Animal Product Manual

Reference

Bones and Related By-Products

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Introduction

What Is Covered

The *Bones and Related By-Products* section covers the following animal parts and by-products, or cross-references to other categories within the *Reference* section:

- **♦** Antlers
- **♦** Bones
- ◆ Carcass, entire, with skin, hide, or feathers attached
- **♦** Chondroitin sulfate
- ♦ Gelatin
- ♦ Hoofs
- ♦ Horns
- **♦** Items made of bony material
- **♦** Skulls
- ◆ Teeth
- ◆ Tusks

If a commercial importation, then regulate an importation of bones as bone. Also, consider a large quantity of unfinished bones as a commercial importation, and regulate as bones rather than trophies.

What Is Not Covered

Not covered in this section are the following animal products and by-products:

- Antlers or their products imported for medicinal use such as an aphrodisiac; regulate as Asian medicinal products under Miscellaneous Products
- ◆ Bone, hoof, and horn meal; regulate these products as rendered products under *Animal Waste and Related By-Products*
- ♦ Bones consigned to a museum
- ◆ Bones or skulls entering as trophies or souvenirs; regulate these importations under *Trophies*. Trophies and souvenirs would include:
 - One to two skulls or horns
 - Skulls or horns that have been lacquered or painted
 - Clean, dry ruminant skulls free from undried pieces of hide, flesh, and sinew imported for display
- ◆ Bones, horns, or hoofs imported for pet toys; regulate these importations under *Pet Food, and Livestock, Poultry, and Aquaculture Feed*
- ◆ Collagen of bones; regulate these products under *Animal Waste* and *Related By-Products*
- Gelatin capsules containing FDA-approved human or veterinary medication and in final, finished form ready for distribution; such capsules and contents are unrestricted
- Gelatin-containing food products (such as candy, drinks with gelatin, film, gelatin desserts (Royal and Jello), jams, jellies, marshmallows, pudding, and sherbert)

3-4-3

When a VS permit authorizes entry of the bones or related by-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 3-4-1** as you match the permit with the shipping documents.

TABLE 3-4-1 Validate Importation Authorized Entry by a VS Permit

If the shipping documents:	And the:	Then:
Match the permit	-	RELEASE or CONTROL as specified on the permit
Do not match the permit	Permit has expired	DO NOT RELEASE the HOLD HAVE the consignee contact VS, TTSPS (seeTable 2-4-16) 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>)

Locator

Locator

When a VS permit **does not** authorize entry, use **Table 3-4-2** to determine the appropriate regulatory action to take.

TABLE 3-4-2 Where to Find the Regulatory Action on Bones and Related By-Products that Are Not Authorized by a VS Permit

If the bones or related by-products are:	And the importation is entering:	Then:
Bone ash, bone black, or bone char		GO to Table 3-4-3
Bones: horns, antlers, skulls, teeth, tusks, dried bones, granulated	For manufacturing or as manufactured items such as pistol grips, knife handles, buttons, souvenirs	GO to Table 3-4-6
bones, crushed bones	For purposes other than described in the cell above	GO to Table 3-4-12
Chondroitin sulfate	-	GO to Table 3-4-11
Entire carcass with skin, hide, or feathers attached	-	GO to Table 3-4-12
Gelatin	As bulk gelatin or empty gel caps	Go to Table 3-4-4
	Other than described in the cell above	Go to Table 3-4-5
Gelatin-containing foods		Unrestricted
Hoofs	As pet chews or toys	GO to Table 3-18-17
	As other than for pet chews or toys	GO to Table 3-4-10

Bone Ash, Bone Black, or Bone Char

TABLE 3-4-3 Bone Ash, Bone Black, or Bone Char

If the importation is derived from:	And the bones originated from a region:	And were processed in a region:	And the importation:	Then:
Ruminant	Affected with		Is accompanied by a VS permit	RELEASE
	BSE		Lacks a VS permit	REFUSE ENTRY
	Free from BSE	Affected with BSE	Is accompanied by a VS permit	RELEASE
			Lacks a VS permit	REFUSE ENTRY
		Free from BSE	Is appropriately certified ¹	RELEASE
			Lacks appropriate certification ¹	REFUSE ENTRY
Other than ruminant			•	RELEASE

¹ A government certificate stating that (a) the product was derived from ruminant bones from a region (**must** state the region) **other than** those considered by the USDA to be affected with BSE, and (b) during processing, there was **no** commingling with any ruminant material from a region considered by the USDA to be affected with BSE.

