DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 92, 93, 94, 95, 96, and 98

[Docket No. APHIS–2008–0010]

RIN 0579–AC68

Bovine Spongiform Encephalopathy; Importation of Bovines and Bovine Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations that govern the importation of animals and animal products to revise the conditions for the importation of live bovines and products derived from bovines with regard to bovine spongiform encephalopathy (BSE). We are basing importation conditions on the inherent risk of BSE infectivity in specified commodities, as well as on the BSE risk status of the region in which the commodities originate. We are establishing a system for classifying regions as to BSE risk that is consistent with the system employed by the World Organization for Animal Health (OIE), the international standard-setting organization for guidelines related to animal health. The conditions we are adopting for the importation of specified commodities are based on internationally accepted scientific literature, and are, in general, consistent with guidelines set out in the OIE's Terrestrial Animal Health Code. We are also classifying certain specified countries as to BSE risk and are removing BSE restrictions on the importation of cervids and camelids and products derived from such animals. We are making these amendments after conducting a thorough review of relevant scientific literature and a comprehensive evaluation of the issues and concluding that the changes to the regulations will continue to guard against the introduction of BSE into the United States, while allowing the importation of additional animals and animal products into this country.

DATES: This rule is effective March 4, 2014. The incorporation by reference of the material described in the rule is approved by the Director of the Federal Register as of March 4, 2014.

FOR FURTHER INFORMATION CONTACT: For information concerning live ruminants, contact Dr. Betzaida Lopez, Import Animal Staff Veterinarian, Technical Trade Services, Animals, Organisms and Vectors, and Select Agents, National Center for Import and Export, VS, APHIS, 4700 River Road, Unit 39, Riverdale, MD 20737–1231; 301–851–3300.

For information regarding ruminant products and for other information regarding this rule, contact Dr. Christopher Robinson, Assistant Director, Technical Trade Services, Animal Products, National Center for Import and Export, VS, APHIS, 4700 River Road, Unit 38, Riverdale, MD 20737–1231; 301–851–3300.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Need for the Regulatory Action

The conditions we are adopting for the importation of specified bovine commodities are based on internationally accepted scientific literature and are, in general, consistent with World Organization for Animal Health (OIE) guidelines. We are making these amendments after conducting a thorough review of relevant scientific literature and a comprehensive evaluation of the issues and concluding that the changes we are making to the regulations will continue to guard against the introduction of bovine spongiform encephalopathy (BSE) into the United States, while allowing the importation of additional animals and animal products into this country.

The OIE recognizes three classifications of countries for BSE: Negligible risk, controlled risk, and undetermined risk. The OIE guidelines recommend that countries allow trade in certain bovine commodities from all three classifications under conditions commensurate with their BSE risk. This final rule generally aligns U.S. regulations with the OIE guidelines and demonstrates to the international community the commitment of the United States to base its BSE regulations on internationally accepted scientific literature.

Legal Authority for the Regulatory Action

Under the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture has the authority to issue orders and promulgate regulations to prevent the introduction into the United States and the dissemination within the United States of any pest or disease of livestock. The Animal and Plant Health Inspection Service's (APHIS') regulations in title 9 of the Code of Federal Regulations, subchapter D, govern the exportation and importation of animals (including poultry) and animal products from and into the United States.

Summary of the Major Provisions of the Regulatory Action

The current regulations prohibit the importation of live ruminants and most ruminant products from regions that have BSE or that present an undue risk for BSE. The regulations are less restrictive for ruminants and ruminant products from BSE minimal-risk regions (currently only Canada). Additionally, the regulations allow the importation of boneless beef from Japan even though Japan is listed as a region that has BSE. We are replacing the current BSE regulations that apply to bovines (cattle and bison) with import conditions based on the inherent risk of BSE infectivity in specified commodities, as well as on the BSE risk status of the region in which the commodities originate. We are establishing a system for classifying regions as to BSE risk that is consistent with the system employed by the OIE, the international standard-setting organization for guidelines related to animal health. We are also classifying certain specified countries as to BSE risk. We are also removing BSE restrictions on the importation of cervids and camelids and products derived from such animals.

Costs and Benefits

Consumers benefit from imports to the extent that consumer choice is broadened and the increased supply of the imported commodity leads to a price decline. We anticipate that the rule will have little impact on consumer choice or import volumes, and therefore little or no impact on U.S. businesses as well. Although the impact of this rule on U.S. consumers and producers is expected to be minimal, the benefits of the rule are expected to justify its costs.

II. Background

In order to guard against the introduction and spread of animal diseases, APHIS, an agency of the U.S. Department of Agriculture (USDA or Department), regulates the importation of animals and animal products into the United States. The regulations in 9 CFR parts 92, 93, 94, 95, 96, and 98 (referred to below as the regulations) govern the importation of certain animals, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases.

On March 16, 2012, we published in the **Federal Register** (77 FR 15848–15913, Docket No. APHIS–2008–0010) a proposal [1] to amend the regulations that

[1] To view the proposed rule, supporting documents, and the comments we received, go to

govern the importation of animals and animal products to revise the conditions for the importation of live bovines and products derived from bovines with regard to BSE. Specifically, we proposed to base our importation conditions on the inherent risk of BSE infectivity in specified commodities, as well as the BSE risk status of the region in which the commodities originate, consistent with the OIE's Terrestrial Animal Health Code. We proposed to establish a system for classifying regions as to BSE risk that is consistent with the system employed by the OIE. The conditions we proposed for the importation of specified commodities are based on internationally accepted scientific literature and, are, in general, consistent with the guidelines set out in the OIE's Terrestrial Animal Health Code. We also proposed to classify certain specified countries as to BSE risk and proposed to remove BSE restrictions on the importation of cervids and camelids and products derived from such animals.

In the same document we also affirmed the position we took in removing the delay of applicability of certain provisions of the rule titled ''Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities,'' published in the **Federal Register** on January 4, 2005 (70 FR 460–553, Docket No. 03–080–3). The delay of applicability was removed in a final rule titled ''Bovine Spongiform Encephalopathy; Minimal Risk Regions; Importation of Live Bovines and Products Derived from Bovines,'' published in the **Federal Register** on September 18, 2007 (72 FR 53314–53379, Docket No. APHIS–2006–0041). However, as ordered by the U.S. District Court on July 3, 2008, APHIS provided additional opportunity for public comment on this action in a notice published in the **Federal Register** on September 18, 2008 (73 FR 54083–54089, Docket No. APHIS–2008–0093). We responded to comments received on that notice in our March 2012 proposed rule.

We solicited comments concerning our proposal for 60 days ending May 15, 2012. We reopened and extended the deadline for comments until June 14, 2012, in a document published in the **Federal Register** on May 21, 2012 (77 FR 29914, Docket No. APHIS–2008–0010). We received 60 comments by that date. They were from private citizens, domestic and foreign industry associations, importers, exporters, and representatives of State and foreign governments. The commenters raised a number of questions and concerns about the proposed rule. These comments and concerns are discussed below by topic.

General Concerns

One commenter stated that APHIS did not give appropriate consideration to, and in some cases did not address at all, some of the concerns raised by the public on the notice requesting comment on the delay of applicability of certain provisions of the rule titled ''BSE; Minimal-Risk Regions and Importation of Meat, Meat Byproducts, and Meat Food Products Derived from Bovines 30 Months of Age or Older'' (the OTM [i.e., over 30 months] rule) (73 FR 54083–54089, Docket No. APHIS–2008–0093).

APHIS disagrees. In the proposed rule, we responded to comments on our removal of the delay of applicability of provisions of our January 2005 final rule. We are confident that we responded to all the comments.

The commenter stated that in the September 2008 request for comments, APHIS mischaracterized its document published in the **Federal Register** on March 8, 2004 (69 FR 10633–10636, Docket No. 03–080–2), as proposing to allow the importation from BSE minimal-risk regions of beef derived from cattle of any age. The March 2004 document reopened a comment period for a proposed rule published on November 4, 2003 (68 FR 62386–62405, Docket No. 03–080–1) and invited public comment on changing that proposed rule to allow the importation of beef from bovines 30 months of age and older based on new requirements issued by USDA's Food Safety and Inspection Service (FSIS). The commenter stated that the March 2004 document contained no reference to the importation of beef from cattle of any age and instead continued to propose a restriction on the age of cattle by retaining the requirement contained in the November 2003 proposed rule that the beef be derived from animals that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.

When we stated in our September 2008 request for comments that our March 2004 document proposed to allow the importation of beef derived from cattle of any age, we meant that the derivation of beef from bovines 30 months of age or older when slaughtered would not in itself preclude the commodities from being imported. We stated further that we were not referring to any effect the feed ban requirement might have on the import eligibility of the commodities.

The terminology regarding ''cattle of any age'' that we used in our September 2008 request for comments was consistent with that which we used in the risk analysis for our January 2005 final rule. The commenter stated that this terminology was not consistent with the risk assessment which supported the January 2005 final rule.

We note that the risk analysis that accompanied the January 2005 final rule stated: ''It is important to note the following change in the final rule. In its proposed rule, APHIS restricted beef imported from Canada to meat derived from cattle under 30 months of age. This requirement has been removed in the final rule, and beef from animals of any age will be allowed to be imported from a Minimal Risk region.'' In the January 2005 final rule, we explained that we did not believe this requirement was necessary, provided that measures equivalent to those of FSIS regarding specified risk material (SRM) removal are in place in the exporting region and other such measures as are necessary (e.g., a prohibition on the use of air injection stunning devices and controls to prevent cross-contamination) are in place. We believe that this clearly lays out the intent that APHIS did not apply any specific age limitation to the import of beef.

One commenter stated that, despite the fact that APHIS stated in the proposed rule that it is not necessary to revise any provisions in the OTM rule, the proposed rule makes substantive revisions to the OTM rule, including revisions to the provisions that APHIS stated were essential to its affirmation of the OTM rule.

The commenter is correct in noting that this rule revises the existing regulations, including the existing regulations that addressed the importation of animals and products from BSE minimal risk regions. As described in the proposed rule, APHIS noted that the existing regulations contain provisions that are not yet fully consistent with the latest scientific literature. APHIS regulations have changed over time, as we gain increased understanding of the science of BSE and conduct further risk assessments. The changes we proposed reflected internationally accepted scientific literature and, in general, are consistent with the OIE Code.

We assume that the commenter is referring to the specific issue of whether or not certification about a feed ban is necessary in the conditions for beef imports. APHIS initially imposed such a certification requirement, noted in both the 2003 proposed rule and the January 2005 final rule. This

http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0010.

requirement was not amended in our 2007 final rule when we lifted the delay of applicability on certain imports from Canada. In contrast, our regulations for the importation of boneless beef from Japan do not include any certification about the feeding practices for the animals from which the beef was derived. In both instances, however, we considered the significant overall risk reduction achieved in each country by their respective feed bans. Such feed bans decrease the overall prevalence of BSE and therefore reduce the risk that any individual animal may be exposed to potentially infected feed. They continue to be a crucial risk mitigation measure that is considered in any overall risk assessment for BSE. However, since they are crucial to the consideration of the overall status of the country, requiring specific certification to that effect for individual animals from which meat for export is derived is redundant. The feed ban requirement is covered in that consideration of the country's BSE risk. Therefore, in line with OIE recommendations, we did not include that specific certification statement in the proposed requirements for beef imports from controlled risk regions. Such certification is, however, required for beef imports from undetermined risk regions. For these regions, either no information is available about any feed ban requirements or other risk mitigation measures, or they have not maintained the relevant risk mitigation measures sufficient to meet the standards for controlled or negligible risk. Therefore, we cannot rely on the overall country evaluation to ensure that a feed ban is in place and will require certification that the animals from which the meat was derived were never fed meat-and-bone meal or greaves derived from ruminants. These requirements are consistent with our risk assessments that demonstrate that an effective feed ban is a critical risk mitigation measure that must be in place in regions that have a potential risk of BSE.

One commenter stated that the OIE Code is not universally recognized as the international standard for BSE prevention, mitigation, and surveillance. The commenter noted that some countries, such as Japan and Australia, have established their own standards, which are stricter than those of the OIE. The commenter stated that APHIS should provide better justification for adopting OIE standards.

As we explained in the proposed rule, the World Trade Organization recognizes the OIE as the international forum for setting animal health standards, reporting global animal disease events, and presenting guidelines and recommendations on sanitary measures relating to animal health. As an OIE Member country, the United States reviews and, where appropriate, comments on all draft OIE chapters and revisions. As part of the United States' consideration of OIE drafts, APHIS distributes these drafts to the U.S. livestock and aquaculture industries, veterinary experts in various U.S. academic institutions, and other interested persons for review and comment. Furthermore, the United States, represented by APHIS, has been actively involved in the development of the OIE Code and fully supports the OIE position that gradations in BSE risk among regions should be recognized and that trade should be commensurate with risk.

One commenter stated that surveillance for BSE in the United States is inadequate. The commenter stated that U.S. surveillance has decreased 90 percent since 2005, and that the United States only tests cattle showing symptoms of BSE. The commenter stated that all cattle should be tested for BSE at slaughter and that such testing would not be prohibitively expensive.

APHIS disagrees with the commenter. BSE surveillance programs in the United States focus on obtaining quality samples from targeted subpopulations rather than looking at the entire adult cattle population. Targeted animals are cattle older than 30 months of age that exhibit signs of central nervous disorders or any other signs associated with BSE, such as emaciation or injury. Dead cattle and non-ambulatory cattle are also targeted. The experience in the United Kingdom (UK) has shown that those populations are most likely to test positive for BSE in the event that the animals were exposed to the agent and lived long enough to develop the disease. We note that surveillance is not a BSE mitigation; that is, it does not provide a level of protection against the disease. It only allows us to understand disease trends such as prevalence and evolution of the disease, and to evaluate the effectiveness of risk mitigation measures. The removal of SRMs and the ruminant-to-ruminant feed ban are the primary safeguards to human and animal health.

