivatives or animal origin components covered by a Veterinary Services guideline. For example, amniotic fluid extract, amniotic liquid, collagen, extracts of connective tissue, or placental extract.

- 2 Guideines are available for the following products: human pharmaceuticals and human vaccines containing animal components; human and non-human primate material (excluding cell cultures); feline and canine material; live laboratory mammals and their material (for research purposes); amphibians, fish, reptiles, shellfish and aquatic species (includes venom); chemically synthesized materials; microbially produced materials; recombinant microbes and their products; non-pathogenic microorganisms; pet chews; cell cultures/lines, recombinant cell cultures/lines, and their products (for in vitro use); test kits; and animal feeds, feed supplements, and pre-mixes. For Veterinary Services guidelines go to:

http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_nopermit.shtml

If you do not have internet access then contact your local PPQ-AQI-VMO listed in [Figure H-1-2](#) or PPQ-VRS-Headquarters Personnel listed in [Figure H-1-1](#).

Asian Medicinal Products

Asian medicinal products are regulated to exclude animal diseases. Importations may include, but are **not** limited to the following animal by-products:

- ◆ Antlers
- ◆ Bones
- ◆ Extracts
- ◆ Glands
- ◆ Hoofs
- ◆ Organs
- ◆ Secretions
- ◆ Skin
- ◆ Tendons
- ◆ Tissue

Examine the by-products to determine their origin. If you **cannot** determine the origin, then look at an invoice or label, and ask the importer.

To locate the regulatory action to take on Asian medicinal products, continue to [Table 3-15-14](#).

TABLE 3-15-14 Asian Medicinal Products



If:	And the products' origin is:	And the source is:	Then:
Asian medicinal products	Animal	◆ Equine ◆ Ruminant ◆ Swine	GO to Table 3-15-15
		◆ Bird ◆ Poultry	GO to Table 3-15-16
		◆ Earthworms	GO to Table 3-8-3
		Other than listed above	RELEASE
	Plant	—————→	REFER to the <i>Plant Import: Nonpropagative Volume of Manuals</i>
Mineral	—————→	RELEASE	

Asian Medicinal Products of Equine, Ruminant, or Swine Origin

TABLE 3-15-15 Asian Medicinal Products of Equine, Ruminant or Swine Origin

If the Asian medicinal product's source is:	And the country or region of export is:	And the product is:	And is:	And:	Then:	
Ruminant	Affected with BSE	—————→			REFUSE ENTRY	
	Minimum Risk for BSE ¹	Cervid only (caribou, deer, elk, moose, reindeer)	—————→			RELEASE
		A mixture of cervid and non-cervid ingredients	—————→	Is accompanied by a VS Permit	RELEASE	
			—————→	Lacks a VS permit	REFUSE ENTRY	
		Non-cervid	—————→	Is accompanied by a VS Permit	RELEASE	
	—————→		Lacks a VS permit	REFUSE ENTRY		
	Free from BSE	Processed	—————→	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit	
			—————→	Lacks a VS permit	REFUSE ENTRY	
		Fresh (chilled or frozen)	<ul style="list-style-type: none"> ◆ Extracts ◆ Glands ◆ Organs ◆ Secretions 	—————→	Consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See Appendix K to complete)
				—————→	Not Consigned to an approved establishment	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
			<ul style="list-style-type: none"> ◆ Tendons ◆ Other than extracts, glands, organs, or secretions 	—————→	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
				—————→	Lacks a VS permit	REFUSE ENTRY

TABLE 3-15-15 Asian Medicinal Products of Equine, Ruminant or Swine Origin (continued)

If the Asian medicinal product's source is:	And the country or region of export is:	And and the product is:	And is:	And:	Then:
<ul style="list-style-type: none"> ◆ Equine ◆ Swine 		Processed		Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
				Lacks a VS permit	REFUSE ENTRY
		Fresh (chilled or frozen)	<ul style="list-style-type: none"> ◆ Extracts ◆ Glands ◆ Organs ◆ Secretions 	Consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See Appendix K to complete)
				Not Consigned to an approved establishment	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
			<ul style="list-style-type: none"> ◆ Tendons ◆ Other than extracts, glands, organs, or secretions 	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
				Lacks a VS permit	REFUSE ENTRY