Gelatin

Gelatin

To determine the regulatory action to take on gelatin, see **Table 3-4-4** (Gelatin as Bulk Gelatin or Empty Gel Caps) or **Table 3-4-5** (Gelatin other than Bulk Gelatin or Empty Gel Caps).

Gelatin as Bulk Gelatin or Empty Gel Caps

TABLE 3-4-4 Gelatin as Bulk Gelatin or Empty Gel Caps

	And the	BSE/HPAI (H5N	N1) status:			
And the species of origin is:	Of the country of origin is:	Of the country of processing is:	Of the country of export is:	And the tissue of origin is:	And the importation:	Then:
Ruminant	BSE affected			Hides or bones	Is accompanied by a VS permit ¹	RELEASE
			-		Lacks a VS permit ¹	REFUSE ENTRY
	BSE free	BSE affected	BSE affected	Hides or bones	Is accompanied by a certificate ²	RELEASE
						REFUSE ENTRY
	BSE free	BSE affected	BSE free Hides or bones		Is accompanied by a certificate ²	RELEASE
					Lacks a certificate ²	REFUSE ENTRY
	BSE free	BSE free	BSE affected	Hides or bones	Is accompanied by a certificate ²	RELEASE
					Lacks a certificate ²	REFUSE ENTRY
	BSE free	BSE free	BSE free	Hides or bones	Is accompanied by a certificate ³	RELEASE
					Lacks a certificate ³	REFUSE ENTRY
	Canada	Canada	Canada	Hides or Bones	Is accompanied by a certificate ⁴	RELEASE
					Lacks a certificate ⁴	REFUSE ENTRY
Equine, Swine or			ı	_	Is accompanied by a certificate ⁵	RELEASE
Fish					Lacks a certificate ⁵	REFUSE ENTRY

TABLE 3-4-4 Gelatin as Bulk Gelatin or Empty Gel Caps (continued)

Avian	HPAI (H5N1) free	HPAI (H5N1) free	HPAI (H5N1) free		Is accompanied by a certificate ⁶	RELEASE
				-	Lacks a certificate ⁶	REFUSE ENTRY
	HPAI (H5N1) free	HPAI (H5N1) free	HPAI (H5N1) affected		Is accompanied by a VS permit ⁷	RELEASE
				-	Lacks a VS permit ⁷	REFUSE ENTRY
	HPAI (H5N1) free	HPAI (H5N1) affected	HPAI (H5N1) affected		Is accompanied by a VS permit ⁷	RELEASE
				-	Lacks a VS permit ⁷	REFUSE ENTRY
	HPAI (H5N1) affected	HPAI (H5N1) affected	HPAI (H5N1) affected		Is accompanied by a VS permit ⁷	RELEASE
				-	Lacks a VS permit ⁷	REFUSE ENTRY

- Gelatin derived from hides or bones of ruminants originating from BSE affected regions. VS import permits for gelatin/empty gelatin capsules derived from ruminants originating from BSE affected regions do not require certification from the exporting government because there is nothing to certify. The permit will read, "Imported product is for INDUSTRIAL or NON-ANIMAL use only. Permit does not authorize use as livestock feed ingredient, veterinary pharmaceutical or veterinary biological product. The permittee is responsible for ensuring that (a) the gelatin/gelatin capsules are not distributed to animal feed industries, (b) the gelatin/gelatin capsules are industrial or non-animal use only, (c) the gelatin/gelatin capsules will not be used as livestock feed ingredient or in veterinary pharmaceutical or veterinary biological product, and (d) any unused gelatin/gelatin capsules will be destroyed by incineration or burial at a landfill.
- 2 Gelatin derived from hides or bones of ruminants originating from BSE free regions may be accompanied by an official certificate issued by a veterinarian employed by the national government of the region of origin stating the species of animal from which the gelatin was derived and certifying that the gelatin was not derived from ruminants that have been in any region listed in 9CFR 94.18(a) or may be accompanied by a VS import permit which identifies the region of origin of the ruminants from which the gelatin was derived.
- 3 Gelatin derived from hides or bones of ruminants originating from BSE free regions may be accompanied by an official certificate issued by a veterinarian employed by the national government of the region of origin stating the species of animal from which the gelatin was derived and certifying that the gelatin was not derived from ruminants that have been in any region listed in 9CFR 94.18(a).