One commenter stated that the proposed testing rates are too low. The commenter asked how a region can be considered negligible risk if only a small percentage of cattle are tested for BSE.

Surveillance is only one part of the evaluation. A region applying for negligible risk status must show compliance with BSE-related mitigations for a period of at least 7 or 8 years. In addition, the region must show that the likelihood of release and exposure to the BSE agent is negligible. As we explained above, BSE surveillance provides information regarding prevalence, changes in the epidemiology of the disease, and effectiveness of the BSE risk mitigation measures.

One commenter stated that the United States typically imports more than 2 million head of cattle each year. The commenter asked how APHIS supported the statement that imported cattle represent only a small portion of cattle in U.S. feedlots.

According to data from the National Agricultural Statistics Service (NASS), of the approximately 2.2 million bovine animals imported annually for the years 2009–2011, about 1.3 million were feeder cattle. NASS data also show that an average of 25.8 million cattle was marketed annually by feedlots in the years 2009–2011. Based on this information, APHIS estimates that approximately 5 percent of cattle in U.S. feedlots were imported.

One commenter stated that APHIS did not address the lack of reported BSE cases in regions where cattle are primarily grass-fed, nor did APHIS evaluate the import and export standards of these countries.

Under Chapter 11.5.2 of the OIE Code, a release assessment must be conducted as the first step in determining the BSE risk status of a region. The release assessment considers the likelihood that the BSE agent has either been introduced into the region via commodities potentially contaminated with it, or is already present in the region. The elements considered include production of meat-and-bone meal or greaves from the indigenous ruminant population, imported meat-and-bone meal or greaves, and imported animal feed and feed ingredients in a region. Furthermore, if the release assessment identifies a risk factor, an exposure assessment is conducted, which considers the likelihood of cattle being exposed to the BSE agent by reviewing such elements as recycling and amplification of the BSE agent through consumption by cattle of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these; the use of ruminant carcasses (including from fallen stock), by-products, and slaughterhouse waste; the parameters of the rendering processes and the methods of animal feed manufacture; and the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including

measures to prevent cross-contamination of animal feed. APHIS notes that those countries where cattle are primarily raised on grass, such as Argentina and Brazil, are considered negligible risk in part because livestock practices in those regions contribute a very low likelihood of exposure to ruminant materials through bovine feed.

One commenter stated that the proposed rule is full of exceptions that would allow importation of live cattle and bovine products from all three risk categories, which presents an unacceptable amount of risk to consumers.

The commenter is incorrect that under the provisions of the proposed rule, live cattle could be imported from regions of all three risk categories. Only cattle born after the date of effective enforcement of a ruminant-to-ruminant feed ban would be allowed entry from controlled risk regions, and live cattle from regions of undetermined risk would be allowed only on a case-by-case basis when the Administrator determines that they do not present a risk of introducing BSE into the United States. While the rule provides for the importation of deboned skeletal meat from all regions, that provision, as well as the provisions for the importation of other products, is closely aligned with international standards, particularly as they require SRM removal and steps to prevent the contamination of the products with SRMs.

Four commenters noted that the phrase ''full-time salaried veterinary officer of the national government of the exporting region'' is used throughout the rule. One commenter stated that the phrase was not in alignment with the provisions in Chapter 5.2.2 of the OIE Code. The commenter asked if a veterinarian employed part-time as a government veterinary officer would be excluded from signing the required certificates. Another commenter asked that we consider eliminating the requirement, noting that in the joint initial action plan for the Regulatory Cooperation Council announced by Canadian Prime Minister Harper and President Obama on December 7, 2011, the current requirement for a veterinary signature for meat export certificates was cited as an example of a requirement which creates a burden for regulators as well as for industry. A third commenter stated that APHIS should build in suitable flexibility to allow certificates to be signed by inspectors who are under the supervision of the official veterinarian. This commenter also suggested that APHIS ensure there is sufficient flexibility to allow for the use of various forms of certification, such as paper and electronic certification.

In the proposed rule, we provided for certificates to be signed either by a full-time salaried veterinary officer of the national government of the exporting region or issued by a veterinarian designated or accredited by the national government of the exporting region and endorsed by a full-time salaried veterinary officer. When evaluating a country we consider whether or not it has the infrastructure and veterinary authority to comply with the APHIS certification requirements. If, as a result of our evaluation, we conclude that the country has the necessary infrastructure, and if the competent veterinary authority can attest to APHIS that the competent official has oversight over certifying a process or product, then APHIS can accept that signature. We have amended the requirements in §§ 94.18, 94.19, 94.20, and 94.21 to require that certificates must be issued and signed by a full-time salaried veterinary officer of the national government of the exporting region or signed by a person authorized to issue such certificates by the veterinary services of the national government of the exporting region. APHIS recognizes the need to move to electronic certification in the trade environment, and is working to find ways to implement it in the future.

Regions of Negligible Risk, Controlled Risk, and Undetermined Risk for BSE

One commenter stated that OIE's risk categorizations of regions are based on self-reported data, and that a scientific committee assesses applications for compliance with OIE standards only after a recommendation for a risk designation is made. The commenter stated that this process is inherently unreliable and not subject to rigorous verification.

The OIE recommendation for a region's BSE risk categorization is based on the decision reached by the Scientific Commission after receiving a recommendation from the OIE BSE ad hoc group. The members of both groups are aware of BSE trends and geographic impacts related to trade among regions. Consequently, the scientific commission's decision is based not only on the country's self-reported data, but also on the potential impact on the country's BSE status of its trading partners' BSE status, the country's historical trade in specific commodities, and the impact of BSE-related risk mitigation in the region.

One commenter asked what the justification was for considering a region to be ''negligible risk'' if it has at least one indigenous case of BSE, but the BSE-positive animal was born more than 11 years ago, is officially identified, is controlled in its movements, and completely destroyed at slaughter or death. The commenter also asked for an explanation of the 11-year limitation.

To achieve negligible risk status, the country must comply with stringent criteria, including the requirement that the youngest case reported by the country has to be older than 11 years. This requirement relates to the likelihood that contaminated feed that the BSE case was potentially exposed to 11 years ago (during its first year of life) will no longer be circulating. This is in line with classical BSE data showing that cattle developed disease between 4.5 and 6 years of age following the 1990–early 2000 European BSE experience. By year 11 after exposure, over 95 percent of the BSE cases in Europe experienced disease. Therefore we expect most cases would be detected within 11 years.

One commenter stated that the definitions of ''negligible risk'' and ''controlled risk'' status in the proposed rule are substantively the same as those of the OIE, and are therefore superfluous in the proposed rule. The commenter stated that OIE classification and interpretation should be sufficient.

The OIE Code consists of guidelines for international trade in live animals and their parts and products. While these guidelines are recognized as international standards, they do not have the force or effect of law within the United States. For this reason we need to establish these definitions in our regulations.

One commenter stated that in the proposed rule, we proposed to establish a notice-based approach for recognizing OIE risk categorization for countries, but then we also solicited comment on certain countries before the process was established. The commenter opposed recognizing the OIE risk categorization for the countries listed before the notice-based approach was established in the regulations.

In the proposed rule, we announced that we were giving preliminary concurrence to the OIE risk classifications of several countries and gave the public opportunity to comment, just as we would have done in a rulemaking. We received no comments that opposed this concurrence for any of the countries we discussed in the proposed rule.

Several commenters noted that the OIE recognizes Singapore and India as countries of negligible risk for BSE, and Taiwan as a region of controlled risk,

but that those countries were not included on the list of regions for which APHIS concurred with the OIE classification.

Singapore was omitted from the list by mistake. In the cases of India and Taiwan, we were not able to complete our review of information in support of concurrence with the OIE designation before the publication of the proposed rule. We have since concluded our review of information for Taiwan and are announcing preliminary concurrence with the OIE designations for Singapore and Taiwan in a notice published today in the **Federal Register** in accordance with the process we are adopting in this final rule. The OIE recommendations regarding Singapore and Taiwan can be viewed at *http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/*. This notice will also announce preliminary concurrence with the most recent OIE designations for Austria, Belgium, Bulgaria, Brazil, Colombia, Costa Rica, Croatia, Israel, Italy, Japan, the Netherlands, Nicaragua, and Slovenia.

Our review of information in support of concurrence with the OIE designation for India is ongoing. When our review is complete, if the findings support concurrence with the OIE designation, we will publish a notice in the **Federal Register** announcing our preliminary concurrence with the OIE's designation for India and provide the public with an opportunity to comment.

One commenter asked if we intended to announce in the final rule the concurrence decision for countries that have already received OIE classification.

Yes. Those regions for which we announced preliminary concurrence will be recognized accordingly.

Two commenters stated that the United States should accept OIE risk classification without conducting duplicative reviews. One of these stated that the United States, as a member of the OIE, should give automatic recognition to the OIE risk classification.

APHIS will not be conducting duplicative reviews, but will verify that the information is provided or is publicly available to support our concurrence with the OIE classification. APHIS' intention is to follow the OIE's BSE guidelines while ensuring that OIE-recognized countries apply adequate BSE risk mitigation measures assuring that bovines and bovine commodities destined for export pose a negligible risk for BSE, and that the country complies with OIE requirements for the specific BSE country recognition. APHIS will thus have greater confidence in the outcomes of the evaluations and will have the necessary documentation to support or defend recognition decisions. The process we will use is described in the regulatory text in this document for § 92.5.

One commenter asked if APHIS would proactively update its lists of regions of negligible and controlled risk according to future changes in the OIE lists, or if APHIS would act only after receiving an official request from the country.

APHIS will automatically look to concur with future OIE recognitions of a region's BSE status.

One commenter asked if APHIS intends to actually reassess each dossier before proposing to concur with OIE classification.

It is not APHIS' intention to do a separate evaluation apart from the OIE's evaluation. Rather, APHIS will confirm that there is information available to support our concurrence with the OIE classification.

One commenter asked if APHIS will accept dossiers written in languages other than English.

No, APHIS will not accept dossiers in languages other than English.

Two commenters expressed concern that APHIS plans to determine the BSE risk designation of any country or region via a rulemaking process. One commenter stated that the length of the rulemaking process is unpredictable and that use of a rulemaking process would introduce uncertainty. The other commenter suggested that APHIS maintain a list on a Web site and harmonize notification with that of the OIE.

Since this final rule establishes our system for classifying regions as to BSE risk be consistent with the OIE's BSE risk categorization of regions, APHIS does not plan to use a rulemaking process to announce concurrence with OIE recognition of BSE status. Instead, when we concur with the OIE decision on the BSE status of a region, we will publish a notice in the **Federal Register** announcing our intention to concur and to solicit public comment. If we do not receive comments that require us to reconsider our decision to concur, we will publish a subsequent notice to announce our concurrence with the OIE classification and we will update our Web site. Announcing our concurrence through this notice process, which includes obtaining and evaluating public comments, among other information, before making a final decision on our concurrence, is an appropriate process to use.

One commenter asked if countries that have received an OIE risk designation will be required to submit any particular information to APHIS in order to receive concurrence.

In order to determine whether we concur with OIE's classification, APHIS will review publicly available information. If sufficient information is not publicly available, we will ask countries to provide us with the documentation submitted to the OIE when that country requested official recognition of its BSE risk status. We will then review the documentation provided and make our evaluation available to the public for comment.

Four commenters noted that we would require regions evaluated by APHIS for BSE risk to submit updated information every year. Some of these commenters asked whether APHIS will rely on OIE's annual review for countries originally classified by OIE, or whether we would expect these countries to provide updated information to APHIS on a yearly basis. One commenter expressed concern that if APHIS requires this information from trading partners classified by OIE, it may set a precedent for other trading partners to ask for the same information, which would undermine OIE's categorization process.

We proposed to allow for APHIS recognition of a region as a region of negligible risk or controlled risk in one of two ways. The first way would be for APHIS to concur with the OIE classification of the region of either negligible or controlled risk. The second way would be for a region that has not been classified by the OIE as either negligible or controlled risk for BSE to submit a request to the Administrator for either classification, along with documentation sufficient to allow the USDA to evaluate whether the region meets the criteria for either classification. The requirement that updated information be submitted every year would apply only to countries that APHIS has evaluated for BSE risk upon the request of those countries and not to countries that have already been classified as negligible or controlled risk by the OIE.

One commenter noted that in proposed § 93.436(b)(2)(iii), the proposed regulatory text mentions ''BSE minimal risk regions.'' The commenter suggested correcting this to ''region of negligible risk for BSE in which there has been an indigenous case of BSE/region of controlled risk for BSE.''

The commenter is correct. We have corrected this error in the final rule.

Conditions for Importation of Commodities

Live Animals

One commenter stated that adopting the changes in the proposed rule could result in BSE-infected cattle entering the United States and cause the loss of export markets. Another commenter expressed concern that detection of BSE in imported cattle could cause domestic consumers to lose confidence in beef, resulting in economic harm to the U.S. cattle industry.

We disagree with the commenters. We will be conducting our own evaluations of the date of effective enforcement of the feed ban in any region that would export live cattle to the United States, and we will accept exports of live cattle from regions of undetermined risk for BSE only on a case-by-case basis when the Administrator determines that they do not present a risk of introducing BSE into the United States. We are confident that these and the other risk mitigation measures in this rule will be effective at preventing BSE-infected cattle from being imported into the United States.

