

3

Animal Product
Manual

Reference

Organs

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Introduction

The *Organs* section covers the internal structure of animals which are imported for purpose **other than** human consumption. This includes the secretions of organs and glands. Organs and related by-products cover whole or partial animal organs and glands, and the excretions, secretions, extracts, and derivatives of organs and glands including the following:

- ◆ Bile (ox gall)
- ◆ Bone marrow
- ◆ Fat
- ◆ Gall stone
- ◆ Gullet (goat)
- ◆ Heart
- ◆ Intestine
- ◆ Kidneys
- ◆ Lips
- ◆ Liver
- ◆ Lungs
- ◆ Musk (including grains and pods)
- ◆ Pancreas
- ◆ Parathyroid gland
- ◆ Pituitary gland
- ◆ Pyloric valve
- ◆ Rennet extract
- ◆ Spleen
- ◆ Stomach (maw)
- ◆ Thyroid gland
- ◆ Tripe
- ◆ Vell (calf)

Not covered in this section are internal animal parts such as:

- ◆ Blood imported for biological use and internal animal parts including organs and glands imported as rendered products; regulate under [*Animal Waste and Related By-Products*](#)
- ◆ Internal animal parts imported as pet food; regulate under [*Pet Food, and Livestock, Poultry, and Aquaculture Feed*](#)
- ◆ Internal animal parts imported for human consumption. May be manifested or invoiced as meat by-products¹ (beef feet, brain, cheeks, heart, hog stomach, kidney, lips, liver, lung, spleen, tail, thymus (sweetbread), tongue, and tripe); regulate under [*Meat and Meat Products*](#)
- ◆ Intestines or bung caps for production of strings or glue; regulate under [*Animal Waste and Related By-Products*](#)
- ◆ Intestines or bung caps for production of casings; regulate under [*Casings*](#)



Organs, glands, and all derivatives of organs and glands of ruminant origin from countries affected with BSE are prohibited, regardless of the purpose for which they are imported.

¹ Formerly called edible offal.

Organs and Glands Labeled for Pharmaceutical or Technical Use Only



Organs and glands labeled "For pharmaceutical use **only**" or "For technical use **only**" are **not** to be referred to FSIS.

Organs and Their Derivatives Moving Under Permit

When a VS permit authorizes entry of the organ or related by-product, match the information on the shipping documents with the information on the permit as follows:

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

Follow [Table 3-16-1](#) as you match the permit with the shipping documents.

TABLE 3-16-1 Action to Take When an Importation Is Authorized Entry with a VS Permit

If the shipping documents:	And the:	Then:
Match the permit	→	RELEASE or CONTROL as specified on the permit
Do not match the permit	Permit has expired	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. HAVE the consignee contact VS, TTSPS (see page 2-4-28) 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 to organs and related by-products harvested from slaughtered animals, use [Table 3-16-2](#) which directs you to the final regulatory action.

TABLE 3-16-2 Determine Where to Find the Regulatory Action on Organs and Derivatives Not Authorized Entry by a VS Permit

If the organ or derivative is from:	And the country or region of export is:	Then:
Any animal	Free from BSE	GO to Table 3-16-3
	BSE Minimal Risk	GO to Table 3-16-3
	Affected with BSE	GO to Table 3-16-3

TABLE 3-16-3 Organs and Derivatives

If the intended use is for:	And the product is:	Then:
Animal feed or fertilizer	Rendered	1. REGULATE as rendered products 2. GO to Animal Waste and Related By-Products
	Not rendered	1. REGULATE as fresh organs and glands 2. GO to Table 3-16-4
Pharmaceutical or for research		GO to Table 3-16-4
Coagulating or curdling milk to make cheese	Rennet (includes calf vells, goat gullets, and lamb stomachs)	GO to Table 3-16-10
	Other than rennet	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)
Manufacturing	Intestines or bung caps for other than casings	GO to Table 3-16-9
	Other than intestines or bung caps	
Not disclosed		1. REGULATE as fresh organs and glands 2. GO to Table 3-16-4

Organs and Their Derivatives for Research or Pharmaceutical Use

Excretions, secretions, extracts, and derivatives of organs and glands may be imported for research and pharmaceutical uses. They are usually in the form of liquids or powders. Some examples of these products follow:

