

proceeding and who is in lawful K-3 or K-4 status shall not be deemed an abandonment of the application if, upon returning to this country, the alien is in possession of a valid K-3 or K-4 visa and remains eligible for K-3 or K-4 status.

\* \* \* \* \*

14. Section 245.5 is amended by revising the second sentence to read as follows:

**§ 245.5 Medical examination.**

\* \* \* A medical examination shall not be required of an applicant for adjustment of status who entered the United States as a nonimmigrant spouse, fiancé, or fiancée of a United States citizen or the child of such an alien as defined in section 101(a)(15)(K) of the Act and § 214.2(k) of this chapter if the applicant was medically examined prior to, and as a condition of, the issuance of the nonimmigrant visa; provided that the medical examination must have occurred not more than 1 year prior the date of application for adjustment of status. \* \* \*

**PART 248—CHANGE OF NONIMMIGRANT STATUS**

15. The authority citation for part 248 continues to read as follows:

**Authority:** 8 U.S.C. 1101, 1103, 1184, 1187; 1258; 8 CFR part 2.

**§ 248.1 [Amended]**

16. Section 248.1(a) is amended by:

a. Revising the phrase "his nonimmigrant" to read "his or her nonimmigrant" wherever that term appears in the paragraph; and by

b. Revising the phrase "that of a fiancé" or fiancé to read "that of a spouse or fiancé(e), or the child of such alien."

**PART 274a—CONTROL OF EMPLOYMENT OF ALIENS**

17. The authority citation for part 274a is revised to read as follows:

**Authority:** 8 U.S.C. 1101, 1103, 1324a; 8 CFR part 2.

18. Section 274a.12(a) is amended by:

a. Revising paragraph (a) heading, and paragraph (a) introductory text;

b. Revising paragraph (a)(6);

c. Adding a new paragraph (a)(9).

The revisions and additions read as follows:

**§ 274a.12 Classes of aliens authorized to accept employment.**

(a) *Aliens authorized incident to status.* Pursuant to the statutory or regulatory reference cited, the following classes of aliens are authorized to be

employed in the United States without restrictions as to location or type of employment as a condition of their admission or subsequent change to one of the indicated classes. Any alien who is within a class of aliens described in paragraphs (a)(3) through (a)(13) of this section, and who seeks to be employed in the United States, must apply with the Service for a document evidencing such employment authorization.

\* \* \* \* \*

(6) An alien admitted to the United States as a nonimmigrant fiancé or fiancée pursuant to section 101(a)(15)(K)(i) of the Act, or an alien admitted as a child of such alien, for the period of admission in that status, as evidenced by an employment authorization document issued by the Service;

\* \* \* \* \*

(9) Any alien admitted as a nonimmigrant spouse pursuant to section 101(a)(15)(K)(ii) of the Act, or an alien admitted as a child of such alien, for the period of admission in that status, as evidenced by an employment authorization document, with an expiration date issued by the Service;

\* \* \* \* \*

Dated: August 2, 2001.

**Kevin D. Rooney,**

*Acting Commissioner, Immigration and Naturalization Service.*

[FR Doc. 01-20302 Filed 8-13-01; 8:45 am]

**BILLING CODE 4410-10-M**

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**9 CFR Parts 94 and 95**

[Docket No. 00-121-1]

RIN 0579-AB26

**Importation Prohibitions Because of Bovine Spongiform Encephalopathy**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule and request for comments.

**SUMMARY:** We are amending the regulations to prohibit, with limited exceptions, the importation of certain animal materials and their derivatives, and any products they are used in, from regions considered to present an unacceptable risk of introducing bovine spongiform encephalopathy into the United States. Additionally, we are requiring that those materials, when imported from regions not considered at

risk for bovine spongiform encephalopathy, be accompanied by government certification regarding the species, region of origin, processing, and handling of the materials and the animals from which they were derived. These actions are necessary to ensure that materials containing the bovine spongiform encephalopathy agent are not imported into the United States.

**DATES:** This rule is effective retroactively to December 7, 2000, except for § 95.29, which is effective August 14, 2001. We invite you to comment on this docket. We will consider all comments that we receive by October 15, 2001.

**ADDRESSES:** Please send four copies of your comment (an original and three copies) to: Docket No. 00-121-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737-1238

Please state that your comment refers to Docket No. 00-121-1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Donna Malloy, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road, Riverdale, MD 20737-1231; (301) 734-3277.