Additionally, we note that economic effects of the most recent BSE case in the United States, confirmed on April 24, 2012, in a dairy cow in California, were not significant, as evidenced by U.S. beef price levels and beef and cattle exports. Monthly retail prices of choice beef averaged $4.93 per pound for the 12 months between April 2011 and March 2012.[2] For the following 12 months, April 2012 through March 2013, the average monthly retail price of choice beef was $5.03 per pound. Comparing narrower time frames, for the 4-month period January 2012 through April 2012, the average monthly retail price was $5.04 per pound, compared to an average monthly price of $4.96 per pound for the 4 months between May 2012 and August 2012; that is, choice beef prices over the 4 months following the BSE discovery were less than 2 percent lower than prices during the 4 months preceding the discovery. A variety of marketing factors influence price movements, and this small percentage decline in 4-month average price levels is well within normal market fluctuations.

With respect to U.S. beef exports, for the 12 months before the BSE discovery, monthly exports averaged about 71,500 metric tons (MT), valued at about $383 million, compared to a monthly average of about 64,300 MT, valued at about $391 million, during the 12 months following the discovery.[3] It appears unlikely that much of this year-on-year quantity decline can be attributed to the BSE discovery when one compares average monthly U.S. beef export levels during the 2 months before and 2 months after the BSE discovery. The quantity of beef exported by the United States in March and April, 2012, averaged about 63,800 MT per month, valued at about $384 million, compared to an average for May and June 2012 of 65,700 MT per month, valued at about $394 million.

U.S. monthly cattle exports averaged about 16,700 head, valued at $32.4 million, during the year preceding the 2012 BSE discovery, compared to a monthly average of about 15,100 head, valued at $30.9 million, during the year following the BSE discovery. Again, this small difference falls well within the range of monthly variation. Considering only the 2 months before and 2 months after the BSE discovery, exports for March and April 2012 averaged about 12,100 head per month, valued at $20.9 million, compared to about 17,900 head per month for May and June 2012, valued at $39.0 million.

One commenter stated that it was unclear if the provisions of the proposed rule would be applicable to domesticated water buffaloes (*Bubalus bubalis*). The commenter stated that the definition of ''bovines'' should be extended to include the domesticated water buffalo, which is commonly raised as a farmed animal in some European Union (EU) Member States.

APHIS disagrees with the commenter that the domesticated water buffalo should be included in the definition of bovines. Current trade in water buffalo products is primarily in semen and embryos and in dairy products; this rule will not affect trade in these articles.

Three commenters noted that the proposed rule addressed only bovines and bovine products, and that BSE-related restrictions on ovines and caprines were not addressed in the proposal. The commenters stated that APHIS should publish a rule lifting BSE-related restrictions on ovines and caprines as soon as possible. One commenter specifically requested that APHIS remove BSE-related import restrictions on ovine casings.

As we explained in the proposed rule, we are in the process of developing a proposal to amend the BSE regulations as they affect the importation of ovines and caprines and products derived from those animals. Upon completion of the proposal, we will publish it in the **Federal Register** for public comment.

One commenter asked that APHIS reconsider its policy on importation of zoo ruminants from Canada. The commenter stated that, since zoo ruminants cannot be imported from Canada, U.S. zoos are reluctant to send animals to Canada on breeding loans because they cannot get them back. The commenter stated that zoo ruminants have no history of BSE and will never come into contact with any domestic livestock in the United States food chain, and therefore they pose little, if any, risk to U.S. agriculture. The commenter stated further that North American zoos are losing tremendous genetic resources due to the inability to exchange hoofstock across the U.S. border. The commenter stated that this could lead to the collapse of valuable captive ruminant populations.

The commenter is incorrect that zoo ruminants have no history of BSE. BSE has been reported in several species of exotic ruminants, including nyala (*Tragelaphus angasi*), kudu (*Tragelaphus strepsiceros*), gemsbok (*Oryx gazella*), eland (*Taurotragus oryx*), Arabian oryx (*Oryx leucoryx*), scimitar-horned oryx (*Oryx dammah*), Ankole cattle, and bison (*Bison bison*). As we explained above, we are in the process of developing a proposal to amend the BSE regulations as they affect the importation of ovines and caprines and products derived from those animals. That proposal will also address the importation of zoo ruminants. Upon completion of that proposal, we will publish it in the **Federal Register** for public comment.

One commenter requested that APHIS add the ear tag system as established in the EU as an acceptable means of permanent identification.

While APHIS could recognize an ear tag system like the one used in the EU as an official identification method, for live bovines imported from BSE-affected countries we also require a permanent identification such as a brand or tattoo. For example, we require a C□N brand or tattoo on cattle imported from Canada. This permanent identification allows APHIS to trace an animal back to the country of origin in the event that the animal shows symptoms of a transmissible spongiform encephalopathy.

One commenter noted that the proposed rule maintains the current policy that any cattle imported from Canada be born after March 31, 1999. The commenter stated that when this requirement was implemented in 2007, it was estimated that 11 percent of the cattle in Canada were born before that

[2] *http://www.ers.usda.gov/data-products/meat-price-spreads.aspx.*

[3] U.S. Census Bureau, as reported by Global Information Services, Inc. This is the source of all trade data reported here.

date, but that according to a January 2012 inventory of cattle in Canada, that number is now approximately 2 percent. The commenter stated that because this number will continue to decline, and because classical BSE is mostly found in cattle between the ages of 4 and 7 years, and is rare in cattle aged over 9 years, APHIS should consider eliminating this requirement, either by adoption in the final rule or by incorporating a reasonable sunset provision in the final rule.

APHIS disagrees with the commenter. We believe that we should keep the date in the regulations because this rule recognizes Canada as a controlled risk region. Live cattle may be safely imported from controlled risk regions provided that the cattle were born after the date the ruminant-to-ruminant feed ban was effectively enforced. In 2007, after a thorough evaluation of several factors contributing to enforcement and compliance of the feed ban, APHIS concluded that the Canadian feed ban was effectively enforced by March 31, 1999.

One commenter noted that while the rule removes BSE-related import restrictions on in vivo-derived embryos, it does not address restrictions on in vitro-derived embryos. The commenter stated that, consistent with international standards, there should be no BSE-related restrictions on either in vivo- or in vitro-derived embryos and that APHIS should revise the provisions for embryos accordingly.

The commenter is correct that the OIE does not recommend restrictions on in vitro-derived embryos with respect to BSE. Our regulations in § 98.3(h) currently require that ruminant and swine embryos have an intact zona pellucida, which effectively prohibits the importation of in-vitro derived and processed embryos. This restriction is not related to BSE risk, but to the risks of other livestock diseases, such as bovine viral diarrhea, foot-and-mouth disease, infectious bovine rhinotracheitis, leptospirosis, leukosis, and mycoplasmosis.

One commenter noted that APHIS proposed to amend the definition of ''recognized slaughter establishment'' to mean a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act or a State meat inspection act. The commenter asked for clarification of whether ''State'' refers only to States of the United States or to territories or nations as well.

The word ''State'' in this definition refers to a State of the United States. The definition specifically addresses slaughter establishments in the United States that are under State inspection rather than Federal inspection. Facilities in the United States that receive imported animals for slaughter must operate under the provisions of the Federal Meat Inspection Act, and overseas facilities approved to export to the United States must be approved by USDA's FSIS.

Feed Bans

One commenter stated that APHIS has been inconsistent in how it characterizes the usefulness of the feed ban. The commenter stated that APHIS now argues that the feed ban serves a different role in BSE mitigation than does SRM removal, and denies that its current requirement that animals from which eligible beef exports are derived must be subject to a feed ban is to prevent the importation of products derived from Canadian cattle that had been exposed to BSE infectivity. The commenter stated that APHIS is positing either that the feed ban serves no role in protecting human health, or that the feed ban's effectiveness in ensuring that food entering the food chain is not derived from infected animals is nonessential to human health.

APHIS believes that the ruminant-to-ruminant feed ban serves an important role in ensuring that live animals are not exposed to the BSE agent, which helps ensure that the disease does not appear in the U.S. cattle population. SRM removal mitigates risk in meat products. Our BSE risk assessments examine the five barriers that must be compromised before BSE could be introduced into the U.S. cattle population: U.S. import restrictions; slaughter controls; rendering inactivation factors; feed manufacturing controls; and dose response. We consider that any feed ban may not have perfect compliance but if the risk of release were to be negligible, the likelihood of amplification or perpetuation within the system would also be considered insignificant. As no indigenous cases of classical BSE [4] have ever been detected in the United States, APHIS remains confident that the risk of release and exposure to BSE in the United States remains negligible.

One commenter stated that the feed ban requirements do not specify how long after the date of effective enforcement live cattle may be imported. The commenter suggested that allowing the importation of live cattle too soon after the date of effective enforcement could result in BSE-exposed cattle entering the United States. The commenter also stated that it was unclear whether the proposal to require documentation of effective enforcement of feed bans would actually provide greater protection against a BSE introduction.

The feed ban requirements apply to animals born at any time after the date of effective enforcement. APHIS notes that at present, the certification statement must only say that the animals were born after the effective enforcement of a feed ban; by requiring documentation of the date of effective enforcement, we will be better able to verify that the bovines were in fact born after that date.

One commenter stated that our proposed standards for determining the date of effective enforcement of a feed ban represent an unnecessary burden because the effectiveness of feed ban enforcement is already assessed as part of the OIE procedure for determining the risk status of a country. The commenter suggested that instead of using a rulemaking process, APHIS should either accept the dates recognized by the EU, or allow, without a rulemaking for the determination of the date of effective enforcement of a feed ban, cattle born after the date of classification of the country.

In the event that an EU Member State wishes to export live cattle to the United States, APHIS will consider using the date recognized by the EU of effective enforcement of the feed ban in that Member State after evaluating publicly available data or data provided by the EU Member State to support such recognition. If the data supports the EU-recognized date of enforcement, then APHIS will accept such date as the date the ruminant-to-ruminant feed ban was effectively enforced in the region. For other regions, APHIS will make a determination based on the information received from the country, which can also include the specific date of feed ban enforcement considered by the country or region.

One commenter stated that determination of the date of effective enforcement of the ruminant-to-ruminant feed ban should be a matter for the OIE, not for the United States.

The OIE ad hoc group evaluation does not determine the date of feed ban enforcement. The OIE assesses whether the feed ban was effectively enforced through audit and compliance for a particular period of time. For controlled risk countries, this time period is for

[4] Immunohistochemistry and Western blot tests at USDA's National Veterinary Services Laboratories confirmed that the most recent case of BSE in the United States was atypical BSE, not classical BSE. The report of the case investigation can be viewed on the APHIS Web site at *http://www.aphis.usda.gov/animal_health/animal_diseases/bse/downloads/BSE_Summary_Report.pdf.*

less than 8 years, and for negligible risk countries, it is for at least 8 years.

The commenter stated that there are dates generally accepted for the effective enforcement of the feed ban in the UK (August 1, 1996) and the EU (January 1, 2001). The commenter asked if APHIS will accept these dates.

As we explained above, in the event that an EU Member State wishes to export live cattle to the United States, APHIS will consider using the date of effective enforcement of the feed ban recognized by the EU after evaluating publicly available data or data provided by the EU Member State to support such recognition. If the data supports the EU-recognized date of enforcement, then APHIS will accept that date as the date the ruminant-to-ruminant feed ban was effectively enforced in the Member State. For other regions, APHIS will make a determination based on the information received from the country, which can also include the specific date of feed ban enforcement considered by the region.

Edible and Inedible Products

One commenter asked if the conditions applying to deboned skeletal muscle in § 94.18(b)(2) would also apply to meat food products and byproducts made from deboned skeletal meat and containing no restricted commodities.

The conditions for deboned skeletal muscle will apply to meat food products made from such, but, as we explained in the proposed rule, imported products must meet all relevant agency requirements, including those of FSIS and the U.S. Food and Drug Administration (FDA). Each agency has the capability to deny imports based on their individual authorities and concerns.

One commenter stated that the proposed rule reaffirms in § 94.25(a)(2) that ovine or caprine meat can derive only from animals that were less than 12 months of age when slaughtered. The commenter stated that the OIE Code does not recommend any restrictions on the import of sheep and goat meat with respect to BSE or scrapie. The commenter asserted that the restriction is unjustified and asked APHIS to confirm that it will be removed in a future rulemaking.

As we explained above, we are in the process of developing a proposal to amend the BSE regulations as they affect the importation of ovines and caprines and products derived from those animals. Upon completion of that proposal, we will publish it in the **Federal Register** for public comment.

One commenter noted that in proposed § 94.23(b), we proposed to allow the importation of gelatin derived from hides and skins regardless of BSE risk classification of the region of origin. The commenter asked why, then, in §§ 94.23(e) and 95.7(e), that the certificate accompanying these commodities is required to indicate the BSE risk category for the exporting region. The commenter also asked what a region not yet classified should indicate on the certificate. The commenter suggested using the language of § 95.8(e) for tallow with 0.15 percent of insoluble impurities.

As we explained in the proposed rule, gelatin and collagen derived from hides and skins do not present a risk for the transmission of BSE. We believe, however, that additional risk mitigations are warranted for gelatin and collagen derived from bones, based on the risk classification of the region of origin. For this reason we are requiring gelatin and collagen imported into the United States be accompanied by an original certificate that indicates the BSE risk classification of the exporting region and that states that the required conditions have been met. Regions not yet classified for BSE risk are considered to be regions of undetermined risk. We agree with the commenter, however, that requiring hide-derived gelatin and collagen to indicate the BSE risk category for the exporting region is unwarranted if the products can be demonstrated to be hide-derived and have amended §§ 94.23(e) and 95.7(e) accordingly.

The commenter asked APHIS to elaborate on the circumstances where the provision for gelatin and collagen from bones that will have no contact with ruminants in the United States could be imported, and under what conditions the gelatin or collagen would be allowed importation.