- ◆ Bile
- ◆ Cholesterol
- ◆ Desiccated (dried) liver

- ◆ Enzymes
- ◆ Gall stone
- ◆ Heparin
- ◆ Hormones
- ◆ Insulin (for research purposes only; for pharmaceutical use, see [Table 3-15-10 on page-3-15-13](#))
- ◆ Liver extract (usually in powder form)
- ◆ Oxytocin
- ◆ Pancreas powder
- ◆ Pancreatin
- ◆ Pepsin
- ◆ Thymosin
- ◆ Thyroid powder
- ◆ Trypsin

Unless consigned to an approved establishment, these products or comparable products of avian or livestock origin require a permit. Avian gall stones from HPAI (H5N1)-affected countries/regions and ruminant gall stones require a permit. Return to [Organs and Their Derivatives Moving Under Permit](#) on page 3-16-3.




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

Fresh, Frozen Organs and Glands

TABLE 3-16-4 Fresh, Frozen Organs and Glands from Countries Free from BSE

If the class of animal the organs, glands or derivatives are from is:	Then:
Avian (bird) or poultry	GO to Table 3-16-5
Ruminant	GO to Table 3-16-6
Swine	GO to Table 3-16-7
Neither avian, ruminant, nor swine	GO to Table 3-16-13

TABLE 3-16-5 Fresh, Frozen Organs, Glands, and their derivatives of Avian Species

If:	And the country or region of export is:	And the importation is:	Then:
Fresh, frozen organs and glands of avian species	Free from BSE, END, and HPAI H5N1	Is appropriately certified ¹	RELEASE
		Lacks the required certificate ¹	GO TO Table 3-16-8
	Affected with BSE, END, or HPAI H5N1	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
		Lacks a VS permit	REFUSE ENTRY
Derivatives of organs or glands of avian species (examples include but are not limited to insulin, heparin, bile, oxytocin, etc.)		Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
		Lacks a VS permit	REFUSE ENTRY

1 A government certificate stating:

- ◆ The species of animal from which the material or product was derived
- ◆ The region where any facility in which the material or product was processed is located
- ◆ The material was derived **only** from animals that have **never** resided in a region listed in 9CFR 94.18(a)
- ◆ The material **did not** originate in and was **never** stored, rendered, or otherwise processed in or otherwise associated with a facility a region listed in 9CFR 94.18(a)
- ◆ The material was **not** otherwise associated with any of the materials listed in 9CFR 95.29(a) which have been in a region listed in 9CFR 94.18(a)

TABLE 3-16-6 Fresh, Frozen Organs, Glands and their Derivatives of Ruminants





If:	And the country or region of export is:	And the importation is:	And:	Then:
Fresh, frozen organs or glands of ruminants	Free from both BSE and FMD		Is appropriately certified ¹	RELEASE
			Lacks the required certificate ¹	GO to Table 3-16-8
	Free from BSE, but affected with FMD		Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	GO to Table 3-16-8
	BSE Minimal Risk	- Cattle	Is accompanied by CFIA Annex A-1	REFER TO FSIS
			Lacks the required CFIA Annex A-1	REFUSE ENTRY
		- Bison - Buffalo - Yak	Is accompanied by CFIA Annex A-1	RELEASE
			Lacks the required CFIA Annex A-1	REFUSE ENTRY
		- Caprine (goats) - Ovine (sheep)	Is accompanied by CFIA Annex A-2	REFER TO FSIS
			Lacks the required CFIA Annex A-2	REFUSE ENTRY
	- Camelid - Cervid		RELEASE	
	Affected with BSE		REFUSE ENTRY	


TABLE 3-16-6 Fresh, Frozen Organs, Glands and their Derivatives of Ruminants (continued)

Derivatives of organs or glands of ruminants (examples include but are not limited to insulin, heparin, bile, oxytocin, etc.)	Free from both BSE and FMD	→	Is appropriately certified ¹	RELEASE
			Lacks the required certificate ¹	GO to Table 3-16-8
	Free from BSE, but affected with FMD	→	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	GO to Table 3-16-8
	BSE Minimal Risk	→	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	REFUSE ENTRY
	Affected with BSE	→		REFUSE ENTRY