Reference: Bones and Related By-Products

Gelatin

- 4 Gelatin, from Canada, may be accompanied by an original certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, certifying that the gelatin is (1) derived from the bones of bovines subject to a ruminant feed ban equivalent to the requirements established by the U. S. Food and Drug Administration at 21 CFR 589.2000, from which the specific risk materials (SRMs) were removed and has not been commingled with materials ineligible for entry into the U.S.; or (2) derived from the hides of bovines and the gelatin has not been commingled with materials ineligible for entry into the U.S. As an alternative to CFIA certification, either commodity may be accompanied by a VS import permit (see footnote #1).
- 5 Gelatin derived from equine, swine, and/or fish must be accompanied by an official certificate issued by a veterinarian employed by the national government of the region of origin stating the species of animal from which the gelatin was derived.
- 6 Gelatin derived from avian species originating from regions classified by the USDA as free from highly pathogenic avian influenza subtype H5N1 (HPAI H5N1) may be accompanied by an official certificate stating the region of origin of the birds from which the gelatin was derived or may be accompanied by a VS import permit which identified the region of origin of the birds from which the gelatin was derived.
- 7 Gelatin derived from avian species originating from regions classified by the USDA as affected with highly pathogenic avian influenza subtype H5N1 (HPAI H5N1) must be accompanied by a VS import permit.

Gelatin Other Than Bulk Gelatin or Empty Gel Caps

TABLE 3-4-5 Gelatin Other Than Bulk Gelatin or Empty Gel Caps

If the type product is:	Imported as:	And the importation:	Then:
Dietary supplements and nutriceuticals containing gelatin as an ingredient, gel caps with nutriceuticals		-	Regulate under Miscellaneous Products
Gel Caps containing pharmaceuticals, in final dosage form, finished packaging, for human use, ready for retail		>	Regulate under Miscellaneous Products
Gelatin-containing food products for human consumption, e.g. candy, drinks with gelatin, film, gelatin desserts, jams, jellies, pudding, sherbet, marshmallows		-	RELEASE
Gelatin-containing food products not for human consumption (i.e.,		Is accompanied by a VS Permit ¹	RELEASE or CONTROL as specified on the permit ¹
pet food, livestock feed)		Lacks a VS permit ¹	REFUSE ENTRY
Gelatin-containing human pharmaceuticals, placebos, and		Is accompanied by a VS permit ²	RELEASE or CONTROL as specified on the permit ²
gel caps for use in clinical trials or other analytical testing		Lacks a VS permit ²	REFUSE ENTRY
Technical gelatin (aka animal	Single commodity		RELEASE ³
glue)	Culture media or imported as an ingredient in a commodity	Is accompanied by a VS permit ⁴	RELEASE or CONTROL as specified on the permit ⁴

TABLE 3-4-5 Gelatin Other Than Bulk Gelatin or Empty Gel Caps (continued)

If the type product is:	Imported as:	And the importation:	Then:
 Veterinary pharmaceutical gel caps, in bulk or final, finished form 		Is a veterinary pharmaceutical approved by the FDA ⁵	CONTACT and REFER to the Food and Drug Administration ⁵
 Veterinary pharmaceutical containing gelatin, in bulk or final, finished form 	containing gelatin, in bulk or		RELEASE or CONTROL as specified on the permit ⁶
		Is not approved by the FDA and lacks a VS permit ⁶	REFUSE ENTRY

- 1 Pet food and livestock feed containing gelatin, requires a VS import permit.
- 2 Pharmaceuticals, placebos, and gel caps containing gelatin destined for clinical trials or other analytical testing require a VS import permit.
- 3 Technical gelatin (also known as animal glue) as a single commodity is unrestricted.
- 4 Technical gelatin (also known as animal glue) as an ingredient in a commodity requires a VS import permit to address all animal origin ingredients.
- 5 FDA approved veterinary pharmaceuticals in gelatin capsules and FDA approved veterinary pharmaceuticals containing gelatin do not require a VS import permit. FDA approved veterinary pharmaceuticals are regulated by the FDA's Center for Veterinary Medicine.
- 6 Veterinary pharmaceutical ingredients contain gelatin, including veterinary pharmaceutical gel caps that are **not** FDA approved, require a VS import permit.