APHIS believes that the rule is clear in what the criteria are for importing gelatin and collagen; specifically, such products may be imported if the Administrator determines that the gelatin and collagen will not come into contact with ruminants in the United States and that the conditions under which it will be imported will prevent the introduction of BSE into the United States. Examples of these uses would include products for human or industrial use, such as film, cosmetics, manufacturing for glue purposes, and so on. Persons wishing to import gelatin and collagen would also need to obtain a United States Veterinary Permit for the Importation and Transportation of Controlled Materials and Organisms and Vectors,[5] and the uses would have to be stated on the permit application. The importation of gelatin and collagen intended solely for human use must still meet the requirements established by other agencies that regulate for public health.

One commenter stated that the definition of ''offal'' in § 95.1 leads the reader to believe that offal is exclusively inedible in the United States and will not be allowed to be imported for human consumption. The commenter stated that this is not true and that it is well known that liver, tripe, and other organ meats are found on the U.S. market. The commenter asked that we clarify that meat by-products may include edible parts of a butchered animal, including brains, thymus, pancreas, liver, heart, and kidneys. The commenter also asked that we define in § 94.0 what products are included in ''meat by-products'' and amend the definition of offal in § 95.1 to make it clear that the parts mentioned, when edible, are not covered by the definition.

FSIS, which has the primary authority for regulating meat and meat products intended for human consumption, does not define offal but does refer to products such as organ meats as ''meat by-products'' when used for human consumption. However, we agree with the commenter that the definition of ''offal'' in § 95.1 may be confusing and have revised it to read ''the inedible parts of a butchered animal.''

One commenter noted that the proposed rule says that APHIS concurs with OIE's recommendations regarding trade of dicalcium phosphate. The commenter stated that Article 11.5.17 of the OIE Code recommends the same conditions for dicalcium phosphate originating in regions of controlled or undetermined risk, and that APHIS should justify its reasons for prohibiting dicalcium phosphate from regions of undetermined risk.

The commenter is correct that the OIE Code recommends no BSE-related restrictions for dicalcium phosphate that is free of protein or fat. However, the OIE Code does recommend that dicalcium phosphate that is not free of protein or fat should originate only in negligible risk or controlled risk regions, and that, if the material originates in a region of controlled risk for BSE,

[5] Application for a permit must be filed on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application must state the intended use of the material and the name and address of the consignee in the United States.

additional risk mitigation measures be applied. Furthermore, as we explained in the proposed rule, there is evidence that dicalcium phosphate produced from bones under normal manufacturing processes can contain a small residual proteinaceous fraction, and would therefore present a risk of transmission for BSE. For these reasons we proposed to limit the importation of dicalcium phosphate that is not free of traces of protein or fat from regions of undetermined risk to a case-by-case basis when the Administrator determines that the dicalcium phosphate will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE. We have amended the regulatory text in § 95.10 to make these requirements clearer.

One commenter stated that the OIE Code does not provide any conditions for the importation of tallow from regions of undetermined risk other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight and derivatives made from this tallow, which are considered safe commodities. The commenter stated that APHIS' proposed prohibition on tallow other than tallow with maximum level of insoluble impurities of 0.15 percent in weight from regions of undetermined risk would not make sense from a technical point of view. The commenter stated that APHIS should either apply the same conditions for the same product from regions of controlled risk or justify why it intends to prohibit the importation of tallow other than tallow with maximum level of insoluble impurities of 0.15 percent in weight from regions of undetermined risk.

While the OIE Code does recommend unrestricted trade in tallow with a maximum level of insoluble impurities of 0.15 percent, the Code also recommends that tallow with more than 0.15 percent of insoluble impurities by weight requires certification that it is sourced from a negligible risk country or, if it is sourced from a controlled risk country, that it is derived from cattle that have passed ante-mortem and post-mortem inspections and does not contain SRMs. We will allow all tallow if it is determined that it will not come in contact with ruminants, for example, if the tallow is intended for use in manufacturing candles and soaps. The importation of tallow intended solely for human use must still meet the requirements established by other agencies that regulate for public health.

One commenter noted that we proposed to prohibit the importation of processed animal protein from regions of controlled risk for BSE unless it can be demonstrated that the product has not been commingled or contaminated with ruminant meat and bone meal or greaves. The commenter stated that the second and third options presented in § 95.5(a) are compatible with an export region of controlled and even undetermined risk, but that the certificate required in § 95.5(b) must state that the exporting region is of negligible risk. The commenter asked APHIS to clarify what risk statuses are allowed for both the exporting regions and the regions in which the ruminants from which the processed animal protein is derived are born and raised, and what the restrictions are in each case. The commenter also stated that the certificate should be able to accommodate each available option.

APHIS agrees with the commenter. Our intention is to allow processed animal protein from all regions if it can be demonstrated that the products are not contaminated with prohibited material, i.e. ruminant meat-and-bone meal and greaves or SRMs. Most of these products, if not all, would need an import permit once it has been demonstrated to APHIS that these products do not contain prohibited material. We have amended § 95.5(a) and (b) to clarify this. We have also amended § 95.13 and § 95.14(g) to require that nonruminant processed animal proteins imported from any region would have to be accompanied by an original certificate and an import permit that indicates that the material is of nonruminant origin.

In addition, we have amended §§ 94.19, 94.20, and 95.5 to remove the requirement that the commodities be derived from bovines that were born and raised in regions of negligible or controlled risk for BSE, respectively. The OIE risk assessment evaluation takes into consideration the risk of release (importation of cattle and cattle products for a particular time period) and the exposure (likelihood that potentially contaminated/infected cattle derived product contain the BSE agent could be recycled into the system). OIE importation standards for countries recognized as either negligible or controlled risk for BSE take into consideration that the risk of importing particular commodities (including live cattle) has already been mitigated and as such contributed to an insignificant risk. For this reason, we do not believe the requirement that the products be derived from bovines born and raised in regions of negligible or controlled risk is necessary. Instead, we will only require that these commodities be exported from regions of negligible or controlled risk for BSE, respectively, and, in the case of processed animal proteins, that the commodity has not been commingled or contaminated with meat and bone meal or greaves from a region of controlled or undetermined risk for BSE.

In the proposed rule, we noted that, of the types of animal products derived from bovines, processed ruminant protein that either contains or has been contaminated by the BSE agent is the means of transmission of BSE. Therefore, in conducting an assessment of the BSE risk in a country, it is important to know the origin of processed animal protein, or feedstuffs containing processed animal protein, that have been imported into the country. Processed animal protein originating from high-risk countries for BSE presents a higher release risk than that originating from low-risk countries. One commenter asked for clarification of the term feedstuffs, and asked specifically if it applies only to feed intended for livestock or is used in a broader sense to apply to pet foods as well.

Yes, the term feedstuffs could apply to pet foods as well as livestock feed. It is possible that pet foods could be used for cattle feed, either by accidental misfeeding of pet foods to cattle or by misusing salvage pet food for cattle. Farms that raise multiple species (e.g. dogs, swine, and cattle) present a particular risk for misfeeding. We would consider both the origin of pet food and pet food ingredients, and the likelihood of exposure through misfeeding or the likelihood of misuse of salvage pet food when evaluating a region for BSE risk.

Specified Risk Materials

Three commenters expressed concern that while the OIE requires removal of SRMs from animals older than 30 months of age, the proposed rule calls for removal of SRMs from animals 30 months of age or older. The commenters stated that while this may not appear to be a significant difference, it will still have a major impact on trade. One commenter noted that the EU uses the OIE wording and would not be able to guarantee compliance with the proposed rule. Another commenter noted that the use of ''thirty months of age or older'' is consistent with FDA regulations and with the rules of Canada and Mexico, and stated that adopting the OIE's language in this rulemaking would be helpful only if the FDA, Canada, and Mexico also adopted it. The commenter suggested that a possible solution would be for USDA

and FDA to develop an equivalency agreement with the OIE/EU.

The commenter is correct that the use of ''thirty months of age or older'' is consistent with FSIS and FDA regulations as well as with Canadian regulations. We note that anyone wishing to import bovine products into the United States would have to meet FSIS or FDA requirements as well as APHIS requirements. We do not anticipate that this difference will have a significant impact on trade.

One commenter expressed concern that the definitions of SRMs in the proposed rule are not consistent with those in the FDA interim rule ''Use of Materials Derived from Cattle in Human Food and Cosmetics'' (69 FR 42256–42274, Docket No. 2004N–0081) and the FDA proposed rule ''Use of Materials derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants'' (72 FR 1582–1619, Docket No. 2005N–0373). The commenter stated that while the APHIS' proposed rule would allow for the importation of some bovine gelatins, the same bovine gelatins would be prohibited on the U.S. market under the FDA rules, or could not further be exported outside the United States due to the inconsistency between the regulations.

As we explained in the proposed rule, APHIS is adopting the definition of SRMs already established by FSIS. APHIS and FSIS carry out their programs in close coordination with the FDA. The USDA coordinates with FDA's Center for Veterinary Medicine regarding animal feed and veterinary pharmaceuticals; the Center for Food Safety and Applied Nutrition regarding foods other than meat, poultry, and egg products; and other Centers regarding drugs, biologics, and devices containing bovine material. These agencies collaborate, issuing regulations under their respective authorities. Imported products must meet all relevant agency requirements. Each agency has the capability to deny imports based on their individual authorities and concerns.

One commenter suggested that in the proposed definitions for ''region of controlled risk for bovine spongiform encephalopathy (BSE)'' and ''region of negligible risk for bovine spongiform encephalopathy (BSE)'' in § 92.1, the wording ''the same feed that potentially contained SRM material'' be rephrased as ''the same potentially contaminated feed.'' The commenter stated that this rephrasing would more closely align with international standards the provisions for identifying and controlling the movements of bovines that, during their first year of life, were reared with a bovine determined to be infected with BSE during its first year of life.

We agree with the commenter and have made those suggested changes in this final rule.

One commenter stated that the requirements in proposed § 94.23 for the importation of bone-derived gelatin are different from the requirements in FDA's interim final rule ''Use of Materials Derived From Cattle in Human Food and Cosmetics'' (70 FR 53063–53069 and 73 FR 20785–20794, Docket No. FDA–2004–N–0188) and also the provisions in FDA's proposed rule ''Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants'' (72 FR 1582–1619, Docket No. 2005N–0373). The commenter stated that under the provisions of our proposed rule, gelatin imported from regions of controlled or undetermined BSE risk would have to be manufactured from bovine bones free from skulls of animals of all ages, but that FDA's SRM definition allows the use of skulls of animals below 30 months of age. The commenter was concerned that some gelatin that could be imported under APHIS' regulations could not be used within the United States under the provisions of FDA's requirements.

The commenter is correct that under FDA's interim final rule pertaining to human food and cosmetics, imported gelatin must not be manufactured from skulls and vertebral columns from cattle 30 months of age or older, regardless of the OIE BSE risk categorization of the exporting country. FDA's regulations that govern the manufacture of gelatin and collagen are found at 21 CFR 189.5 and 21 CFR 700.27. FDA's regulations in § 189.5(e) do allow a process for designating countries as exempt from the restrictions contained in the regulations. A country seeking designation must send a written request to the Office of the Center Director, Center for Food Safety and Applied Nutrition. FDA will respond in writing to any such request and may impose conditions in granting any such request.

The medical products proposed rule that FDA published in 2007 would have the same restrictions for gelatin in medical products intended for use in humans, and drugs intended for use in ruminants. FDA has not finalized the medical products proposed rule.

One commenter expressed concern that APHIS' list of SRMs differs from the OIE list and the EU list. The commenter noted especially the inclusion of the trigeminal ganglia in the list of SRMs and asked APHIS to explain why the trigeminal ganglia were included.

As we explained in the proposed rule and in supporting scientific documentation, APHIS is adopting the definition of SRMs already established by FSIS. FSIS has designated as SRMs the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age or older, and the tonsils and distal ileum of the small intestine of all cattle because these tissues have demonstrated BSE infectivity.

One commenter stated that APHIS' list of SRMs is stricter than FSIS' list with respect to regions of undetermined risk in that the SRM list applies at 12 months instead of 30. The commenter asked if this list would supersede FSIS' for commodities imported from regions of undetermined risk.

The list of SRMs in our proposed rule is consistent with FSIS' list; however, the commenter is correct that we proposed that the SRM removal requirements apply to cattle 12 months of age and older from undetermined risk regions. This requirement is consistent with the OIE recommendations for the importation of meat and meat products from regions of undetermined risk. If an undetermined risk region wants to export beef to the United States then the product must meet the requirements of this rule for removal of SRMs.

Blood and Blood Products

Three commenters raised concerns about the proposed requirements for blood and blood products. The commenters stated that neither OIE nor EU regulations require that blood be collected in a hygienic manner. The commenters also stated that the OIE recommendation that blood be collected from cattle which were not subject to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process is meant to prevent the contamination of the blood with SRMs. One commenter stated that the additional requirement that blood be collected in a hygienic manner was therefore unjustified and that APHIS should either remove the requirement or provide further justification and details regarding what the Administrator would consider a hygienic manner to collect blood at slaughter. The other two commenters stated that the inclusion of dried plasma and blood products in the definition of ''processed animal

proteins'' was inconsistent with Chapter 11.5 of the OIE Code.

While we agree with the OIE recommendations, we also recognize that there are various methods that can be used for blood collection. It is not our intent to dictate which methods can be used, but it must be demonstrated that the method used in any given case does not result in contamination of the blood with SRMs. We recognize blood being collected in a closed system as one such method.

APHIS included dried plasma and other blood products in the definition of ''processed animal proteins'' to allow the agency to address the potential of such products to be commingled with materials that would be prohibited.

One commenter stated that APHIS should provide details regarding what the Administrator would consider to be a hygienic manner to collect blood from live donors.

The risk with blood collection at slaughter is potential contamination of the blood with SRMs through brain emboli or cross-contamination after slaughter. While these risks are not associated with the collection of blood from live donors, we want to ensure that there is no cross-contamination in the collection process with blood from slaughtered animals that was not collected via a closed system or some other hygienic method. In our September 2007 final rule, we recognized a closed system as one hygienic method of blood collection from live donors.

