Suspect for a transmissible spongiform encephalopathy. (1) A sheep or goat that has tested positive for a transmissible spongiform encephalopathy or for the proteinase resistant protein associated with a transmissible spongiform encephalopathy, unless the animal is designated as positive for a transmissible spongiform encephalopathy; or

(2) A sheep or goat that exhibits any of the following signs and that has been determined to be suspicious for a transmissible spongiform encephalopathy by a veterinarian: Weight loss despite retention of appetite; behavior abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, ''star gazing,'' head pressing, recumbency, or other signs of neurological disease or chronic wasting.

United States means the several States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

Veterinary Services means the Veterinary Services unit of the Animal and Plant Health Inspection Service, United States Department of Agriculture.

[28 FR 5981, June 13, 1963, as amended at 56 FR 19796, Apr. 30, 1991; 56 FR 63869, Dec. 6, 1991; 62 FR 56024, Oct. 28, 1997; 66 FR 42600, Aug. 14, 2001; 70 FR 551, Jan. 4, 2005; 70 FR 71218, Nov. 28, 2005]

EFFECTIVE DATE NOTE: At 74 FR 66226, Dec. 15, 2009, §95.1 was amended by adding, in alphabetical order, a new definition of *bird trophy*, effective Jan. 14, 2010. For the convenience of the user, the added text is set forth as follows:

§95.1 Definitions.

* * * * *

Bird trophy. A carcass or part of a carcass of a wild bird taken as game during a hunting expedition for the purpose of processing into taxidermy mounts for personal exhibition.

* * * * *

§95.2 Region of origin.

No products or materials specified in the regulations in this part shall be imported unless there be shown upon the commercial invoice, or in some other manner satisfactory to the Deputy Administrator, Veterinary Services, the name of the region of origin of such product or material: *Provided*, That the region of origin shall be construed to mean (a) in the case of an animal byproduct, the region in which such product was taken from an animal or animals, and (b) in the case of other materials, the region in which such materials were produced.

[28 FR 5981, June 13, 1963, as amended at 62 FR 56024, Oct. 28, 1997]

§95.3 Byproducts from diseased animals prohibited.

The importation of any animal byproduct taken or removed from an animal affected with anthrax, foot-and-mouth disease, or rinderpest is prohibited.

§95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and blood and blood products due to bovine spongiform encephalopathy.

(a) Except as provided in paragraphs (c) through (i) of this section, the importation of the following is prohibited:

(1) Any of the materials listed in paragraphs (a)(1)(i) through (a)(1)(iv) of this section that have been derived from animals that have been in any region listed in §94.18(a) of this chapter:

(i) Processed animal protein, tankage, offal, and tallow other than tallow derivatives, unless, in the opinion of the Administrator, the tallow cannot be used in feed, regardless of the animal species from which the material was derived;

(ii) Glands, unprocessed fat tissue, and blood and blood products derived from ruminants;

(iii) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal, regardless of the animal species from which the material was derived; and

(iv) Derivatives of glands and blood and blood products derived from ruminants.

(2) Any of the materials listed in paragraphs (a)(2)(i) through (a)(2)(iv) of this section that have been stored, rendered, or otherwise processed in a region listed in §94.18(a) of this chapter, or that have otherwise been associated with a facility in a region listed in §94.18(a) of this chapter or with any material listed in paragraph (a)(1) through (a)(3) of this section:

(i) Processed animal protein, tankage, offal, and tallow other than tallow derivatives, unless, in the opinion of the Administrator, the tallow cannot be used in feed, regardless of the animal species from which the material was derived;

(ii) Glands and unprocessed fat tissue derived from ruminants;

(iii) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal, regardless of the animal species from which the material was derived; and

(iv) Derivatives of glands from ruminants.

(3) Products containing any of the items prohibited importation under paragraphs (a)(1) and (a)(2) of this section.

(b) Except as provided in paragraphs (d), (e), and (i) of this section, the importation of serum from ruminants that have been in any region listed in §94.18(a) of this chapter is prohibited, except that serum from ruminants may be imported for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of bovine spongiform encephalopathy into the United States. Serum from ruminants imported in accordance with this paragraph must be accompanied by a permit issued by APHIS in accordance with §104.4 of this chapter, and must be moved and handled as specified on the permit.