**SUPPLEMENTARY INFORMATION:**

**Background**

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of bovine animals and possibly other ruminants and is not known to exist in the United States.

It appears that BSE is primarily spread through the use of ruminant feed containing certain protein products from ruminants infected with BSE. Currently, the U.S. Food and Drug Administration (FDA) regulations at 21 CFR 589.2000 prohibit the feeding of protein products that contain or may contain certain protein derived from mammalian tissues to cattle and other ruminants. However, BSE could be introduced into the United States if foreign-source protein materials carrying the BSE agent, such as meat, animal products, animal byproducts, and related materials are imported into the United States from regions where BSE exists, or from regions that present an undue risk of introducing BSE into the United States, and are ingested by cattle or other ruminants in the United States. BSE could also be introduced into the United States if ruminants from regions where BSE exists, or ruminants from regions that present an undue risk of introducing BSE into the United States, are imported into the United States.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions where BSE exists or regions that present an undue risk of introducing BSE into the United States.

In § 94.18, paragraph (a)(1) contains a list of regions where BSE exists, while paragraph (a)(2) contains a list of regions that, because of import requirements less restrictive than those that would be acceptable for importation into the United States and/or because of inadequate surveillance, present an undue risk of introducing BSE into the United States. Together, the lists in § 94.18(a)(1) and (a)(2) consist of all the countries of Europe and the country of Oman.

Section 94.18 also prohibits the importation into the United States of certain products. Specifically, § 94.18(b) prohibits the importation of fresh (chilled or frozen) meat, meat products, and edible products other than meat (excluding milk and milk products and, under certain conditions, gelatin) from ruminants that have been in any of the regions listed in § 94.18(a).

Section 95.4(a) of the regulations prohibits the importation of certain other products because of BSE. These products include—with certain exceptions for materials used in cosmetics and for materials transiting the United States for immediate export—bone meal, blood meal, meat meal, tankage, offal, fat, and glands from ruminants that have been in any region

listed in § 94.18(a). In this interim rule, we are adding materials to the list of prohibited products in § 95.4(a). These amendments to the list in § 95.4(a) are effective retroactively to December 7, 2000.

#### Additions to List of Prohibited Items

With limited exceptions described below, the importation of the following materials, if derived from an animal that has been in any region listed in § 94.18(a), is prohibited:

1. Processed animal protein, offal, tankage, processed fats and oils, and tallow other than tallow derivatives, unless, in the opinion of the Administrator of the Animal and Plant Health Inspection Service (APHIS), the tallow cannot be used in feed, regardless of the animal species from which such materials are derived; and glands and unprocessed fat tissue derived from ruminants.
2. Derivatives of processed animal protein, offal, and tankage, regardless of the species of origin; processed fats and oils, regardless of the species of origin; and derivatives of glands from ruminants.
3. Products containing any of the materials included in items 1 or 2 above.

Additionally, we are prohibiting the importation of any of the types of materials included in items 1, 2, and 3 above, if the material:

- Originates in, or is stored, rendered, or otherwise processed in, a region listed in § 94.18(a) as a region where BSE exists or that presents an undue risk of introducing BSE into the United States;
- Is otherwise associated with a facility located in a region listed in § 94.18(a); or
- Is otherwise associated with any of the materials included in items 1, 2, or 3 above that have been in a region listed in § 94.18(a).

As noted above, the only regions currently listed in § 94.18(a) are Oman and the countries of Europe.

In this interim rule, we have also added a definition of *processed animal protein* to § 95.1. We have defined that term to mean meat meal, bone meal, meat and bone meal, blood meal, dried plasma and other blood products, hydrolyzed proteins, poultry meal, feather meal, fish meal, and any other similar products.

#### Reasons for Additional Prohibitions

We consider it necessary to expand the importation prohibitions in § 95.4(a) to include certain products derived from animals other than ruminants because of the possibility that those products may

have been cross-contaminated by products derived from ruminants.

A ban on the feeding of ruminant products to other ruminants was enacted in the United Kingdom in 1988 and in certain other European countries in the early 1990's. A ban on the feeding of all mammalian products to ruminants was enacted in the European Union (EU) in 1994. However, several EU countries have identified cases of BSE in animals born after these bans were imposed. This has led to the conclusion among experts studying these cases that feed that was not prohibited by the bans was cross-contaminated by feed of ruminant origin. It appears likely that such cross-contamination occurred at facilities that process both prohibited and nonprohibited products.