One commenter stated that proposed § 95.5 appears internally inconsistent with proposed § 95.12 on the subject of blood and blood products.

The commenter is mistaken. Section 95.5 refers to processed animal proteins derived from ruminants. Section 95.12 refers to bovine blood and products derived from bovine blood. These are different commodities and represent a different risk with respect to BSE.

One commenter asked why, in § 95.15(b), which contains provisions for processed animal proteins from nonruminants, it was necessary to exempt eligible blood meal, blood plasma, and other blood products from the prohibition. The commenter stated that it seemed contradictory for processed animal proteins derived from nonruminants to possibly contain protein from ruminant blood. The commenter stated that either the product is a processed animal protein from nonruminants and does not include any ruminant origin protein, or it should be designated as a mixed processed animal protein from nonruminants and ruminants.

We note that these provisions actually appear in § 95.14(c), not § 95.15(b), and disagree that they are contradictory. APHIS wants to ensure that nonruminant processed animal protein mixed with products derived from ruminant blood meets the requirements we have for blood and blood products derived from bovines.

Date of Effective Enforcement of Feed Ban in Mexico

In the proposed rule, we announced that we had conducted an evaluation to determine the date of effective enforcement of a feed ban in Mexico, and that based on that evaluation, we consider the date of effective enforcement of a feed ban in Mexico to be November 30, 2007. We received no comments on either the evaluation or on the date of effective enforcement on the feed ban in Mexico. Therefore, we are recognizing November 30, 2007, as the date of effective enforcement of the feed ban in Mexico in this document.

Miscellaneous Changes

One commenter noted that proposed § 95.4(c)(7) refers to ''the conditions of paragraphs (d)(1) through (d)(5) of this section.'' The commenter asked if the reference should be to paragraphs (c)(1) through (c)(5) of the section instead.

The commenter is correct. We have corrected the reference in this final rule.

We proposed in § 92.7 to incorporate by reference Article 11.6.22 of the OIE Code, effective 2009. This article of the OIE Code sets out guidelines for surveillance activities related to BSE. We are updating this to incorporate by reference Article 11.5.22 of the OIE Code, effective 2013. In 2013, the OIE updated these guidelines to adjust the surveillance points required for risk status recognition of countries with small populations of cattle. The OIE made these changes at the request of the BSE ad hoc group, supported by the scientific commission and endorsed by the OIE member states.

We proposed in § 94.27(a) to require that, meat, meat products, and other edible products derived from bovines, ovines, or caprines that are otherwise prohibited importation into the United States may transit ports in the United States for immediate export, or transit the United States by overland transport if certain conditions were met. We have decided to remove the requirement that the person moving these articles must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. We have also amended the transit shipment requirements in § 95.15 to remove the permit requirement for prohibited articles transiting air and ocean ports in the United States for immediate export. We are making these changes in order to be consistent with the existing requirements for meat and other products of ruminants and swine in § 94.15(d).

Issues Outside the Scope of the Rulemaking/Outside APHIS Authority

One commenter stated that the Geographical BSE Risk rating (GBR) for the United States should be raised because there are many different prion strains present in North America and those strains are spreading and mutating.

The GBR is a qualitative indicator of the likelihood of the presence of one or more cattle within the native population of a country being infected with BSE, pre-clinically as well as clinically, at a given point in time. Where its presence is confirmed, the GBR gives an indication of the level of infection. The GBR methodology was developed, and is used, by the European Commission as the basis for trade legislation rules for cattle and their products. APHIS is not involved with this process.

One commenter stated that under APHIS' proposed rule, no bovine tissues from a negligible risk region are considered to be SRMs. The commenter asked why a negligible risk region willing to export products other than skeletal meat should have to demonstrate to FSIS that its BSE risk status can be reasonably expected to provide the same level of protection from human exposure to the BSE agent as prohibiting SRMs for use as human food does in the United States. The commenter stated that this provision should be removed or amended to bring the regulations in line with international standards, and that APHIS should coordinate with FSIS toward that end. The commenter also asked what information should be provided to FSIS, and what would be the decision procedure, should the provision remain unchanged. The commenter asked if this demonstration would be required even if the exported cuts do not include any of the tissues considered as SRMs in regions of controlled or undetermined risk.

The FSIS regulations in 9 CFR 327.2 provide that, to be eligible to export meat and meat products to the United States for human consumption, a foreign country must be able to certify that it meets FSIS requirements. Therefore, prior to exporting meat and meat products to the United States, countries are required to be approved by FSIS as having an inspection system equivalent to that in the United States. FSIS

maintains a list of countries eligible to export meat to the United States on its Web site at *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/eligible-foreign-establishments.* In the affirmation of its SRM interim rule, published in the **Federal Register** on July 13, 2007 (72 FR 38700–38730, Docket No. 03–025F), FSIS stated that it will also consider whether APHIS or FDA imposes any BSE-related restrictions on imports from the country and, if so, the basis for those restrictions when developing equivalence criteria.

One commenter stated that APHIS should adopt the same standards required by the EU and Japan, including mandatory testing for all cattle brought to slaughter and banning the feeding of blood, manure, and slaughterhouse waste to animals.

As we explained above, BSE surveillance programs in the United States focus on obtaining quality samples from targeted subpopulations rather than looking at the entire adult cattle population. Cattle typically only test positive for BSE when they are in the last few months of what can be a very long incubation period. Testing all animals at slaughter would not improve our understanding of disease trend because not all the exposed cattle will be infected, nor would all infected cattle test positive. We continue to believe that FDA's BSE feed regulations are science based and appropriate for the BSE risk in the United States.

One commenter stated that the United States is covering up the scope of BSE and variant Creutzfeldt-Jakob disease (vCJD) in the United States by not requiring medical professionals to report vCJD cases and not allowing individual producers to test for BSE.

Requiring medical professionals to report vCJD cases is outside of APHIS' statutory authority. With respect to individual producers testing for BSE, we note that for a diagnostic test to be considered valid anywhere in the world, it must be done by the competent veterinary authority of the national government of the region where the animals are kept. Furthermore, as we explained above, increased testing would not provide better understanding of disease trend, nor would it provide better protection against the spread of the disease.

Three commenters stated that APHIS should also harmonize its other import regulations, especially those for foot-and-mouth disease (FMD), with OIE standards.

Amending our other import regulations for consistency with OIE standards is outside the scope of this rulemaking.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document. Additionally, we are adopting as final our preliminary BSE risk classifications of countries that were announced in the proposed rule, and we are recognizing November 30, 2007, as the date of effective enforcement of a feed ban in Mexico.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This final 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 have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

This rule will make our bovine and bovine product import restrictions related to BSE more reflective of current scientific thinking while continuing to guard against the introduction of BSE. The process for classifying regions with respect to BSE risk will be based on the comprehensive review of relevant, internationally accepted scientific literature and will be consistent with the process employed by the OIE. The rule will also remove BSE-related restrictions on the importation of live cervids and camelids and their products.

While benefits of the rule are expected to justify its costs, effects on U.S. imports are expected to be minimal. Potential impacts of the rule on U.S. export markets, by influencing trading partners' import policies, are not considered in this analysis.

Live Bovines (Cattle and Bison)

Essentially all U.S. imports of cattle and bison are from Canada and Mexico. Over the 10 years 2002–2011, the only live bovine imports that did not come from Canada or Mexico were 33 animals from Australia, 12 from New Zealand, and 1 from Guatemala. APHIS is classifying Canada and Mexico as countries of controlled risk for BSE (their classification by the OIE).

Imports from Canada will be unaffected by this rule because the requirements will cause no change in the number or type of animals that are eligible for importation, based on Canada's status as a BSE minimal-risk region under APHIS' existing regulations. Imports from Mexico also will be essentially unaffected, since nearly all cattle imported from Mexico (98 to 99 percent) are estimated to be less than 24 months of age; with this rule APHIS is establishing November 30, 2007, as the date of effective enforcement of a ruminant-to-ruminant feed ban in Mexico (the earliest date that bovines imported from Mexico could be born).

Products Derived From Bovines

Six countries, Argentina, Australia, Brazil, Canada, New Zealand, and Uruguay, accounted for 91 percent of all U.S. bovine product import volume (and 90 percent of the import value) over the 5-year period 2007–2011. Imports from each of the six countries should continue essentially unchanged and without interruption under the rule, because the protocols in place in these countries are already in full compliance with the rule's criteria. Argentina, Australia, New Zealand, and Uruguay will be classified by APHIS as negligible risk regions for BSE; they have never reported a case of BSE. Canada and Brazil, which will be classified by APHIS as controlled risk regions for BSE, already satisfy FSIS inspection requirements and prohibitions on certain animal stunning or pithing and mechanically separated meat.

Imports allowed by the rule from the 36 (primarily European) countries listed in 9 CFR 94.18 as prohibited from shipping bovine products to the United States likely will be insignificant. In none of the years from 1990 through 1996, that is, prior to the prohibition on ruminant product imports from all of Europe in 1997, did the volume of U.S. bovine product imports from the 36

countries account for more than 0.6 percent of imports of these products.

Nor does recent EU trade in bovine products suggest a significant volume of imports from the 36 countries in the future, at least in the near term. While the nominal value of bovine product exports by the European Union (EU–27) increased more than four-fold in 5 years, from $0.36 billion in 2007 to nearly $1.57 billion in 2011, the value of bovine product imports by EU–27 Member States in 2011 ($2.42 billion) exceeded the value of their bovine product exports by more than $850 million. The EU–27 continues to be a large net importer of bovine products overall. Emerging markets, such as Russia, are likely to take a growing share of Europe's bovine product exports.

Bovine product imports from other countries that are not currently subject to BSE-related restrictions are not expected to be significantly affected. Over the 5 years 2007–2011, annual imports from such countries as a group averaged 8 to 9 percent of all U.S. bovine product imports by volume (10 to 11 percent by value), with over 95 percent of these products coming from Mexico, Nicaragua, and Costa Rica. Imports from Mexico already meet the requirements of a region of controlled risk for BSE largely by way of FSIS requirements. The potential impact on imports from Nicaragua and Costa Rica, which APHIS is classifying as regions of undetermined risk for BSE, should be minimal at most. Almost all imports from those two countries are of boneless beef that already satisfy the rule's requirements, again, largely by way of FSIS requirements.

Live Cervids and Camelids and Their Products

Removal of the prohibition on the importation of live cervids and camelids and their products from the 36 countries listed in 9 CFR 94.18 will likely have little or no economic impact on the United States. The United States has not imported any live cervids or camelids from these countries since at least 1990. In none of the years from 1990 through 1996, before the prohibition of ruminant meat, meat products, and other edible products from all of Europe in 1997, did the volume of U.S. imports of meat and edible offal of deer from the 36 countries account for more than 3.3 percent of total imports. Over the 5 years 2007–2011, more than 99 percent of U.S. imports of meat and edible offal of deer have come from New Zealand, and that country's dominance of this market is unlikely to change as a result of this rule. The volume of U.S. imports of camelid products is very small. Their annual value averaged less than $50,000 over the 5-year period 2006–2010 (most recent data available), and 90 percent of those imports were supplied by Canada and China.

Benefits, Costs, and Alternatives

Consumers benefit from imports to the extent that consumer choice is broadened and the increased supply of the imported commodity leads to a price decline. We anticipate that the rule will have little impact on consumer choice or import volumes, and therefore little or no impact on U.S. businesses as well.

Although the impact of this rule on U.S. consumers and producers is expected to be minimal, the benefits of the rule are expected to justify its costs. Leaving the bovine regulations unchanged would be unsatisfactory because it would perpetuate the current situation in which our BSE-related import conditions are not consistent with current scientific evidence. Additionally, by maintaining the status quo APHIS would forgo the opportunity to establish a process for classifying a region's BSE risk status in a more timely fashion than is possible under current regulations.

Another alternative, amending the BSE regulations related to the importation of bovines and bovine-derived products to match precisely the OIE Code would also be unsatisfactory because it would not allow APHIS to independently interpret the scientific literature and findings that underlie OIE risk categorization recommendations. Making no changes to the regulations that govern the importation of cervids and camelids would also be unsatisfactory because it would perpetuate an unnecessary constraint on trade in those commodities.

Effects on Small Entities

Small entities prevail among the industries that may be affected by this rule, including cow-calf producers, cervid and camelid producers, feedlot establishments, slaughtering establishments, meat packing and processing establishments, meat wholesalers, importers and exporters, grocery stores and meat markets, and manufacturers of cosmetics and pharmaceuticals. However, as has been described, any changes because of this rule in U.S. imports of live bovines, cervids, camelids, or their products are expected to be minor. U.S. small entities are unlikely to be significantly affected. This rule contains no mandatory reporting, recordkeeping, or other compliance requirements for U.S. entities.

Executive Order 12988

This final 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 no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the importation of live bovines and bovine products under the conditions specified in this rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov Web site.[6] Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799–7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping

[6] Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0010.* The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

requirements included in this final rule, which were filed under 0579–0393, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

List of Subjects

9 CFR Part 92

Animal diseases, Imports, Incorporation by reference, Livestock, Poultry and poultry products, Region, Reporting and recordkeeping requirements.

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

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

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

9 CFR Part 98

Animal diseases, Imports.

Accordingly, we are amending 9 CFR parts 92, 93, 94, 95, 96, and 98 as follows:

PART 92—IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS: PROCEDURES FOR REQUESTING RECOGNITION OF REGIONS

■ 1. The authority citation for part 92 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 92.1, definitions of *approved laboratory, bovine, exporting region, OIE, OIE Code, OIE Terrestrial Manual, processed animal protein, region of controlled risk for BSE, region of negligible risk for BSE, region of undetermined risk for BSE, specified risk materials (SRMs) from regions of controlled risk for BSE,* and *specified risk materials (SRMs) from regions of undetermined risk for BSE* are added in alphabetical order to read as follows:

§ 92.1 Definitions.