Bones, Etc. for Manufacturing

Bones (horns, antlers, skulls, teeth, tusks, dried bones, granulated bones, crushed bones) imported for manufacturing may still require some drilling, shaping, or grinding. If the bones require further processing, then they **must** be finished at an establishment that is approved to properly dispose of the residue (pieces, chips, or dust).

TABLE 3-4-6 Bones for Manufacturing

If the bones are:	And the bones are from:	Then:
Fully finished, ready to use such as:		RELEASE
◆ Buttons		
◆ Knife handles		
◆ Pistol grips		
◆ Souvenirs		
Not fully finished; still requiring some drilling, shaping, sanding, or grinding	Ruminant	GO to Table 3-4-8
	Other than a ruminant	GO to Table 3-4-7

Bones, Etc. for Manufacturing

Bones Not Fully Finished, and from Other than Ruminants

TABLE 3-4-7 Bones that Are Not Fully Finished, and Are from Other Than Ruminants

If the importation is:	And is:	Then:
Bones that are not fully finished, and are from other than ruminants	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see <i>Appendix K</i> to complete form)
	Not consigned to an approved establishment	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)

Ruminant Bones Not Fully Finished

TABLE 3-4-8 Ruminant Bones that Are Not Fully Finished

If the ruminant bones are:	And the bones are derived from:	And the country or region of export is:	And the importation:	Then:
Not fully-finished	Cervid, not including antlers	Affected with BSE	-	REFUSE ENTRY
		Minimal risk for BSE ¹	Consigned to an approved establishment ²	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete the form)
			Not consigned to an approved establishment ²	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)
		Free from BSE	Consigned to an approved establishment ²	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete the form)
			Not consigned to an approved establishment ²	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)
	Cervid, antlers only	Affected with BSE		REFUSE ENTRY
		Minimal risk for BSE ¹		GO to Table 3-4-9
		Free from BSE		GO to Table 3-4-9
	◆ Bovine◆ Ovine (sheep)◆ Caprine (goat)	Affected with BSE		REFUSE ENTRY
		Minimal risk for BSE ¹	Is accompanied by a VS permit	RELEASE
			Lacks a VS permit	REFUSE ENTRY
		Free from BSE	Is consigned to an approved establishment ²	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete the form)
			Is not consigned to an approved establishment ²	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)

¹ Currently Canada is the **only** country designated at minimal risk for BSE.

² Since **cervid** commodities from a country at minimal risk for BSE are **not** restricted because of BSE, the approved establishments will treat materials for other diseases.

Reference: Bones and Related By-Products

Bones, Etc. for Manufacturing

TABLE 3-4-9 Cervid Antlers from a Region Known to Be Free from BSE or Minimal Risk for BSE

If:	And the country or region of origin is:	And:	And the shipment is:	
Cervid antlers	Free from both BSE and FMD	Is accompanied by the appropriate certification ¹		RELEASE
		Not accompanied by the appropriate certification ¹	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete the form)
			Not consigned to an approved establishment	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)
	Free from BSE, but affected with FMD		Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete the form)
			Not consigned to an approved establishment	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)
	Minimal risk for BSE ² , and free from FMD	Is accompanied by the appropriate certification ¹		RELEASE
		Not accompanied by the appropriate certification ¹	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete the form)
			Not consigned to an approved establishment	 DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)
	Minimal risk for BSE ² , but affected with FMD	-	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS Form 16-78 (see <i>Appendix K</i> to complete the form)
			Not consigned to an approved establishment	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)

¹ An original health certificate endorsed by a full-time salaried veterinarian of the agency responsible for animal health of the country of origin certifying the:

[◆] Name of the FMD-free country of origin

Antlers are clean, dry, and free of soil, clay, sand, tissue, and undried pieces of hide, flesh, sinew, and other related materials

² Currently Canada is the **only** country designated at minimal risk for BSE.

Hoofs Other than for Pet Toys

To determine the action to take for importations of hoofs that are for other than pet toys, see **Table 3-4-10**.

