

Contents

Reference

Miscellaneous Products

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 Nutriceuticals 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 3-15-23 Chemically Synthesized, Biosynthesized, and Natural Products page 3-15-25 Proteins/Peptides/Enzymes/Hormones of Microbial Origin Including Recombinants page 3-15-27 Chemically Synthesized Proteins, Peptides, Enzymes, Hormones page 3-15-28 Plasmids, Nucleic Acids (RNA, DNA), Primers, Probes page 3-15-29 Salt Scrapings page 3-15-31

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.

lf:	And the shipping documents:	And the:	Then:
Miscellaneous products imported	Match the permit	>	RELEASE or CONTROL as specified on the permit
under VS Permit	Do not match the permit	Permit has expired	 DO NOT RELEASE the HOLD HAVE the consignee contact VS, TTSPS for renewal (see Table 2-4-17) SAFEGUARD the importation until you hear from VS, TTSPS
		Discrepancy is other than an expired permit	 DO NOT RELEASE the HOLD CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see <i>Appendix H</i>)

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

Locator

When a VS permit does **not** authorize entry, use **Table 3-15-2** which directs you to the final regulatory action to take.

lf:	And the importation is:	Then:
Miscellaneous products that are not authorized	Animal products to be incorporated into cosmetics	GO to Table 3-15-13
by a permit	Antibiotics	RELEASE
	Asian medicinal products	GO to Table 3-15-14
	Birds' nests	GO to Table 3-15-3
	Cheese and yogurt starters	RELEASE
	◆ Lactobacillus sp.	
	♦ Streptococcus sp.	
	 Fungi, including yeast 	
	Chemically synthesized, biosynthesized, and natural products	GO to Chemically Synthesized, Biosynthesized, and Natural Products on page 3-15-25
	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

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

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.

If the birds' nests are:	And the country or region of export is:	And the importation:	Then:	
EdibleInedible	Affected with HPAI (H5N1) only	Is accompanied by a VS permit	RELEASE The importation may b subject to plant regulations.	
		Lacks a VS permit	REFUSE ENTRY	
	Affected with both HPAI (H5N1) and END Affected with END only	Is accompanied by a VS permit	RELEASE Important	The importation may be subject to plant regulations.
		Lacks a VS permit	REFUSE ENTRY	
		Is appropriately certified ¹	RELEASE	
		Lacks certification ¹	REFUSE ENTRY	
	Free from both HPAI (H5N1) and END		RELEASE	

TABLE 3-15-3 Birds' Nests

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.

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

TABLE 3-15-4 Egg Cartons, Crates, Flats, or 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).

lf:	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	 COMPLETE PPQ Form 523, Emergency Action Notification PROVIDE the importer with the appropriate options Re-export Clean and wash³
		Lacks certification	—	REFUSE ENTRY
	Free from FMD		Is clean	RELEASE
			Is dirty ²	 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) REQUIRE that the equipment be cleaned and washed prior to entry

TABLE 3-15-5 Imported, Used Farm Machinery

- 1 A government certificate signed by an official representative of the national health service of the region or area of origin [for example, UK Department of Environment, Food and Rural Affairs (DEFRA)]. 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.

lf:	And the country or region of export is:	And:	And:	Then:
♦ Grass♦ Hay	Canada, New Zealand or Norway			1. RELEASE for animal health concerns
◆ Hay◆ Straw	Mexico	The State of Chihuahua, or Sonora, or the Mexicale region of Baja California Norte	Certified ¹	2. APPLY plant quarantines as appropriate
			Lacks certification 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

TABLE 3-15-6 Straw, Hay and Grass

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.

lf:	And the country or region of export is:	And is the importation is to be used for:	And the importation is:	Then:
♦ Grass	Other than	Animal feed or		1. DO NOT RELEASE the HOLD
◆ Hay◆ Straw	Canada, Mexico, New Zealand, or Norway	bedding		2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Figure H-1-2)
				 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 <i>Appendix K</i> to complete the form)
			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)
		Packing material		 ALLOW importer to remove if practicable; otherwise REFUSE ENTRY DECURPT that the peaking
				 REQUIRE that the packing material be destroyed
				3. GO to <i>Disinfection</i> on page 2-4-13 ¹
		Samples for	Accompanied by a VS permit	RELEASE
		research	Lacks a VS permit	REFUSE ENTRY
		Not listed above		 DO NOT RELEASE the HOLD CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Figure H-1-2)
				 If released for animal health concerns, apply plant quarantines as appropriate

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

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.



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.*

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

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

or FMD

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**.