1 A government certificate stating:

- ◆ The species of animal from which the material or product was derived
- ◆ The region where any facility in which the material or product was processed is located
- ◆ The material was derived **only** from animals that have **never** resided in a region listed in 9CFR 94.18(a)
- ◆ The material **did not** originate in and was **never** stored, rendered, or otherwise processed in or otherwise associated with a facility a region listed in 9CFR 94.18(a)
- ◆ The material was **not** otherwise associated with any of the materials listed in 9CFR 95.29(a) which have been in a region listed in 9CFR 94.18(a)

TABLE 3-16-7 Fresh, Frozen Organs, Glands, and their Derivatives of Swine

If:	And the country or region of export is:	And the importation is:	Then:
Fresh, frozen organs or glands of swine	Free from ASF, BSE, CSF, FMD, and SVD	Is appropriately certified ¹	RELEASE
		Lacks the required certificate ¹	GO to Table 3-16-8
	Affected with ASF, BSE, CSF ² , FMD, or SVD	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
		Lacks a VS permit	REFUSE ENTRY
Derivatives of organs or glands of swine (examples include but are not limited to insulin, heparin, bile, oxytocin, etc.)		Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
		Lacks a VS permit	REFUSE ENTRY

1 A government certificate stating:

- ◆ The species of animal from which the material or product was derived
- ◆ The region where any facility in which the material or product was processed is located
- ◆ The material was derived **only** from animals that have **never** resided in a region listed in 9CFR 94.18(a)
- ◆ The material **did not** originate in and was **never** stored, rendered, or otherwise processed in or otherwise associated with a facility a region listed in 9CFR 94.18(a)
- ◆ The material was **not** otherwise associated with any of the materials listed in 9CFR 95.29(a) which have been in a region listed in 9CFR 94.18(a)

2 Policy has been established for swine glands from any country affected with CSF. Contact PPQ, VRS for further action.

Shipping Requirements for Fresh, Frozen Organs and Glands from Countries with Diseases of Concern

All importations of fresh, frozen organs and glands from countries with diseases of concern **must** be shipped in tight, leakproof containers. A sealed, leakproof layer is placed around the absorbent material.



TABLE 3-16-8 Determine Action to Take on Fresh, Frozen Organs and Glands from Countries with Diseases of Concern

If:	And the country or region of export is:	And the containers are:	And the importation is:	Then:
Fresh, frozen organs and glands	Affected with diseases of concern	Not tight and leakproof	→	REFUSE ENTRY
		Tight and leakproof	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see Appendix K to complete form)
			Not consigned to an approved establishment	<ol style="list-style-type: none"> DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)

Intestines, Bung Caps, and Other Animal Parts for Manufacturing

Moist intestines and bung caps, primarily of ruminants (sheep), are imported for manufacturing into articles such as prophylactics.

TABLE 3-16-9 Intestines, Bung Caps, and Other Animal Parts for Manufacturing from Countries Free from BSE

If:	And the country or region of export is:	And the importation is:	And the importation is:	Then:
Intestines, bung caps, and other animal parts for manufacturing	Free from both BSE and FMD	Accompanied by an official certificate of origin		RELEASE
		Not accompanied by the required certification	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see Appendix K to complete 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)	
	Free from BSE, but affected with FMD			Consigned to an approved establishment
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)

Rennets

A rennet is the membranous lining of the fourth stomach of calves, lambs, or kids. Rennet is also a dried extract made from the stomach lining of a ruminant. To further complicate matters, there are also vegetable rennets (coagulating enzymes from plants), like thistle rennet.

Rennin (or chymosin) is the enzyme in rennet that catalyzes the coagulation of milk in making cheese. Rennin is more commonly produced by recombinant microorganisms than from calf vells. Today, about 90% of hard cheese is made from rennin obtained from genetically modified microbes.

Therefore, to regulate rennets or rennin, you **must** determine the source, as follows:

- ◆ Derived from a ruminant
- ◆ Derived from microbes (recombinant chymosin or rennin)
- ◆ Derived from a plant

Ruminant Derived Rennets or Rennin

The following by-products from ruminants are regulated as ruminant derived rennets:

- ◆ Calf vell
- ◆ Gullet (goat)
- ◆ Rennet extract
- ◆ Stomach

Continue to [Table 3-16-10](#) once you have established the source of the rennet or rennin.