Opinions issued in July and November 2000 by the European Commission's (EC's) Scientific Steering Committee stated that such cross-contamination has prolonged the BSE epidemic in Europe. In December 2000, the EC announced a temporary prohibition on the feeding of processed animal protein to all farmed animals. This prohibition became effective on January 1, 2001.

Because of the possibility that animal-based feeds or other processed animal proteins have been cross-contaminated by ruminant material, we have established (effective as of December 7, 2000) the prohibitions set forth in this interim rule to prohibit, with certain limited exceptions, the importation of the products described above under the heading "Additions to List of Prohibited Items." We are taking this action on an emergency basis to help ensure that the BSE agent is not introduced into the United States. If, as further information becomes available to us, we determine that any of the prohibited products can be brought into the United States without risk of introducing the BSE agent into this country, we will initiate rulemaking to amend the regulations to allow the importation of those products, along with any conditions necessary to reduce the disease risk associated with such importations to a negligible level.

#### Tallow

Prior to this interim rule, the regulations in § 95.4 prohibited the importation of fat from ruminants that have been in any region listed in § 94.18(a). We are clarifying in this interim rule that tallow—which, according to standard dictionary definition, is rendered fat—is included among the materials to which the prohibitions of § 95.4 apply. However, we are excluding tallow derivatives from this prohibition, because such

products are so highly processed that it is highly unlikely they contain any protein. Further, we are not prohibiting all tallow, but only that tallow that is in a form that can be incorporated into feed, such as, but not limited to, bulk tallow. Generally, tallow is used for many industrial purposes, such as in soaps, candles, and lubricants for industrial equipment. These products would pose no risk of infecting animals in the United States with the BSE agent, and tallow in such forms will not be prohibited importation into the United States. However, we consider it necessary to prohibit the tallow if it could be used in feed of any type, because of the risk that tallow used in feed for animals other than ruminants might be diverted for use as ruminant feed.

#### **Fat Tissue and Glands**

The prohibitions in this interim rule regarding the importation of glands and unprocessed fat tissue apply only if such materials are derived from ruminants; they do not apply to glands and unprocessed fat tissue derived from any other animal species. We do not consider it necessary to prohibit the importation of glands and unprocessed fat tissue from animal species other than ruminants because those articles are, by standard collection methods, not combined with any other materials. However, the prohibitions in this rule do apply to fat from any animal species if the fat has been processed in any way, because processed fat from various species may be commingled with or cross-contaminated by processed fat from ruminants.

#### **Exceptions for Materials From Certain Facilities**

With certain exceptions discussed in this supplementary information, we are applying the prohibitions contained in § 95.4 to materials derived from all animal species because of the risk the materials could become cross-contaminated by materials derived from ruminants. However, in certain situations, we consider there to be a negligible risk that materials that would otherwise be prohibited importation by this interim rule will be cross-contaminated by materials derived from ruminants. In those situations, we do not consider it necessary to prohibit the importation of such materials.

Specifically, the importation prohibition will not apply to materials if, prior to importation, the following conditions have been met:

1. The materials are 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 the regulations.

2. All steps of processing and storing the material are carried out in a foreign 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 the regulations.

3. The facility has demonstrated 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.

4. If the facility processes or handles any materials derived from mammals, the facility has entered into a cooperative service agreement executed by the operator of the facility and APHIS. Under that cooperative service agreement, the facility is current in paying all costs for a veterinarian of APHIS to inspect the facility (we anticipate that such inspections will occur approximately once per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including excess baggage provisions of up to 150 pounds). Additionally, the facility has 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.

5. The foreign facility allows periodic APHIS inspection of its facilities, records, and operations.

6. 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 conditions 1, 2, and 3, above, have been met.

7. 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>.)

#### **Materials Used for Cosmetics and Insulin for Personal Use**

Animal-derived materials that are used for cosmetics will continue to be allowed importation into the United States under the existing conditions in § 94.5, because such use should not allow the materials to come into contact with animals. For the same reason, we are adding a new § 95.4(e), so as not to prohibit under § 95.4(a) the importation of insulin for the personal medical use of the person importing it (i.e., small quantities of ready-to-administer insulin). (Please note: We have determined that insulin for personal medical use that is imported in accordance with the regulations should not pose a risk to livestock. This does not imply endorsement of the safety of such insulin for human use. Further, importation of insulin for personal medical use may be prohibited by other Federal laws, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, which is administered by the FDA.) A permit will continue to be required for the importation of materials to be used for cosmetics, and will also be required for the importation of insulin for personal medical use.