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

lf:	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 Nutriceuticals Containing Animal-derived Components

lf:	And the product is:	And:	And the importation:	And:	Then:
 Human pharmaceuticals containing 	Other than antivenom, dietary	ls in final dosage form	Is accompanied by VS recommended documentation ¹		A USDA permit is not required. RELEASE
animal- derived components ◆ Human vaccines containing animal- derived components	supplements, organs and their derivatives, or nutriceuticals (including chondroitin		Lacks the VS recommended document ¹	>	 A USDA permit is not required. CONTACT and REFER to the Food and Drug Administration
	sulfate and glucosamine)	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	Is accompanied by a VS Permit	RELEASE or CONTROL as specified on the permit
			products or animal origin ingredients in combination with milk/milk products	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 Nutriceuticals Containing Animal-derived Components

lf:	And the product is:	And:	And the importation:	And:	Then:
Dietary supplements, nutriceuticals, homeopathic			Contains milk/milk products as the only animal-origin ingredient	>	GO TO Table 3-15-12
medicines			Contains porcine gelatin as the only	Is appropriately certified ²	RELEASE
			animal origin ingredient	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 Lacks a shipper's or producer's declaration ³	RELEASE 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 no animal origin ingredients		RELEASE

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

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

lf:	And the product is:	And:	And the importation:	And:	Then:
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	Canada			Is appropriately certified ²	RELEASE
vaccines containing milk/ milk products as the only animal origin ingredient ¹				Lacks the required certification ²	 DO NOT RELEASE the HOLD PROVIDE the importer the opportunity to obtain the appropriate certification
	Other than CanadaMilk/milk products originated in a FMD-free region	products	Human pharmaceutical a or human	Is appropriately certified ³	RELEASE
		vaccine was processed in a FMD-free region	Lacks the required certificate ³	REFUSE ENTRY	
			Human pharmaceutical or human vaccine was processed in a FMD-affected	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	
	FMD-affected region			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 (CBP Form 434, available at https://forms.customs.gov/ customsrf/getformharness.asp?formName=cf-434-form.xft); 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

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

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

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 (CBP Form 434, available at https://forms.customs.gov/ customsrf/getformharness.asp?formName=cf-434-form.xft); 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§94.1(a)(2).

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.

lf:	And the cosmetics are:	And are:	And the importation:	Then:
Cosmetics containing animal products	Shipped In final, finished packaging and ready for sale			RELEASE
products	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	Shipped as bulk components of animal origin ¹ , other than tallow	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
sections of the Animal Product Manual	derivatives or animal origin components covered by a Veterinary Services guideline ² , to be incorporated into cosmetics	Lacks a VS permit	REFUSE ENTRY	
		Shipped as bulk components of animal origin ¹ , other than tallow	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
		derivatives or animal origin components covered by a Veterinary Services guideline ² , to be repackaged into final, finished form and ready for sale	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

TABLE 3-15-13 Cosmetics Containing Animal Products

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/vs/ncie/fac_imp.html. If you do not have internet access then contact your local PPQ-AQI-VMO list 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.

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

TABLE 3-15-14 Asian Medicinal Products

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
	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)	ExtractsGlands	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete)
			OrgansSecretions	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)
			 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
◆ Equine◆ Swine		Processed	_	Is accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
◆ Swine				Lacks a VS permit	REFUSE ENTRY
		Fresh (chilled or frozen)	ExtractsGlands	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete)
			 Organs Secretions 	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)
			 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, and Swine Origin

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:
◆ Bird◆ Poultry	Affected with END only			Is consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See <i>Appendix K</i> to complete)
				Is not consigned to an approved establishment	 DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)
	Fresh (chilled or frozen)	 Extracts Glands Organs 	Is consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See <i>Appendix K</i> to complete)	
		◆ Secretions	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)	
			◆ 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

If the Asian medicinal product's source is:	And the country or region of export is:	And the product is:	And is:	And:	Then:
 Bird Poultry Affected with HPAI (H5N1) OR 	HPAI (H5N1)	Processed		Is accompanied by a VS permit	RELEASE
			Lacks a VS permit	REFUSE ENTRY	
	Affected with HPAI (H5N1) and END	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 <i>Appendix K</i> to complete)	
			Is not consigned to an approved establishment	 DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11) 	
		Fresh (chilled or frozen)	 Extracts Glands Organs 	Is consigned to an approved establishment	Authorize release under seal with VS Form 16-78 (See <i>Appendix K</i> to complete)
			◆ Secretions	Is not consigned to an approved establishment	 DO NOT RELEASE the HOLD 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, 	Is accompanied by a VS permit	RELEASE
				Lacks a VS permit	REFUSE ENTRY