TABLE 3-4-10 Hoofs Other Than for Pet Toys

If the importation is:	And the hoofs are derived from:	And the country or region of export is:	And the importation:	And is:	Then:
Hoofs other than for pet	Ruminant	Affected with BSE			REFUSE ENTRY
toys		Minimal risk for BSE ¹	Is appropriately certified ²	>	RELEASE
			Lacks appropriate certification ²	Consigned to an approved establishment	Authorize shipment under seal with VS Form 16-78 (see Appendix K 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)
		Free from BSE	Is appropriately certified ²	-	RELEASE
			Lacks appropriate certification ²	Consigned to an approved establishment	Authorize shipment under seal with VS Form 16-78 (see Appendix K 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)
	Swine	Swine	Is appropriately certified ²		RELEASE
			Lacks appropriate certification ²	Consigned to an approved establishment	Authorize shipment under seal with VS Form 16-78 (see Appendix K to complete the form)

TABLE 3-4-10 Hoofs Other Than for Pet Toys (continued)

If the importation is:	And the hoofs are derived from:	And the country or region of export is:	And the importation:	And is:	Then:
Hoofs other than for pet toys	Swine		Lacks appropriate certification ²	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)
	Other than ruminant or swine		-		

- 1 Currently Canada is the only country designated at minimal risk for BSE.
- 2 One of the following approved methods for processing must appear on the certificate from the government of origin:
 - ◆ Dry heat at 180°F (82.2°C) for 30 minutes
 - ◆ Soaking in boiling water for 20 minutes
 - ♦ Soaking for 2 hours in a 0.1 percent solution of chlorine bleach
 - ◆ Soaking for 2 hours in a 5 percent solution of acetic acid
 - ◆ Soaking for 2 hours in a 5 percent solution of hydrogen peroxide

Chondroitin Sulfate and Glucosamine

TABLE 3-4-11 Chondroitin Sulfate and Glucosamine

If the importation is:	And is derived from:	And:	Then:
Chondroitin sulfate and/or glucosamine	◆ Ruminant	Is accompanied by a VS permit	RELEASE
	◆ Swine		
	◆ Avian	Lacks a VS permit	REFUSE ENTRY
	◆ Equine (horses)		
	◆ Other than listed above		
	Marine species (usually shark)	Is appropriately certified ¹	RELEASE
		Lacks appropriate certification ¹	REFUSE ENTRY

- 1 A declaration which provides, in a clear and concise manner, the following information:
 - ♦ Identification of the material and species of origin
 - Written declaration indicating the material does not include any equine, ruminant, swine, or avian species or their materials (such as in transport media or stabilizers)

Bones and Related By-Products Not Specifically Mentioned Elsewhere

Use **Table 3-4-12** when the importation is bones (horns, antlers, skulls, teeth, tusks, dried bones, granulated bones, crushed bones) or entire carcasses with skin, hide, or feathers attached that are being imported for purposes **other than** what is covered in this section.

TABLE 3-4-12 Bones and Related By-Products Not Specifically Mentioned Elsewhere

If the importation is:	And is derived from:	And the country or region of export is:	And:	And is:	Then:
Bones and related by-products mentioned elsewhere	Ruminant	Affected with BSE	-		REFUSE ENTRY
		Minimal risk for BSE ¹	Is accompanied by a VS permit	-	RELEASE
			Lacks a VS permit	Consigned to an approved establishment ²	AUTHORIZE shipment under seal with VS 16-78 (see <i>Appendix K</i> to complete the form)
				Not consigned to an approved establishment ²	DO NOT RELEASE the HOLD PROVIDE the importer with the appropriate options (see Table 2-2-11)
		Free from BSE		Consigned to an approved establishment ²	AUTHORIZE shipment under seal with VS 16-78 (see <i>Appendix K</i> to complete the form)
				Not consigned to an approved establishment ²	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
	Other than ruminant			Consigned to an approved establishment ²	AUTHORIZE shipment under seal with VS 16-78 (see <i>Appendix K</i> to complete the form)
		→		Not consigned to an approved establishment ²	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)

Reference: Bones and Related By-Products Bones and Related By-Products Not Specifically Mentioned Elsewhere

- 1 Currently Canada is the *only* country designated at minimal risk for BSE.
- The approved establishments will treat materials for other diseases, including anthrax.