1 Currently Canada is the only country designated as minimal risk for BSE

Asian Medicinal Products of Bird or Poultry Origin

TABLE 3-15-16 Asian Medicinal Products of Bird or Poultry Origin


If the Asian medicinal product's source is:	And the country or region of export is:	And the product is:	And is:	And:	Then:
<ul style="list-style-type: none"> ◆ Bird ◆ Poultry 	Affected with END only	Processed		Is consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See Appendix K to complete)
				Is not consigned to an approved establishment	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
		Fresh (chilled or frozen)	<ul style="list-style-type: none"> ◆ Extracts ◆ Glands ◆ Organs ◆ Secretions 	Is consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See Appendix K to complete)
				Is not consigned to an approved establishment	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
			◆ Tendons	Is accompanied by a VS permit	RELEASE
				Lacks a VS permit	REFUSE ENTRY
		◆ Other than extracts, glands, organs, secretions, or tendons	Is accompanied by a VS permit	RELEASE	
			Lacks a VS permit	REFUSE ENTRY	

TABLE 3-15-16 Asian Medicinal Products of Bird or Poultry Origin (continued)

If the Asian medicinal product's source is:	And the country or region of export is:	And the product is:	And is:	And:	Then:		
<ul style="list-style-type: none"> ◆ Bird ◆ Poultry 	Affected with HPAI (H5N1) only OR Affected with HPAI (H5N1) and END	Processed	→	Is accompanied by a VS permit	RELEASE		
				Lacks a VS permit	REFUSE ENTRY		
		Fresh (chilled or frozen)	→		REFUSE ENTRY		
	Free from END and HPAI (H5N1)	Processed		→	Is consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See Appendix K to complete)	
					Is not consigned to an approved establishment	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)	
					<ul style="list-style-type: none"> ◆ Extracts ◆ Glands ◆ Organs ◆ Secretions 	Is consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See Appendix K to complete)
						Is not consigned to an approved establishment	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
		Fresh (chilled or frozen)	◆ Tendons			Is accompanied by a VS permit	RELEASE
						Lacks a VS permit	REFUSE ENTRY
			◆ Other than extracts, glands, organs, secretions, or tendons				Is accompanied by a VS permit
Lacks a VS permit							REFUSE ENTRY

Chemically Synthesized, Biosynthesized, and Natural Products

The chemically synthesized, biosynthesized, and natural products section covers chemically synthesized products and products having to do with or formed from biotechnology. These recombinant products result from foreign genes being inserted into microorganisms (for example, yeast and bacteria) or cells (i.e., cell culture). Genetic materials (DNA or RNA for example) can be produced either through biotechnology or chemical synthesis.

A list of some chemically synthesized and biosynthesized (recombinant), and natural products and their categories follows in [Figure 3-15-1](#).

Biosynthesized Proteins	Chemically Synthesized Products	Genetic Materials
<ul style="list-style-type: none">◆ Amino acids◆ Enzymes◆ Growth factors◆ Hormones◆ Interleukins	<ul style="list-style-type: none">◆ Chemicals◆ Lipopeptides◆ Oligopeptides◆ Polypeptides◆ Steroids	<ul style="list-style-type: none">◆ cDNA probes◆ DNA vector◆ Nucleic acids (DNA, RNA)◆ Plasmids (DNA, cDNA)◆ Primers (nucleotides)

FIGURE 3-15-1 List of Chemically Synthesized, Biosynthesized, and Natural Products and Their Categories

In regulating these products, you need to determine whether the product was chemically synthesized (i.e., synthetic) or biosynthesized (recombinant). If the product was biosynthesized, you need to further determine whether the product was produced in cell culture or microbially.