(c) Materials that are otherwise prohibited importation into the United States under paragraph (a) of this section may be imported into the United States if the following conditions are met prior to importation:

(1) The material is derived from a nonruminant species, or from a ruminant species if the ruminants have never been in any region listed in §94.18(a) of this chapter.

(2) In regions listed in §94.18(a)(1) or (a)(2) of this subchapter as regions in which BSE exists or that present an undue risk of introducing BSE into the United States, all steps of processing and storing the material are carried out in a facility that has not been used for the processing and storage of materials derived from ruminants that have been in any region listed in §94.18(a) of this subchapter.

(3) In regions listed in §94.18(a)(3) of this subchapter as BSE minimal-risk regions, all steps of processing and storing the material are carried out in a facility that has not been used for the processing and storage of materials derived from ruminants that have been in any region listed in §94.18(a)(1) or (a)(2) of this subchapter as a region in which BSE exists or a region that presents an undue risk of introducing BSE into the United States.

(4) The facility demonstrates to APHIS that the materials intended for exportation to the United States were transported to and from the facility in a manner that would prevent cross-contamination by or commingling with prohibited materials.

(5) Except for facilities in regions listed in §94.18(a)(3) of this subchapter, if the facility processes or handles any material derived from mammals, the facility has entered into a cooperative service agreement executed by the operator of the facility and APHIS. In accordance with the cooperative service agreement, the facility must be current in paying all costs for a veterinarian of APHIS to inspect the facility (it is anticipated that such inspections will occur approximately once per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including excess baggage provisions up to 150 pounds). In addition, the facility must have on deposit with APHIS an unobligated amount equal to the cost for APHIS personnel to conduct one inspection. As funds from that amount are obligated, a bill for costs incurred based on official accounting records

will be issued to restore the deposit to the original level, revised as necessary to allow for inflation or other changes in estimated costs. To be current, bills must be paid within 14 days of receipt. In facilities in regions listed in § 94.18(a)(3) of this subchapter, the inspections that would otherwise be conducted by APHIS must be conducted at least annually by a representative of the government agency responsible for animal health in the region.

(6) The facility allows periodic APHIS inspection of its facilities, records, and operations.

(7) Each shipment to the United States is accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the conditions of paragraphs (c)(1) through (c)(4) of this section have been met; except that, for shipments of animal feed from a region listed in § 94.18(a)(3) of this subchapter, the certificate may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

(8) The person importing the shipment has applied for and obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3. (VS Form 16–3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/ncie.*)

(d) Except as provided in paragraph (e) of this section, the importation of serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ruminants that have been in any region listed in § 94.18(a) of this chapter, and collagen and collagen products that meet any of the conditions listed in paragraphs (a)(1) through (a)(3) of this section, is prohibited unless the following conditions have been met:

(1) The article is imported for use as an ingredient in cosmetics;

(2) The person importing the article has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3 (VS Form 16–3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/ncie.*); and

(3) The permit application states the intended use of the article and the name and address of the consignee in the United States.

(e) Bovine blood and blood products that are otherwise prohibited importation under paragraph (a)(1) or (d) of this section may be imported into the United States if they meet the following conditions:

(1) For blood collected at slaughter and for products derived from blood collected at slaughter:

(i) The blood was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in a hygienic manner that prevents contamination of the blood with SRMs.

(ii) The slaughtered animal passed ante-mortem inspection and was not subjected to a pithing process or to a stunning process with a device injecting compressed air or gas into the cranial cavity;

(2) For fetal bovine serum:

(i) The blood from which the fetal bovine serum was derived was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in a hygienic manner that prevents contamination of the blood with SRMs;

(ii) The dam of the fetal calf passed ante-mortem inspection and was not subjected to a pithing process or to a stunning process with a device injecting compressed air or gas into the cranial cavity;

(iii) The uterus was removed from the dam's abdominal cavity intact and taken to a separate area sufficiently removed from the slaughtering area of the facility to ensure that the fetal blood was not contaminated with SRMs when collected.

(3) For blood collected from live donor bovines and for products derived

from blood collected from live donor bovines:

(i) The blood was collected in a closed system in which the blood was conveyed directly from the animal in a closed conduit to a closed receptacle, or was collected otherwise in a hygienic manner that prevents contamination of the blood with SRMs;

(ii) The donor animal was free of clinical signs of disease.

(4) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (e)(1), (e)(2), or (e)(3) of this section, as applicable, have been met.