#### **Certification Requirements**

We are also adding a new § 95.29 to help ensure that products that are prohibited from being imported into the United States under § 95.4(a) due to their origin are not moved to a country not listed in § 94.18(a) and then to the United States. We are providing in new § 95.29 that each shipment of the following material from any region not listed in § 94.18(a) must be accompanied by an original certificate signed by a full-time salaried veterinarian of the agency responsible for animal health in the exporting region:

1. Processed animal protein, offal, tankage, processed fats and oils, 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 such materials are derived; and glands and unprocessed fat tissue derived from ruminants.

2. Derivatives of processed animal protein, offal, and tankage, regardless of the animal species from which the material is derived; and derivatives of glands from ruminants.

3. Products containing any of the materials included in items 1 or 2 above.

The certification would have to include the following information:

- The animal species from which the material was derived;

- The region where any facility in which the material was processed is located;
- That the material was derived only from animals that have never been in any region listed in § 94.18(a);
- That the material did not originate in, and was never stored, rendered, or otherwise processed in, a region listed in § 94.18(a);
- That the material was not otherwise associated with a facility located in a region listed in § 94.18(a), or with any materials included in items 1, 2, or 3, above, that have been in a region listed in § 94.18(a).

As part of our ongoing efforts to ensure that the BSE agent is not introduced into the United States, we are in the process of obtaining data from each of our trading partners regarding all of the factors that could contribute to the risk that a country or other region might contain animals or products contaminated with the BSE agent. If this information demonstrates that a particular country or region poses an unacceptable risk of introducing BSE into the United States, we will take action to restrict or prohibit animals and animal products from that country or region.

Among the requirements that might be considered for imports would be certification by the exporting country that ruminant material imported into the United States comes from ruminants that have never been fed ruminant material from BSE-affected regions. At this time, evidence does not exist to indicate that countries from which imports are currently not restricted due to BSE pose enough of a risk to make such a certification requirement an effective or justifiable mitigation measure for exports from these countries. However, as part of our ongoing BSE-prevention program, we welcome comment from the public on the need for or effectiveness of such measures, as well as on any other issues related to mitigating the risk of the introduction of the BSE agent into the United States.

#### **Nonsubstantive Changes**

We are making a nonsubstantive change to the definition of *Animal and Plant Health Inspection Service* in § 95.1 to indicate that the acronym “APHIS” can be used in the regulations in place of the full name of the agency.

Additionally, we are clarifying in § 94.18(b) that the term “fresh meat” as used in that paragraph means chilled or frozen meat. This clarification makes the wording in § 94.18(b) consistent with the wording used elsewhere in part 94.

#### **Emergency Action**

This rulemaking is necessary on an emergency basis to ensure that materials that contain the BSE agent are not imported into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**. We are making this action effective retroactively to December 7, 2000, except for the certification requirement of § 95.29, which is effective upon publication. December 7, 2000, is the date APHIS issued a policy stating it had stopped issuing import permits for, and would prohibit the importation of, the materials covered by this interim rule. These effective dates are necessary to ensure that animal products containing the BSE agent are not imported into the United States.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We are amending the regulations to prohibit, with limited exceptions, the importation into the United States of certain animal materials and their derivatives, and any products they are used in, if, because of origin, processing, or other handling, the item intended for importation presents an unacceptable risk of containing the BSE agent. The types of prohibited materials include: Processed animal protein (including poultry meal and fish meal), offal, tankage, processed fats and oils, and tallow (other than tallow derivatives), unless the tallow cannot be used in feed, regardless of the animal species from which such materials are derived; and glands and unprocessed fat tissue derived from ruminants.

The following economic analysis provides a cost-benefit analysis as required by Executive Order 12866 and an analysis of the potential economic

effects on small entities as required by the Regulatory Flexibility Act.

As one major exception to the prohibitions imposed by this rule, we will allow the importation of materials derived from nonruminant species, or from ruminant species if the ruminants have never been in any region listed in § 94.18(a) of the regulations, if all steps of processing and storing the material are carried out in a foreign 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 the regulations.