* * * * *

Approved laboratory. A properly equipped institution in the exporting region, approved by the official authority who is responsible for animal health matters in that region, that is staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods who is responsible for the results.

Bovine. Bos taurus, Bos indicus, and *Bison bison.*

* * * * *

Exporting region. A region from which shipments are sent to the United States.

* * * * *

OIE. The World Organization for Animal Health.

OIE Code. The Terrestrial Animal Health Code of the World Organization for Animal Health.

OIE Terrestrial Manual. The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organization for Animal Health.

* * * * *

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

* * * * *

Region of controlled risk for bovine spongiform encephalopathy (BSE).[1] A region for which a risk assessment has been conducted sufficient to identify the historical and existing BSE risk factors in the region and that:

(1) Has demonstrated that appropriate mitigations are being taken to manage all identified risks, but may not have been taken for the periods of time necessary to be classified as a region of negligible risk for BSE.

(2) Is a region in which it can be demonstrated through an appropriate control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants.

(3) Has demonstrated that Type A surveillance in accordance with Article 11.5.22 of the OIE Code, incorporated by reference in § 92.7, or with equivalent guidelines recognized by the Administrator is in place and the relevant points target, in accordance with Table 1 of Article 11.5.22 of the OIE Code, or with equivalent guidelines recognized by the Administrator has been met. Type B surveillance in accordance with Article 11.5.22 of the OIE Code, or with equivalent guidelines recognized by the Administrator, is sufficient in place of Type A surveillance or its equivalent once the relevant points target for Type A surveillance or its equivalent has been met.

(4) Meets one of the following conditions:

(i) Has had no case of BSE in the region or every case has been demonstrated to have been imported and has been completely destroyed; or

(ii) Has had at least one indigenous case, and all bovines described in either paragraph (4)(ii)(A) or (4)(ii)(B) of this definition, if still alive, are officially identified with unique individual identification that is traceable to the premises of origin of the animal, have their movements controlled, and, when slaughtered or at death, are completely destroyed:

(A) All bovines that, during their first year of life, were reared with a bovine determined to be infected with BSE during its first year of life, and that investigation showed consumed the same potentially contaminated feed as the infected animal during that period; or

(B) If the investigation was unable to determine whether the feed source that was used to feed the bovine known to be infected was also used to feed other bovines in the herd of the infected animal, all bovines born in the same herd as a BSE-infected bovine either within 12 months before or 12 months after the birth of the infected animal.

(5) Meets the conditions in one of or both paragraphs (5)(i) or (5)(ii) of this definition:

(i) Has met the following conditions, but not for at least the past 7 years:

(A) Conducted an ongoing awareness program for veterinarians, farmers, and workers involved in transportation, marketing, and slaughter of bovines to encourage reporting of bovines showing

[1] A list of regions classified by APHIS as regions of controlled risk for BSEs is available at *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.*

clinical signs that could be indicative of BSE;

(B) Required notification and investigation of all bovines showing clinical signs consistent with BSE; and

(C) Has carried out the examination, in accordance with internationally accepted diagnostic tests and procedures and in approved laboratories, of brain or other tissues collected as part of the surveillance and monitoring described in paragraphs (3) and (5)(i)(A) and (5)(i)(B) of this definition; or

(ii) Has prohibited the feeding to ruminants in the region of meat-and-bone meal and greaves derived from ruminants, but it cannot be demonstrated through an appropriate level of control and audit that the prohibited materials have not been fed to ruminants in the region for at least the past 8 years.

Region of negligible risk for bovine spongiform encephalopathy (BSE).[2] A region for which a risk assessment has been conducted sufficient to identify the historical and existing BSE risk factors in the region and that:

(1) Has demonstrated that appropriate mitigations to manage all identified risks have been taken for each relevant period of time to meet each identified risk, as set forth in this definition.

(2) Has demonstrated that Type B surveillance in accordance with Article 11.5.22 of the OIE Code, incorporated by reference in § 92.7, or with equivalent guidelines recognized by the Administrator is in place and the relevant points target, in accordance with Table 1 of Article 11.5.22 of the OIE Code, or with equivalent guidelines recognized by the Administrator has been met.

(3) Meets one of the following conditions:

(i) Has had no case of BSE in the region or every case has been demonstrated to have been imported and has been completely destroyed; or

(ii) Has had at least one indigenous case, but every indigenous case was born more than 11 years ago, and all bovines described in either paragraph (3)(ii)(A) or (3)(ii)(B) of this definition, if still alive, are officially identified with unique individual identification that is traceable to the premises of origin of the animal, have their movements controlled, and, when slaughtered or at death, are completely destroyed:

(A) All bovines that, during their first year of life, were reared with a bovine determined to be infected with BSE during its first year of life, and that investigation showed consumed the same potentially contaminated feed as the infected animal during that period; or

(B) If the investigation was unable to determine whether the feed source that was used to feed the bovine known to be infected was also used to feed other bovines in the herd of the infected animal, all bovines born in the same herd as a BSE-infected bovine either within 12 months before or 12 months after the birth of the infected animal.

(4) Has, for at least the past 7 years:

(i) Conducted an ongoing awareness program for veterinarians, farmers, and workers involved in transportation, marketing, and slaughter of bovines to encourage reporting of bovines showing clinical signs that could be indicative of BSE;

(ii) Required notification and investigation of all bovines showing clinical signs consistent with BSE; and

(iii) Carried out the examination, in accordance with internationally accepted diagnostic tests and procedures and in approved laboratories, of brain or other tissues collected as part of the required surveillance and monitoring described in paragraphs (2) and (4)(i) and (4)(ii) of this definition.

(5) Has demonstrated through an appropriate level of control and audit that, for at least the past 8 years, neither meat-and-bone meal nor greaves derived from ruminants have been fed to ruminants in the region.

Region of undetermined risk for bovine spongiform encephalopathy (BSE). Any region that is not classified as either a region of negligible risk for BSE or a region of controlled risk for BSE.

* * * * *

Specified risk materials (SRMs) from regions of controlled risk for BSE. Those bovine parts considered to be at particular risk of containing the BSE agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a).

Specified risk materials (SRMs) from regions of undetermined risk for BSE. Those bovine parts considered to be at particular risk of containing the BSE agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a), except that the following bovine parts from regions of undetermined risk for BSE are considered SRMs if they are derived from bovines over 12 months of age: Brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and the dorsal root ganglia.

* * * * *

■ 3. Subpart A, consisting of existing §§ 92.2 through 92.4, is added under the following heading:

Subpart A—Procedures for Requesting Recognition of Regions Other Than for BSE

■ 4. Subpart B, consisting of §§ 92.5, 92.6, and 92.7, is added to read as follows:

Subpart B—Procedures for Requesting BSE Risk Status Classification With Regard to Bovines

Sec.

Subpart B—Procedures for Requesting BSE Risk Status Classification With Regard to Bovines

§ 92.5 Determination of the BSE risk classification of a region.

All countries of the world are considered by APHIS to be in one of three BSE risk categories—negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The listing of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS Web site at *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.* The listing can also be obtained by writing to APHIS at National Import Export Services, 4700 River Road Unit 38, Riverdale, MD 20737. APHIS may classify a region for BSE according to either paragraph (a) or paragraph (b) of this section.

(a) *BSE risk classification based on OIE classification.* If the OIE has classified a country as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support concurrence with the OIE classification. This information could be publicly available information, or APHIS could request that countries supply the same information given to the OIE. APHIS will announce in the **Federal Register**, subject to public comment, each intent to concur with an OIE classification. APHIS will also post the summary of the BSE OIE ad hoc group conclusions for review during the comment period.

[2] A list of regions classified by APHIS as regions of negligible risk for BSEs is available at *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.*

The summaries would be available for review on the APHIS Web site at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml*. Following review of any comments received, the Administrator will announce his or her final determination regarding classification of the country in the **Federal Register**, along with a discussion of and response to pertinent issues raised by commenters. If APHIS recognizes a country as either negligible risk or controlled risk for BSE, the Agency will include that country in a list of regions of negligible risk or controlled risk for BSE, as applicable, that APHIS will make available to the public on the Agency's Web site at *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml*.

(b) *Regions seeking classification as negligible or controlled risk that have not been classified by the OIE.* A region that has not received classification by OIE as either negligible risk or controlled risk for BSE and that wishes to be classified by APHIS as negligible risk or controlled risk must submit to the Administrator a request for classification, along with documentation sufficient to allow APHIS to conduct an evaluation of whether the region meets the criteria for classification. A list of the documentation required can be accessed on the APHIS Web site at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml*. If, following evaluation of the information submitted, the Administrator determines that the region meets the criteria for classification as negligible risk or controlled risk, APHIS will announce that determination in the **Federal Register** and will make available to the public on the APHIS Web site the evaluation conducted by APHIS, as well as the information provided by the requesting region. APHIS will accept public comment on its intent. Following review of any comments received, the Administrator will announce his or her final determination regarding classification of the region in the **Federal Register**, along with a discussion of and response to pertinent issues raised by commenters.

(c) *Retention of classification as either negligible risk or controlled risk.* (1) As required by the OIE for countries classified as either negligible risk or controlled risk by the OIE, regions evaluated by APHIS and classified as negligible or controlled risk would need to submit updated information to APHIS each year. The required information includes documentation of the following:

(i) Relevant changes in BSE legislation, compared to the previous year;

(ii) The importation into the region during the year of cattle, processed animal protein, and products containing processed animal protein;

(iii) Audit findings in rendering plants and feed mills that process ruminant material or material from mixed species that contains ruminant material, related to the prohibition of the feeding to ruminants of processed animal protein;

(iv) Audit findings in rendering plants and feed mills that process nonruminant material, related to the prohibition of the feeding to ruminants of processed animal protein;

(v) Infractions at the types of facilities listed above;

(vi) If and why, in light of the audit findings, there has been no significant exposure of cattle to the BSE agent through consumption of processed animal protein of bovine origin;

(vii) Surveillance efforts;

(viii) All clinical BSE suspects; and

(ix) Any new cases of BSE.

(2) If APHIS at any time determines that a region no longer meets the criteria for the risk classification it had previously received, APHIS will remove the region from its list of regions so classified. If the OIE determines the region no longer meets the criteria for the risk classification it had previously received, APHIS may concur with the OIE determination or may request updated information from the region and determine whether to concur with the OIE decision APHIS will announce its intent in the **Federal Register** and accept public comment regarding that intent. Following review of any comments received, the Administrator will announce in the **Federal Register** his or her final determination regarding classification of the region, along with a discussion of and response to pertinent issues raised by commenters.

(Approved by the Office of Management and Budget under control number 0579–0393)

§ 92.6 Determination of the date of effective enforcement of a ruminant-to-ruminant feed ban.

(a) In order for APHIS to determine the eligibility of live bovines for importation from a region classified as BSE negligible risk or BSE controlled risk, APHIS must determine the date from which a ban on the feeding of ruminant material to ruminants has been effectively enforced in the region. APHIS will base its determination of the date of effective enforcement on the information included in the dossier the region submitted when it requested to be classified regarding BSE risk. The information APHIS will consider will include, but not be limited to:

(1) Policies and infrastructure for feed ban enforcement, including an awareness program for producers and farmers;

(2) Livestock husbandry practices;

(3) Disposition of processed animal protein produced from domestic bovines, including the feeding of such material to any animal species;

(4) Measures taken to control cross-contamination and mislabeling of feed; and

(5) Monitoring and enforcement of the ruminant-to-ruminant feed ban, including audit findings in rendering plants and feed mills that process ruminant material.

(b) After conducting its evaluation, APHIS will announce in the **Federal Register** for public comment the date APHIS considers to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the requesting region, and will make available to the public the evaluation conducted by APHIS, as well as the supporting documentation. Following review of any comments received, the Administrator will announce his or her final determination in the **Federal Register**, along with a discussion of and response to pertinent issues raised by commenters.

§ 92.7 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, USDA must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the Animal and Plant Health Inspection Service (APHIS), and is available from the sources listed below. For information about the availability of this material at APHIS, call 301–851–3300 or write to National Import Export Services, 4700 River Road Unit 38, Riverdale, MD 20737. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) World Organization for Animal Health (OIE), 12, rue de Prony 75017 Paris, France, or email oie@oie.int, *http://www.oie.int/eng/normes/Mcode/en_sommaire.htm*.

(1) Terrestrial Animal Health Code, Chapter 11.5–Bovine Spongiform Encephalopathy, Article 11.5.22 (Surveillance activities), 22nd Edition, 2013.

(2) [Reserved]

(Approved by the Office of Management and Budget under control number 0579–0393)

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 5. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 6. Section 93.400 is amended by adding definitions of *exporting region* and *processed animal protein* in alphabetical order and revising the definition of *recognized slaughtering establishment* to read as follows:

§ 93.400 Definitions.

* * * * *

Exporting region. A region from which shipments are sent to the United States.

* * * * *

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

* * * * *

Recognized slaughtering establishment. Any slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or a State meat inspection act.[2]

* * * * *

[2] See footnote 1.

§ 93.401 [Amended]

■ 7. In § 93.401, paragraph (a), the second sentence is amended by adding the word ''non-bovine'' before the word ''ruminant'' and by removing the citation ''§ 94.18(a)(1) or (a)(2)'' and adding the citation ''§ 94.24(a)'' in its place.