Use the [Glossary](#) and [Index](#) to determine if a product fits under this section of synthetic or biosynthesized products. Determine whether a product is synthetic by using accompanying statements from producers and shippers.

When a VS permit does **not** authorize entry to the material, use [Table 3-15-17](#) which directs you to the final regulatory action to take.

TABLE 3-15-17 Locator for Chemically Synthesized, Biosynthesized, and Natural Products

If:	And the product is:	And is:	Then:
<ul style="list-style-type: none"> ◆ Biosynthesized products ◆ Chemically synthesized products ◆ Natural products 	<ul style="list-style-type: none"> ◆ Nucleic acid (RNA, DNA) ◆ Plasmid ◆ Primer ◆ Probe 	—————→	GO to Table 3-15-21
		Livestock or avian	CONTACT PPQ-AQI-VMO or PPQ-VRS-Headquarters Personnel for further action (see Appendix H)
		Derived from infectious livestock or avian microorganisms (bacteria, viruses)	CONTACT PPQ-AQI-VMO or PPQ-VRS-Headquarters Personnel for further action (see Appendix H)
		Unrelated to any livestock (ruminant, equine, or swine) or avian (bird) species	GO to Table 3-15-19
		Recombinant, microbial, or synthetic	GO to Table 3-15-19
	Not a tissue, protein, peptide, or plasmid	—————→	CONTACT PPQ-AQI-VMO or PPQ-VRS-Headquarters Personnel for further action (see Appendix H)

Proteins/Peptides/Enzymes/Hormones

TABLE 3-15-18 Proteins/Peptides/Enzymes/Hormones

If:	And:	And the origin is:	Then:
<ul style="list-style-type: none"> ◆ Enzymes ◆ Hormones ◆ Peptides ◆ Proteins 	Unrelated to any livestock (ruminant, equine, or swine) or unrelated to any avian (bird species)	Recombinant, microbial	GO to Table 3-15-19
		Chemically synthesized materials (amino acids, hormones, steroids)	GO to Table 3-15-20
		Amphibian, aquatic species, or reptile	GO to Table 3-8-11
		Feline (cat) or canine (dog)	GO to Table 3-8-10
		Laboratory animal (includes gerbils, guinea pigs, hamsters, mice, rabbits, and rats)	GO to Table 3-8-7
		Nonhuman primate	GO to Table
		Cell culture	CONTACT PPQ-AQI-VMO or PPQ-VRS-Headquarters Personnel for further action (see Appendix H)
	Related to livestock or avian species	—————→	CONTACT PPQ-AQI-VMO or PPQ-VRS-Headquarters Personnel for further action (see Appendix H)

Proteins/Peptides/Enzymes/Hormones of Microbial Origin Including Recombinants

TABLE 3-15-19 Proteins/Peptides/Enzymes/Hormones of Microbial Origin Including Recombinants

If:	And the origin is:	And the preparation:	And the importation:	Then:
<ul style="list-style-type: none"> ◆ Enzymes ◆ Hormones ◆ Peptides ◆ Proteins 	Microbial and not recombinant	Contains animal-derived additives or stabilizers	Is accompanied by a shipper's or producer's declaration ¹	RELEASE
			Lacks the shipper/producer's declaration ¹	REFUSE ENTRY
		Does not contain animal-derived additives or stabilizers	Is accompanied by a shipper's or producer's declaration ²	RELEASE
			Lacks the shipper/producer's declaration ²	REFUSE ENTRY
	Microbial and recombinant	Contains animal-derived additives or stabilizers	Is accompanied by a shipper's or producer's declaration ³	RELEASE
			Lacks the shipper/producer's declaration ³	REFUSE ENTRY
		Does not contain animal-derived additives or stabilizers	Is accompanied by a shipper's or producer's declaration ⁴	RELEASE
			Lacks the shipper/producer's declaration ⁴	REFUSE ENTRY