Additionally, we are requiring that such materials imported from regions other than those in which BSE exists or that present an undue risk of introducing BSE into the United States be accompanied by government certification regarding the animal species of origin, processing, handling, and region of origin of the animals from which the materials were derived.

Information on import levels is more readily available for some materials affected by this rule than for others. Our discussion of potential imports is based on data for the principal commodity categories expected to be affected. Additionally, we identify other potentially affected commodity categories.

The principal commodity categories of prohibited items for which an assessment of imports from Europe is possible (none of these categories of commodities is imported from Oman) are the following: Powder and waste of bones; lard and other fat; flours, meals, and pellets containing meat or meat offal; flours, meals, and pellets containing fish or crustaceans; dog or cat food; and animal feed preparations other than dog or cat food. For each of these commodity categories except animal feed preparations other than dog or cat food, the percentage of U.S. imports supplied by Europe is minor—about 1 percent or less for lard and for flours, meals, and pellets made of meat or meat offal, and of fish or crustaceans; about 6 percent for powder and waste of bones and for dog or cat food. The average annual value, from 1997 to 1999, of animal feed preparations other than dog or cat food that were supplied by Europe was about \$49 million, and represented about 22 percent of such imports.

About 18 percent of animal feed preparations imported by the United States, by value, is composed of prepared poultry and swine feed. These types of feed comprise about one-third of the animal feed preparations imported from Europe. (Other products used in animal feed preparations

include egg, milk, or vegetable products.)

The United States is a net exporter of all of the above categories of commodities. For dog or cat food and for animal feed preparations other than dog or cat food—the two categories with the highest import volumes—annual import values were about 22 and 40 percent of export values, respectively.

The relatively small value of dog or cat food and of other animal feed preparations imported from Europe is apparent when compared to the value of annual U.S. exports of these products. Imports from Europe comprise only about 0.1 percent of the value of U.S. exports of dog or cat food. For other animal feed preparations, imports from Europe are less than 0.3 percent of the value of U.S. exports.

In addition to the principal commodity categories discussed above, it is possible there will be other items whose importation will be prohibited by this interim rule, such as certain other animal fat products and certain animal-derived substances used in medicament preparations. We are unable to identify affected products under these headings, nor the value of any such products supplied by Europe.

The Regulatory Flexibility Act requires that agencies assess the potential economic effects of rules on small entities. Whether affected entities within a particular industry are considered small by the U.S. Small Business Association depends either on the number of employees or annual gross receipts. Two industries that will likely be affected are “dog and cat food manufacturing” and “other animal food manufacturing,” for both of which the criterion for being considered a small entity is whether the establishment has 500 or fewer employees. The 1997 “Economic Census” reports that 186 of the 188 dog and cat food manufacturing establishments in the United States had 500 or fewer employees, and that all of the 1,514 establishments categorized as “other animal food manufacturing establishments” had 500 or fewer employees.

Other entities that may be affected by this rule are livestock producers who use nonruminant animal feed preparations that have been imported from Europe. U.S. dairy, beef, and hog producers are predominantly small entities, based on the criterion of having annual gross receipts of \$500,000 or less. Cattle feedlot operations that could also be affected are predominantly small entities, based on the criterion of having annual gross receipts of \$1.5 million or less.

Although manufacturing establishments and agricultural firms that could be affected by this rule are predominantly small entities, the fact that very small volumes of the items prohibited under this interim rule are imported from Europe suggests that any effects will be similarly small. For manufacturers of dog or cat food and other animal feed preparations, imports from Europe are but a fraction of 1 percent of industry sales. Nonruminant lard imports and imports of animal feed preparations from Europe are also small compared to overall import levels. Additionally, although we are unable to assess at this time the possible effects of the provisions in this interim rule with regard to certain exceptions to the general prohibitions (e.g., for nonmammalian materials processed in a plant dedicated to processing only nonmammalian animal species), they can be expected to reduce any economic effects of this rule even further.

For the commodities examined, some U.S. small entities are likely to be affected by this rule. However, the volumes imported from Europe suggest that a substantial number of entities will not be affected, and that those that are will not be affected significantly.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### **Executive Order 12988**

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effect to December 7, 2000; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### **Paperwork Reduction Act**

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0579–0183 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC

20503; and (2) Docket No. 00–121–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 00–121–1 and send your comments within 60 days of publication of this rule.