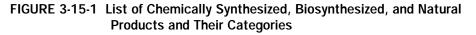
TABLE 3-15-16 Asian Medicinal Products of Bird or Poultry Origin (continued)

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
 Amino acids 	♦ Chemicals	♦ cDNA probes
◆ Enzymes	♦ Lipopeptides	 DNA vector
 Growth factors 	♦ Oligopeptides	♦ Nucleic acids (DNA, RNA)
♦ Hormones	 Polypeptides 	 Plasmids (DNA, cDNA)
♦ Interleukins	♦ Steroids	 Primers (nucleotides)



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.

lf:	And the product is:	And is:	Then:	
 Biosynthesized 	◆ Nucleic acid (RNA, DNA)		GO to Table 3-15-21	
products	♦ Plasmid			
 Chemically synthesized products 	◆ Primer	Livestock or avian	CONTACT PPQ-AQI-VMO or PPQ-VRS-Headquarters	
◆ Natural products	♦ Prohe		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)	

TABLE 3-15-17	Locator for Chemical	ly Synthesized.	Biosynthesized.	and Natural Products
	Ecoulor for ononinoun	., ojnanooizou,	Bioghthiodizou	

Proteins/Peptides/Enzymes/Hormones

TABLE 3-15-18	Proteins/Pe	ptides/Enzymes/	/Hormones
	1 10101107 1 0		110111101100

lf:	And:	And the origin is:	Then:	
 Enzymes Hormones 	Unrelated to any livestock (ruminant,	Recombinant, microbial	GO to Table 3-15-19	
Peptides	equine, or swine) or unrelated to any avian (bird species)	unrelated to any avian (ar (bird species)	Chemically synthesized materials (amino acids, hormones, steroids)	GO to Table 3-15-20
♦ Proteins			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 <i>PPQ-AQI-VMO</i> or <i>PPQ-VRS-Headquarters</i> <i>Personnel</i> for further action (see <i>Appendix H</i>)	
	Related to livestock or avian species	>	CONTACT <i>PPQ-AQI-VMO</i> or <i>PPQ-VRS-Headquarters</i> <i>Personnel</i> for further action (see <i>Appendix H</i>)	

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

lf:	And the origin is:	And the preparation:	And the importation:	Then:
EnzymesHormones	Microbial and not recombinant	Contains animal-derived additives or	Is accompanied by a shipper's or producer's declaration ¹	RELEASE
PeptidesProteins		stabilizers	Lacks the shipper/ producer's declaration ¹	REFUSE ENTRY
		Does not contain animal-derived	Is accompanied by a shipper's or producer's declaration ²	RELEASE
		additives or stabilizers	Lacks the shipper/ producer's declaration ²	REFUSE ENTRY
	recombinant ani	Contains animal-derived additives or	Is accompanied by a shipper's or producer's declaration ³	RELEASE
		stabilizers Does not contain animal-derived	Lacks the shipper/ producer's declaration ³	REFUSE ENTRY
			Is accompanied by a shipper's or producer's declaration ⁴	RELEASE
		additives or stabilizers	Lacks the shipper/ producer's declaration ⁴	REFUSE ENTRY

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

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
 - Confimation 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
 - Confimation 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

lf:	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	CONTACT
 Chemically synthesized peptides 	VS-recommended documentation ¹	USDA-APHIS-VS-National Center for Import and Export at 301/734-3277
 Chemically synthesized proteins 		to determine if a USDA permit is required
 Chemically synthesized materials other than listed above 		

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

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

lf:	And origin is:	And the preparation:	And the importation:	Then:
 Plasmids Microbial and not recombinant Nucleic acids (RNA, 	Contains animal-derived additives or	Is accompanied by shipper or producer's declaration ¹	RELEASE	
DNA)Primers		stabilizers Does not contain animal-derived additives or stabilizers	Lacks the shipper/ producer's declaration ¹	REFUSE ENTRY
♦ Probes			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	Is accompanied by shipper or producer's declaration ³	RELEASE
	Does anim addit	stabilizers	Lacks the shipper/ producer's declaration ³	REFUSE ENTRY
		animal-derived shi additives or dec stabilizers Lac pro	Is accompanied by shipper or producer's declaration ⁴	RELEASE
			Lacks the shipper/ producer's declaration ⁴	REFUSE ENTRY

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

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 stabiizer

Confimation 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 Confimation 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.

lf:	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		 DO NOT RELEASE the HOLD 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

TABLE 3-15-22 Salt Scrapings from Animal Casings

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

lf:	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