§ 93.405 [Amended]

■ 8. Section 93.405 is amended as follows:

■ a. In paragraph (a)(4), by removing the words ''bovines, sheep, or goats from regions listed as BSE minimal-risk regions in § 94.18(a)(3) of this subchapter'' and adding the words ''sheep or goats from Canada'' in their place and by removing the words ''and 93.436(a)(3) and (b)(4)''; and

■ b. In the OMB citation at the end of the section, by removing the words ''numbers 0579–0040, 0579–0165, and 0579–0234'' and adding the words ''numbers 0579–0040, 0579–0165, 0579–0234, and 0579–0393'' in their place.

■ 9. Section 93.418 is amended as follows:

■ a. By revising the section heading;

■ b. By adding paragraph (d); and

■ c. By adding an OMB citation to the end of the section.

The revision and additions read as follows:

§ 93.418 Cattle and other bovines from Canada.

* * * * *

(d) In addition to meeting the requirements of paragraphs (a) through (c) of this section, bovines may be imported from Canada only under the following conditions:

(1) The bovines are imported for immediate slaughter under § 93.420; or

(2) The bovines are imported for other than immediate slaughter under the following conditions:

(i) The bovines were born after March 1, 1999, the date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada;

(ii) The bovines are imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f);

(iii) The bovines were officially identified prior to arriving at the port of entry in the United States with unique individual identification that is traceable to each bovine's premises of origin. No person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at slaughter; and

(iv) The bovines are permanently and humanely identified using one of the following additional methods:

(A) A ''C□N'' mark properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. Such a mark must be not less than 2 inches nor more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first coccygeal vertebrae); or

(B) A tattoo with the letters ''CN'' applied to the inside of one ear of the animal; or

(C) Other means of permanent identification upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from Canada.

(3) The bovines are accompanied by a certificate issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of paragraph (d)(2) of this section, as applicable, have been met.

(Approved by the Office of Management and Budget under control number 0579–0393)

■ 10. Section § 93.420 is revised to read as follows:

§ 93.420 Ruminants from Canada for immediate slaughter other than sheep and goats.

(a) *General requirements.* The requirements for the importation of sheep and goats from Canada for immediate slaughter are contained in § 93.419. There are no BSE-related restrictions on the importation of cervids or camelids from Canada. All other ruminants imported from Canada for immediate slaughter, in addition to meeting all other applicable requirements of this part, may be imported only under the following conditions:

(1) The ruminants must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and be inspected at the port of entry and otherwise handled in accordance with § 93.408.

(2) The ruminants must be moved directly from the port of entry to a recognized slaughtering establishment in conveyances that are sealed with seals of the U.S. Government at the port of entry. The seals may be broken only at the recognized slaughtering establishment by an authorized USDA representative.

(3) The ruminants must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33, which must include the location of the recognized slaughtering establishment.

(b) *Bovines.* In addition to meeting the requirements of paragraph (a) of this section, bovines may be imported from Canada for immediate slaughter only under the following conditions:

(1) The bovines must have been born after March 1, 1999, the date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada;

(2) Before the animal's arrival at the port of entry into the United States, each bovine imported into the United States from Canada must be officially identified with unique individual identification that is traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at slaughter; and

(3) The bovines must be accompanied by a certificate issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of paragraphs (b)(1) and (b)(2) of this section have been met.

(Approved by the Office of Management and Budget under control numbers 0579–0234 and 0579–0393)

■ 11. In § 93.423, paragraph (e) is added to read as follows:

§ 93.423 Ruminants from Central America and the West Indies.

* * * * *

(e) In addition to meeting all other applicable requirements of this part, bovines from Central America and the West Indies may be imported only in accordance with § 93.436.

* * * * *

■ 12. Section 93.427 is amended as follows:

■ a. By revising the section heading;

■ b. By adding paragraph (e); and

■ c. By adding an OMB citation at the end of the section.

The revision and additions read as follows:

§ 93.427 Cattle and other bovines from Mexico.

* * * * *

(e) *BSE.* In addition to meeting the requirements of paragraphs (a) through (d) of this section and all other applicable requirements of this part, bovines may be imported from Mexico only under the following conditions:

(1) The bovines were born after November 30, 2007, the date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in Mexico.

(2) The bovines were officially identified prior to arriving at the port of entry in the United States with unique individual identification that is traceable to each bovine's premises of origin. No person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at slaughter.

(3) The bovines, if sexually intact, are permanently and humanely identified using one of the following additional methods:

(i) An ''MX'' mark properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. Such a mark must be not less than 2 inches nor more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first coccygeal vertebrae); or

(ii) A tattoo with the letters ''MX'' applied to the inside of one ear of the animal; or

(iii) Other means of permanent identification upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from Mexico.

(4) The bovines are accompanied by a certificate issued in accordance with § 93.405 that states, in addition to the statements required by § 93.405, that the conditions of paragraphs (e)(1) through (e)(3) of this section have been met.

(Approved by the Office of Management and Budget under control number 0579–0393)

■ 13. In § 93.432, the section heading is revised and paragraph (e) is added to read as follows:

§ 93.432 Cattle and other bovines from the Republic of Ireland.

* * * * *

(e) In addition to meeting all other applicable requirements of this part, bovines from the Republic of Ireland may be imported only in accordance with § 93.436.

■ 14. Section § 93.436 is revised to read as follows:

§ 93.436 Bovines from regions of negligible risk, controlled risk, and undetermined risk for BSE.

The importation of bovines is prohibited, unless the conditions of this section and any other applicable conditions of this part are met. Once the bovines are imported, if they do not meet the conditions of this section, they must be disposed of as the Administrator may direct.

(a) *Bovines from a region of negligible risk for BSE in which there has been no indigenous case of BSE.* Bovines from a region of negligible risk for BSE, as defined in § 92.1 of this subchapter, in which there has been no indigenous case of BSE, may be imported only if the bovines are accompanied by an original certificate issued by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated or accredited by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so, and the certificate attests that the exporting region of the bovines is classified by APHIS as a negligible-risk region for BSE in which there has been no indigenous case of BSE.

(b) *Bovines from a region of negligible risk for BSE in which there has been an indigenous case of BSE and bovines from a region of controlled risk for BSE.* Bovines from a region of negligible risk for BSE, as defined in § 92.1 of this subchapter, in which there has been an indigenous case of BSE, and bovines from a region of controlled risk for BSE, as defined in § 92.1 of this subchapter, may be imported only under the following conditions:

(1) Prior to importation into the United States, each bovine is officially identified with unique individual identification that is traceable to the premises of origin of the animal. No person may alter, deface, remove, or otherwise tamper with the official identification while the animal is in the United States or moving into or through the United States, except that the identification may be removed at slaughter.

(2) The bovines are permanently and humanely identified before arrival at the port of entry with a distinct and legible mark identifying the exporting country. Acceptable means of permanent identification include the following:

(i) A mark properly applied with a freeze brand, hot iron, or other method, and easily visible on the live animal and on the carcass before skinning. Such a mark must be not less than 2 inches nor more than 3 inches high, and must be applied to each animal's right hip, high on the tail-head (over the junction of the sacral and first coccygeal vertebrae);

(ii) A tattoo with letters identifying the exporting country must be applied to the inside of one ear of the animal; or

(iii) Other means of permanent identification upon request if deemed adequate by the Administrator to humanely identify the animal in a distinct and legible way as having been imported from a region of negligible risk for BSE in which there has been an indigenous case of BSE or from a region of controlled risk for BSE.

(3) The bovines were born after the date from which the ban on the feeding of ruminants meat-and-bone meal or

greaves derived from ruminants has been effectively enforced.

(4) The bovines are accompanied by an original certificate issued by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated or accredited by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so, and the certificate attests to the BSE risk classification of the exporting region and that the conditions of paragraphs (b)(1) through (b)(3) of this section have been met.

(5) If there has been an indigenous case of BSE in the exporting region, the following restrictions apply:

(i) Bovines that, during their first year of life, were reared with a bovine determined to be infected with BSE during its first year of life, and that an investigation showed consumed the same potentially contaminated feed as the infected animal during that period are not eligible for importation into the United States; and

(ii) If the investigation was unable to determine whether the feed source that was used to feed the bovine known to be infected was also used to feed other bovines in the herd of the infected animal, all bovines born in the same herd as a BSE-infected bovine either within 12 months before or 12 months after the birth of the infected animal are not eligible for importation into the United States.

(c) *Bovines from a region of undetermined risk for BSE.* Importation of bovines from a region of undetermined risk for BSE, as defined in § 92.1 of this subchapter, is prohibited; *Except that:* The Administrator may allow such imports on a case-by-case basis if the live bovines are imported for specific uses, including, but not limited to, show or exhibition, and under conditions determined by the Administrator to be adequate to prevent the spread of BSE.

(Approved by the Office of Management and Budget under control number 0579–0234)

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

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

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 16. Section 94.0 is amended by removing the definitions of *cervid* and *specified risk materials (SRMs)* and adding definitions of *exporting region, mechanically separated meat, processed animal protein, specified risk materials (SRMs) from regions of controlled risk for BSE,* and *specified risk materials (SRMs) from regions of undetermined risk for BSE* in alphabetical order to read as follows:

§ 94.0 Definitions.

* * * * *

Exporting region. A region from which shipments are sent to the United States.

* * * * *

Mechanically separated meat. A finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of bovine carcasses that meets the FSIS specifications contained in 9 CFR 319.5.

* * * * *

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

* * * * *

Specified risk materials (SRMs) from regions of controlled risk for BSE. Those bovine parts considered to be at particular risk of containing the BSE agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a).

Specified risk materials (SRMs) from regions of undetermined risk for BSE. Those bovine parts considered to be at particular risk of containing the BSE agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a), except that the following bovine parts from regions of undetermined risk for BSE are considered SRMs if they are derived from bovines over 12 months of age: Brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and the dorsal root ganglia.

* * * * *

§ 94.1 [Amended]

■ 17. In § 94.1, paragraphs (b)(4) and (d) are amended by removing the citation ''§ 94.22'' both times it appears and adding the citation ''§ 94.29'' in their place.

§ 94.9 [Amended]

■ 18. In § 94.9, paragraph (c) is amended by removing the citation ''§ 94.24'' and adding the citation ''§ 94.31'' in its place.

§ 94.10 [Amended]

■ 19. In § 94.10, paragraph (c) is amended by removing the citation ''§ 94.24'' and adding the citation ''§ 94.31'' in its place.

■ 20. Section 94.18 is revised to read as follows:

§ 94.18 Bovine spongiform encephalopathy; importation of edible products derived from bovines.

(a) The importation of meat, meat products, and other edible products derived from bovines is prohibited with regard to BSE, except as provided in this section and in §§ 94.19, 94.20, 94.21, 94.22, 94.23, and 94.27.

(b) The following commodities derived from bovines may be imported into the United States without restriction regarding BSE, provided that all other applicable requirements of this part are met:

(1) Milk and milk products;

(2) Boneless skeletal muscle meat (excluding mechanically separated meat) that:

(i) Is derived from bovines that were not, prior to slaughter, subjected to a pithing process or to stunning with a device injecting compressed air or gas into the cranial cavity, and that passed ante-mortem and post-mortem inspection;

(ii) Has been prepared in a manner to prevent contamination with SRMs; and

(iii) Is accompanied to the United States by an original certificate stating that the conditions of paragraphs (b)(2)(i) and (b)(2)(ii) of this section have been met. The certificate must be issued and signed by a full-time salaried veterinary officer of the national government of the exporting region or signed by a person authorized to issue such certificates by the veterinary services of the national government of the exporting region.

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

■ 21. Section 94.19 is revised to read as follows:

§ 94.19 Importation of meat, meat byproducts, and meat food products derived from bovines from regions of negligible risk for BSE.

Meat, meat byproducts, and meat food products, as defined by FSIS in 9 CFR 301.2–except that those terms as applied to bison shall have a meaning comparable to those provided in 9 CFR 301.2 with regard to cattle, and other than boneless skeletal meat that meets the conditions of § 94.18(b)(2)—may be imported from a region of negligible risk for BSE, as defined in § 92.1 of this subchapter, if the following conditions and all other applicable requirements of this part are met:

(a) The commodities were exported from a region of negligible risk for BSE.

(b) If BSE has been diagnosed in one or more indigenous bovines in the region of negligible risk, the commodities were derived from bovines subject to a ban on the feeding to ruminants of meat-and-bone meal or greaves derived from ruminants.

(c) The commodities were derived from bovines that passed ante-mortem and post-mortem inspections.

(d) The commodities are accompanied by an original certificate stating that the exporting region is classified by APHIS as a region of negligible risk for BSE and that the conditions of paragraphs (a) through (c) of this section, as applicable, have been met. The certificate must be issued and signed by a full-time salaried veterinary officer of the national government of the exporting region, or signed by a person authorized to issue such certificates by the veterinary services of the national government of the exporting region.

Note: To be eligible to export meat, meat byproducts, and meat food products under the conditions of this section for human consumption, a region must also be one that has demonstrated to FSIS in accordance with 9 CFR 310.22 that its BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as does prohibiting specified risk materials for use as human food in the United States.

(Approved by the Office of Management and Budget under control number 0579–0393)

■ 22. Section 94.20 is revised to read as follows:

§ 94.20 Importation of meat, meat byproducts, and meat food products derived from bovines from regions of controlled risk for BSE.

Meat, meat byproducts, and meat food products, as defined by FSIS in 9 CFR 301.2—except that those terms as applied to bison shall have a meaning comparable to those provided in 9 CFR 301.2 with regard to cattle, and other than boneless skeletal meat that meets the conditions of § 94.18(b)(2)—may be imported from a region of controlled risk for BSE, as defined in § 92.1 of this subchapter, if the following conditions and all other applicable requirements of this part are met:

(a) The commodities were exported from a region of controlled risk for BSE.

(b) The commodities were derived from bovines that passed ante-mortem and post-mortem inspections.