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

- ◆ A detailed and accurate description of the material
- ◆ Confirmation, if applicable, that the material is produced by microbial fermentation
- ◆ Identification of the animal derived additive or stabilizer
- ◆ Confirmation that the material will be used only in vitro

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

- ◆ A detailed and accurate description of the material
- ◆ Confirmation if applicable, that the material is produced by microbial fermentation
- ◆ Confirmation that the preparation **does not** contain any animal-derived additives, such as albumin

3 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 the 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

4 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

Chemically Synthesized Proteins, Peptides, Enzymes, Hormones

TABLE 3-15-20 Chemically Synthesized Proteins/Peptides/Enzymes/Hormones

If:	And the importation:	Then:
◆ Chemically synthesized enzymes	Is accompanied by VS-recommended documentation ¹	A USDA permit is not required. RELEASE
◆ Chemically synthesized hormones	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
◆ Chemically synthesized peptides		
◆ Chemically synthesized proteins		
◆ Chemically synthesized materials other than listed above		

1 VS recommends the following documentation accompany each shipment: a written statement
 Identifying the material (name)
 Confirming the material is chemically synthesized
 Confirming that the material does not contain any animal or cell culture derived products
 Confirming that the material was not derived from any animal or cell culture derived products

Plasmids, Nucleic Acids (RNA, DNA), Primers, Probes

TABLE 3-15-21 Plasmids, Nucleic Acids (RNA, DNA), Primers, Probes

If:	And origin is:	And the preparation:	And the importation:	Then:
<ul style="list-style-type: none"> ◆ Plasmids ◆ Nucleic acids (RNA, DNA) ◆ Primers ◆ Probes 	Microbial and not recombinant	Contains animal-derived additives or stabilizers	Is accompanied by shipper or producer's declaration ¹	RELEASE
			Lacks the shipper/producer's declaration ¹	REFUSE ENTRY
		Does not contain animal-derived additives or stabilizers	Is accompanied by shipper or producer's declaration ²	RELEASE
			Lacks the shipper/producer's declaration ²	REFUSE ENTRY
	Microbial and recombinant	Contains animal-derived additives or stabilizers	Is accompanied by shipper or producer's declaration ³	RELEASE
			Lacks the shipper/producer's declaration ³	REFUSE ENTRY
		Does not contain animal-derived additives or stabilizers	Is accompanied by shipper or producer's declaration ⁴	RELEASE
			Lacks the shipper/producer's declaration ⁴	REFUSE ENTRY

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

- A detailed and accurate description of the material
- Confirmation, if applicable, that the material is produced by microbial fermentation
- Identification of the animal derived additive or stabilizer
- Confirmation that the material will be used only in vitro

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

- A detailed and accurate description of the material
- Confirmation if applicable, that the material is produced by microbial fermentation
- Confirmation that the preparation **does not** contain any animal-derived additives, such as albumin

3 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 the 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

- 4 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

Salt Scrapings

Salt scrapings is salt that has been reclaimed from salted casings. The product is usually imported as a brine solution discolored with a red dye. The discoloration is used so the scrapings **do not** enter the human food chain.

TABLE 3-15-22 Salt Scrapings from Animal Casings

If:	And the salt scrapings are from a country or region that is:	And the importation:	Then:
Salt scrapings from animal casings	Affected with ASF or BSE	→	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
	Free from ASF and BSE	Is accompanied by a veterinary certificate ¹	RELEASE
		Lacks the certification ¹	REFUSE ENTRY

1 A veterinary certificate endorsed by the veterinary service of the country from which the salt (brine) from animal casings was reclaimed. The certificate **must** identify the following:

- ◆ The species of animal the casings were from
- ◆ The country or region where the animal casings were processed

TABLE 3-15-23 Tallow derivatives

If:	Then:
The product is only tallow derivatives	RELEASE
The product contains components of animal origin that are only tallow derivatives	RELEASE
The product contains components of animal origin combined with tallow derivatives	Regulate as per other components and RELEASE if other animal origin component requirements are met