This interim rule prohibits the importation of certain animal materials into the United States because of the risk of the introduction of BSE into this country. Additionally, it requires that certain animal materials imported into the United States be accompanied by certification by the veterinary authorities of the national government of the country from which the materials are shipped regarding the origin and processing of the products. We are soliciting comments from the public, as well as affected agencies, concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency’s functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 10 minutes per response.

*Respondents:* Producers and importers of certain animal products.

*Estimated annual number of respondents:* 1,000.

*Estimated annual number of responses per respondent:* 9.

*Estimated annual number of responses:* 9,000.

*Estimated total annual burden on respondents:* 1,500 hours.

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS’ Information Collection Coordinator, at (301) 734–7477.

#### **List of Subjects**

9 CFR Part 94

Animal diseases, Imports, Livestock, Poultry and poultry products,

Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

Accordingly, we are amending 9 CFR parts 94 and 95 as follows:

**PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY; PROHIBITED AND RESTRICTED IMPORTATIONS**

1. The authority citation for part 94 continues to read as follows:

**Authority:** 7 U.S.C. 450, 7711, 7712, 7713, 7714, 7751, and 7754; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

**§ 94.18 [Amended]**

2. In § 94.18, paragraph (b) is amended by removing the words “fresh, frozen, and chilled” and adding in their place the words “fresh (chilled or frozen)”.

**PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES**

3. The authority citation for part 95 continues to read as follows:

**Authority:** 21 U.S.C. 111, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

4. In § 95.1, the definition of *Animal and Plant Health Inspection Service* is revised and a new definition of *processed animal protein* is added, in alphabetical order, to read as follows:

**§ 95.1 Definitions.**

\* \* \* \* \*

*Animal and Plant Health Inspection Service (APHIS)* means the Animal and Plant Health Inspection Service of the United States Department of Agriculture.

\* \* \* \* \*

*Processed animal protein* means meat meal, bone meal, meat and bone meal, blood meal, dried plasma and other blood products, hydrolyzed proteins, hoof meal, horn meal, poultry meal, feather meal, fish meal, and any other similar products.

\* \* \* \* \*

5. Section 95.4 is revised to read as follow:

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

(a) Except as provided in paragraphs (c) through (f) 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 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.

(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 listed in paragraphs (a)(1) and (a)(2) of this section.

(b) Except as provided in paragraphs (d) and (f) 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) All steps of processing and storing the material are carried out in a foreign 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 chapter.

(3) 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.

(4) 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.

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

(6) 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)(3) of this section have been met.

(7) 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) 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 of 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) 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:** 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.*

(f) Articles that are prohibited importation into the United States in accordance with this section may transit the United States for immediate export if the following conditions 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 Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the port of export prior to such transit. The notification includes the:

(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 transit the United States in Customs bond.

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

6. A new § 95.29 is added to read as follows:

**§ 95.29 Certification for certain materials.**

(a) In addition to meeting any other certification or permit requirements of this chapter, the following articles may be imported into the United States from any region not listed in § 94.18(a) only if they are accompanied by a certificate, as described in paragraph (b) of this section:

(1) 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 is derived;

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

(3) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal, regardless of the

animal species from which the material is derived;

(4) Derivatives of glands from ruminants; and

(5) Any product containing any of the materials listed in paragraphs (a)(1) through (a)(4) of this section.

(b) The certificate required by paragraph (a) of this section must be an original official certificate, signed by a full-time, salaried veterinarian of the agency responsible for animal health in the exporting region, that states the following:

(1) The animal species from which the material was derived;

(2) The region in which any facility where the material was processed is located;

(3) That the material was derived only from animals that have never been in any region listed in § 94.18(a) of this chapter, with the regions listed in § 94.18(a) specifically named;

(4) That the material did not originate in, and was never stored in, rendered or processed in, or otherwise associated with a facility in a region listed in § 94.18(a); and

(5) The material was never associated with any of the materials listed in paragraph (a) of this section that have been in a region listed in § 94.18(a).

(c) The certification required by paragraph (a) of this section must clearly correspond to the shipment by means of an invoice number, shipping marks, lot number, or other method of identification.

(Approved by the Office of Management and Budget under control number 0579-0183)

Done in Washington, DC, this 8th day of August 2001.

**Bill Hawks,**

*Under Secretary for Marketing and Regulatory Programs.*

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BILLING CODE 3410-34-P

**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 117**

[CGD01-01-125]

**Drawbridge Operation Regulations: Piscataqua River, ME**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Sara Long (Route 1