Action to Take on Rennet or Rennin after Determining the Source

TABLE 3-16-10 Action to Take on Rennet or Rennin (chymosin)

If the rennet or rennin (chymosin) is:	And the country or region of export is:	And is derived from:	And:	Then:
Derived from a ruminant	Affected with BSE	—————→		REFUSE ENTRY
	Minimal Risk for BSE	<ul style="list-style-type: none"> ◆ Cattle ◆ Bison ◆ Buffalo ◆ Yak 	Is accompanied by CFIA Annex-5	RELEASE
			Lacks the required CFIA Annex-5	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. Provide the importer with the option of obtaining the appropriate certification 3. If the importer is unable to obtain the appropriate certification, the PROVIDE the importer with the appropriate options (Table 2-2-11)
		<ul style="list-style-type: none"> ◆ Caprine (goat) ◆ Ovine (sheep) 	Is accompanied by CFIA Annex-6	RELEASE
			Lacks the required CFIA Annex-6	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. Provide the importer with the option of obtaining the appropriate certification 3. If the importer is unable to obtain the appropriate certification, the PROVIDE the importer with the appropriate options (Table 2-2-11)
	Free from BSE	—————→		GO to Table 3-16-11
Microbially produced ¹	—————→			GO to Table 3-15-19
Derived from plants (bromelin, ficin, papain, or thistle rennet for example)	—————→			RELEASE

¹ May be produced by fungi (*Rhizomucor meihei*, *Endothia parasitica*, or *Rhizomucor pusillus*) or genetically modified microbes (*Escherichia coli*, *Kluyveromyces lactis*, and *Aspergillus niger*).

TABLE 3-16-11 Rennets from Countries Free from BSE


And the country or region of export is:	And the importation:	Then:
Free from FMD	Is accompanied by a government of origin certificate	RELEASE
	Lacks the required certificate	GO to Table 3-16-12
Affected with FMD		

TABLE 3-16-12 Rennets Derived from a Country Known to Be Free from BSE, but Affected with FMD

If the importation is:	Then:
Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see Appendix K to complete 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)

Fresh Frozen Organs, Glands, and their Derivatives from Other than Avian, Ruminant or Swine

TABLE 3-16-13 Fresh, Frozen Organs, Glands and their Derivatives of Other than Avian, ruminant, or Swine

If:	And the animal species is:	And the country or region of export is:	And the importation:	Then:
Fresh, frozen organs or glands	Equine	Free from AHS and BSE	Is appropriately certified ¹	RELEASE
			Lacks the required certificate ¹	REFUSE ENTRY
		Affected with AHS or BSE	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	REFUSE ENTRY
	Fish, shellfish, or other marine species	Free from BSE	Is appropriately certified ¹ or is accompanied by a shipper's or producer's declaration ²	RELEASE
			Lacks both the certificate ¹ and a shipper's or producer's declaration ²	REFUSE ENTRY
Affected with BSE		Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit	
		Lacks a VS permit	REFUSE ENTRY	
Derivatives of organs or glands of Equine species (examples include but are not limited to insulin, heparin, bile, oxytocin, etc.)	Equine	→	Accompanied by a VS permit	RELEASE or CONTROL as specified on the permit
			Lacks a VS permit	REFUSE ENTRY
Derivatives of organs or glands of fish, shellfish, or other marine species (examples include but are not limited to insulin, heparin, bile, oxytocin, etc.)	Fish, shellfish, or other marine species	→	Is accompanied by a shipper's or producer's declaration ²	RELEASE
			Lacks a shipper's or producer's declaration ²	REFUSE ENTRY

Reference: Organs

Fresh Frozen Organs, Glands, and their Derivatives from Other than Avian, Ruminant or Swine

- 1 An original certificate signed by a full-time veterinarian of the agency responsible for animal health in the exporting region, and declaring the following:

The animal species from which the material was derived

The region where any facility in which the material was processed is located

The material was derived **only** from animals that have **never** resided in a region listed in 9CFR 94.18(a)

The material **did not** originate in and was **never** stored, rendered, or otherwise processed in or otherwise associated with a facility a region listed in 9CFR 94.18(a)

The material was **not** otherwise associated with any of the materials listed in 9CFR 95.29(a) which have been in a region listed in 9CFR 94.18(a)

- 2 An **original**, written declaration and signed statements on the producer's or shipper's letterhead which states and affirms in a clear and concise manner, the following information:

Identification of the material and species of origin

Material **does not** include any avian, equine, ruminant, or swine species or their materials (such as in transport media or stabilizers)