(f) Insulin otherwise prohibited from importation into the United States under paragraph (a) of this section is not prohibited from importation under that paragraph if the insulin is for the personal medical use of the person importing it and if the person importing the shipment has applied for and obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3. (VS Form 16–3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/ncie*.

NOTE TO PARAGRAPH (f): Insulin that is not prohibited from importation under this paragraph may be prohibited from importation under other Federal laws, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C, 321 *et seq*.)

(g) Tallow otherwise prohibited importation under paragraph (a)(1) of this section may be imported into the United States if it meets the following conditions:

(1) The tallow is derived from bovines that have not been in a region listed in §94.18(a)(1) or (a)(2) of this subchapter;

(2) The tallow is composed of a maximum level of insoluble impurities of 0.15 percent in weight;

(3) After processing, the tallow was not exposed to or commingled with any other animal origin material; and

(4) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by 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. The certificate must state that the requirements of paragraphs (f)(1) through (f)(3) of this section have been met; and

(5) The shipment, if arriving at a U.S. land border port, arrives at a port listed in §94.19(g) of this subchapter.

(h) Offal that is otherwise prohibited importation under paragraph (a)(1) of this section may be imported if the offal is derived from cervids or the offal is derived from bovines, ovines, or caprines from a region listed in §94.18(a)(3) of this subchapter that have not been in a region listed in §94.18(a)(1) or (a)(2) of this subchapter, and the following conditions are met:

(1) If the offal is derived from bovines, the offal:

(i) Contains no SRMs and is derived from bovines from which the SRMs were removed;

(ii) Is derived from bovines for which an air-injected stunning process was not used at slaughter; and

(iii) Is derived from bovines that are subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(2) If the offal is derived from ovines or caprines, the offal:

(i) Is derived from ovines or caprines that were less than 12 months of age when slaughtered and that are from a flock or herd subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;

(ii) Is not derived from ovines or caprines that have tested positive for or are suspect for a transmissible spongiform encephalopathy;

(iii) Is not derived from animals that have resided in a flock or herd that has been diagnosed with BSE; and

(iv) Is derived from ovines or caprines whose movement was not restricted in the BSE minimal-risk region as a result of exposure to a transmissible spongiform encephalopathy.

(3) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by 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. The certificate must state that the requirements of paragraph (g)(1) or (g)(2) of this section have been met; and

(4) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(g) of this subchapter.

(i) *Transit shipment of articles.* Articles that are prohibited importation into the United States in accordance with this section may transit air and ocean ports in the United States for immediate export if the conditions of paragraphs (i)(1) through (i)(3) of this section are met. If such commodities are derived from bovines, sheep, or goats from a region listed in § 94.18(a)(3) of this subchapter, they are eligible to transit the United States by overland transportation if the requirements of paragraphs (i)(1) through (i)(4) of this section are met:

(1) The person moving the articles has obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16–3. (VS Form 16–3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/ncie.*)

(2) The articles are sealed in leakproof containers bearing serial numbers during transit. Each container remains sealed during the entire time that it is in the United States.

(3) The person moving the articles notifies, in writing, the inspector at both the place in the United States where the articles will arrive and the port of export before such transit. The notification includes the following:

(i) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;

(ii) Times and dates of arrival in the United States;

(iii) Times and dates of exportation from the United States;

(iv) Mode of transportation; and

(v) Serial numbers of the sealed containers.

(4) The articles are eligible to enter the United States in accordance with this section and are accompanied by the certification required by this section. Additionally, the following conditions must be met:

(i) The shipment is exported from the United States within 7 days of its entry;

(ii) The commodities are not transloaded while in the United States, except for direct transloading under the supervision of an inspector, who must break the seals of the national government of the region of origin on the means of conveyance that carried the commodities into the United States and seal the means of conveyance that will carry the commodities out of the United States with seals of the U.S. Government;

(iii) A copy of the import permit required under paragraph (i)(1) of this section is presented to the inspector at the port of arrival and the port of export in the United States.

(Approved by the Office of Management and Budget under control numbers 0579–0015 and 0579–0183)

[66 FR 42600, Aug. 14, 2001, as amended at 70 FR 552, Jan. 4, 2005; 70 FR 12113, Mar. 11, 2005; 70 FR 71218, Nov. 28, 2005; 71 FR 12998, Mar. 14, 2006; 72 FR 53378, Sept. 18, 2007; 73 FR 3384, Jan. 18, 2008]