(c) The commodities were derived from bovines that were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

(d) The commodities were produced and handled in a manner that ensured that such commodities do not contain and are not contaminated with either of the following:

(1) SRMs from regions of controlled risk for BSE; or

(2) Mechanically separated meat from the skull and vertebral column from bovines 30 months of age or older.

(e) The commodities are accompanied by an original certificate stating that the exporting region is classified by APHIS as a region of controlled risk for BSE, and that the conditions of this section have been met. The certificate must be issued and signed by a full-time salaried veterinary officer of the national government of the exporting region, or signed by a person authorized to issue such certificates by the veterinary services of the national government of the exporting region.

(Approved by the Office of Management and Budget under control numbers 0579–0015 and 0579–0393)

■ 23. Section 94.21 is added to read as follows:

§ 94.21 Importation of meat, meat byproducts, and meat food products derived from bovines from regions of undetermined risk for BSE.

Meat, meat byproducts, and meat food products, as defined by FSIS in 9 CFR 301.2–except that those terms as applied to bison shall have a meaning comparable to those provided in 9 CFR 301.2 with regard to cattle, and other than boneless skeletal meat that meets the conditions of § 94.18(b)(2)—may be imported from regions of undetermined risk for BSE, as defined in § 92.1 of this subchapter, if the following conditions and all other applicable requirements of this part are met:

(a) The commodities were derived from bovines that have never been fed meat-and-bone meal or greaves derived from ruminants.

(b) The commodities were derived from bovines that passed ante-mortem and post-mortem inspections.

(c) The commodities were derived from bovines that were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

(d) The commodities were produced and handled in a manner that ensured that such commodities do not contain and are not contaminated with any of the following:

(1) SRMs from regions of undetermined risk for BSE; or

(2) Mechanically separated meat from the skull and vertebral column from bovines over 12 months of age.

(e) The commodities are accompanied by an original certificate stating that the exporting region is a region of undetermined risk for BSE and that the conditions of this section have been met. The certificate must be issued and signed by a full-time salaried veterinary officer of the national government of the exporting region, or signed by a person authorized to issue such certificates by the veterinary services of the national government of the exporting region.

(Approved by the Office of Management and Budget under control number 0579–0393)

§ 94.27 [Removed]

■ 24. Section 94.27 is removed.

§§ 94.22 through 94.26 [Redesignated §§ 94.29 through 94.33]

■ 25. Sections 94.22 through 94.26 are redesignated as §§ 94.29 through 94.33, respectively.

■ 26. New §§ 94.22 through 94.27 are added to read as follows:

Sec.

* * * * *

* * * * *

§ 94.22 Meat or dressed carcasses of hunter-harvested bovines.

The meat or dressed carcass (eviscerated and the head is removed) is

derived from a wild bovine that has been legally harvested in the wild, as verified by proof such as a hunting license, tag, or the equivalent that the hunter must show to the authorized inspector.

(Approved by the Office of Management and Budget under control number 0579–0393)

§ 94.23 Importation of gelatin derived from bovines.

(a) The importation of gelatin derived from bovines is prohibited because of BSE, unless:

(1) The gelatin meets the requirements of either paragraph (b), (c), or (d), as well as the requirements of paragraph (e) of this section and all other applicable requirements of this part; or

(2) The gelatin is authorized importation under paragraph (f) of this section and meets all other applicable requirements of this part.

(b) The gelatin is derived from hides and skins, provided the gelatin has not been commingled with materials ineligible for entry into the United States.

(c) The gelatin is derived from the bones of bovines and originates in a region of negligible risk for BSE.

(d) The gelatin is derived from the bones of bovines, originates in a region of controlled risk or undetermined risk for BSE, and meets the requirements of paragraphs (d)(1) through (d)(4) of this section:

(1) The bones from which the gelatin was derived were derived from bovines that passed ante-mortem and post-mortem inspection.

(2) The bones from which the gelatin was derived did not include the skulls of bovines or the vertebral column of bovines 30 months of age or older.

(3) The bones were subjected to a process that includes all of the following steps, or to a process at least as effective in reducing BSE infectivity:

(i) Degreasing;

(ii) Acid demineralization;

(iii) Acid or alkaline treatment;

(iv) Filtration; and

(v) Sterilization at 138 °C (280.4 °F) or greater for a minimum of 4 seconds; and

(4) The gelatin has not been commingled with materials ineligible for entry into the United States.

(e) The gelatin is accompanied to the United States by an original certificate signed by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (b), (c), or (d) of this section, as applicable, have been met and, for gelatin other than that described in paragraph (b) of this section, must indicate the BSE risk classification of the exporting region.

(f) The Administrator determines that the gelatin will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the gelatin has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the gelatin and name and address of the consignee in the United States.

§ 94.24 Restrictions on importation of meat and edible products from ovines and caprines due to bovine spongiform encephalopathy.

(a) Except as provided in paragraph (b) of this section and in § 94.25, the importation of meat, meat products, and edible products other than meat (excluding milk and milk products) from ovines and caprines that have been in any of the following regions is prohibited: Albania, Andorra, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Canada, Croatia, the Czech Republic, Denmark, the Federal Republic of Yugoslavia, Finland, France, Germany, Greece, Hungary, the Republic of Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, the Former Yugoslav Republic of Macedonia, Monaco, Norway, Oman, the Netherlands, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

(b) The importation of gelatin derived from ovines or caprines that have been in any region listed in paragraph (a) of this section is prohibited unless the following conditions have been met:

(1) The gelatin is imported for use in human food, human pharmaceutical products, photography, or some other use that will not result in the gelatin coming in contact with ruminants in the United States.

(2) The person importing the gelatin obtains 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. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the gelatin and name and address of the consignee in the United States.

§ 94.25 Restrictions on the importation from Canada of meat and edible products from ovines and caprines other than gelatin.

The commodities listed in paragraphs (a) and (b) of this section may be imported from Canada if the conditions of this section are met.

(a) *Meat, carcasses, meat byproducts, and meat food products from ovines or caprines.* (1) The meat, carcass, meat byproduct, or meat food product, as defined by FSIS in 9 CFR 301.2, is derived from ovines or caprines 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, and the ovines or caprines:

(i) Were less than 12 months of age when slaughtered;

(ii) Were slaughtered at a facility that either slaughters only ovines or caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States;

(iii) Did not test positive for and were not suspect for a transmissible spongiform encephalopathy;

(iv) Never resided in a flock or herd that has been diagnosed with BSE; and

(v) Were not subject to any movement restrictions within Canada as a result of exposure to a transmissible spongiform encephalopathy.

(2) The commodities are accompanied by an original certificate of such compliance issued by a full-time salaried veterinary officer of Canada, or issued by a veterinarian designated by the Canadian government and endorsed by a full-time salaried veterinary officer of the Government of Canada, representing that the veterinarian issuing the certificate was authorized to do so; and if all other applicable requirements of this part are met.

(b) *Meat or dressed carcasses of hunter-harvested ovines or caprines.* (1) The meat or dressed carcass (eviscerated and the head is removed) is derived from a wild ovine or caprine that has been legally harvested in the wild, as verified by proof such as a hunting license, tag, or the equivalent that the hunter must show to the United States Customs and Border Protection official; and

(2) The animal from which the meat is derived was harvested within a jurisdiction specified by the Administrator for which the game and wildlife service of the jurisdiction has informed the Administrator either that the jurisdiction conducts no type of game feeding program, or has complied with, and continues to comply with, a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000.

(c) *Ports.* All products to be brought into the United States under this section must, if arriving at a land border port, arrive at one of the following ports: Eastport, ID; Houlton, ME; Detroit (Ambassador Bridge), Port Huron, and Sault St. Marie, MI; International Falls, MN; Sweetgrass, MT; Alexandria Bay, Buffalo (Lewiston Bridge and Peace Bridge), and Champlain, NY; Pembina and Portal, ND; Derby Line and Highgate Springs, VT; and Blaine (Pacific Highway and Cargo Ops), Lynden, Oroville, and Sumas (Cargo), WA.

§ 94.26 Gelatin derived from horses or swine or from ovines or caprines that have not been in a region restricted because of BSE.

Gelatin derived from horses or swine, or from ovines or caprines that have not been in any region listed in § 94.24(a) must be accompanied at the time of importation into the United States by an official certificate issued by a veterinarian employed by the national government of the region of origin. The official certificate must state the species of animal from which the gelatin is derived and, if the gelatin is derived from ovines or caprines, certify that the gelatin is not derived from ovines or caprines that have been in any region listed in § 94.24(a).

§ 94.27 Transit shipment of articles.

Meat, meat products, and other edible products derived from bovines, ovines, or caprines that are otherwise prohibited importation into the United States in accordance with § 94.18 through § 94.26 may transit air and ocean ports in the United States for immediate export if the conditions of paragraphs (a) through (c) this section are met. Meat, meat products, and other edible products derived from bovines, ovines, or caprines are eligible to transit the United States by overland transportation if the requirements of paragraphs (a) through (d) of this section are met:

(a) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed during the entire time that it is in the United States.

(b) The person moving the articles must notify, 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 must include the:

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

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

(3) Mode of transportation; and

(4) Serial numbers of the sealed containers.

(c) The articles must transit the United States in Customs bond.

(d) The commodities must be eligible to enter the United States in accordance with the provisions of this part and must be accompanied by the certification required by that section. Additionally, the following conditions must be met:

(1) The shipment must be exported from the United States within 7 days of its entry; and

(2) The commodities may not be transloaded while in the United States, except for direct transloading under the supervision of an authorized 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.

(Approved by the Office of Management and Budget under control number 0579–0393)

§ 94.28 [Amended]

■ 27. In § 94.28, paragraph (c) is amended by removing the citation ''§ 94.28(b)(5)'' and adding ''paragraph (b)(5) of this section'' in its place.

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

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

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 29. Section 95.1 is amended by removing the definition of *specified risk materials (SRMs),* by revising the definition of *offal,* and by adding definitions of *exporting region, specified risk materials (SRMs) from regions of controlled risk for BSE, specified risk materials (SRMs) from regions of undetermined risk for BSE,* and *tallow derivative* in alphabetical order to read as follows:

§ 95.1 Definitions.

* * * * *

Exporting region. A region from which shipments are sent to the United States.

* * * * *

Offal. The inedible parts of a butchered animal.

* * * * *

Specified risk materials (SRMs) from regions of controlled risk for BSE. Those bovine parts considered to be at particular risk of containing the BSE agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a).

Specified risk materials (SRMs) from regions of undetermined risk for BSE. Those bovine parts considered to be at particular risk of containing the BSE agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a), except that the following bovine parts from regions of undetermined risk for BSE are considered SRMs if they are derived from bovines over 12 months of age: Brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and the dorsal root ganglia.

* * * * *

Tallow derivative. Any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

* * * * *

■ 30. Section 95.4 is revised to read as follows:

§ 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), (d), (e), (f), or (g) of this section or in § 95.15, any of the materials listed in paragraph (b) of this section derived from animals, or products containing

such materials, are prohibited importation into the United States if paragraph (a)(1), (a)(2), or (a)(3) of this section applies:

(1) The animals have been in any region listed in paragraph (a)(4) of this section;

(2) The materials have been stored, rendered, or otherwise processed in a region listed in paragraph (a)(4) of this section; or

(3) The materials have otherwise been associated with a facility in a region listed in paragraph (a)(4) of this section.

(4) Albania, Andorra, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Canada, Croatia, the Czech Republic, Denmark, the Federal Republic of Yugoslavia, Finland, France, Germany, Greece, Hungary, the Republic of Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, the Former Yugoslav Republic of Macedonia, Monaco, Norway, Oman, the Netherlands, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

(b) *Restricted materials:* (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;

(2) Glands, unprocessed fat tissue, and blood and blood products;

(3) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal; or

(4) Derivatives of glands and blood and blood products.

(c) The import prohibition in paragraph (a) of this section does not apply if the following conditions are met prior to importation:

(1) The material is derived from one of the following:

(i) A nonruminant species and the material is not ineligible for importation under § 95.13 or § 95.14;

(ii) Cervids or camelids;

(iii) Bovines, and the material is not ineligible for importation under the conditions of § 95.5, § 95.6, § 95.7, § 95.8, § 95.9, § 95.10, or § 95.12; or

(iv) Ovines or caprines that have never been in any region listed in paragraph (a)(4) of this section.

(2) In any region other than Canada that is listed in paragraph (a)(4) of this section, 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 ovines or caprines that have been in any region that is listed in paragraph (a)(4) of this section.

(3) In Canada, 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 ovines and caprines that have been in any region other than Canada that is listed in paragraph (a)(4) of this section.

(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) If the facility processes or handles any material derived from mammals, inspection of the facility for compliance with the provisions of this section is conducted at least annually by a representative of the government agency responsible for animal health in the region, unless the region chooses to have such inspection conducted by APHIS. If APHIS conducts the inspections required by this section, 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.

(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 exporting region certifying that the conditions of paragraphs (c)(1) through (c)(5) of this section have been met.

(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 and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*.)

(d) Except as provided in paragraph (e) of this section and in § 95.15, serum from ovines or caprines that have been in any region listed in paragraph (a)(4) of this section is prohibited importation into the United States, except for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of BSE into the United States. Such serum 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.

(e) The importation of serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines or caprines that have been in any region listed in paragraph (a)(4) of this section, and collagen and collagen products that are derived from ovines or caprines and that would otherwise be prohibited under paragraphs (a) and (b) 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 and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*.); and

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

(f) Insulin otherwise prohibited under paragraphs (a) and (b) of this section may be imported 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. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/*

permits/). The application for such a permit must state the intended use of the insulin and the name and address of the consignee in the United States.

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) Offal that is otherwise prohibited under paragraphs (a) and (b) of this section because it is derived from ovines or caprines that have been in a region listed in paragraph (a)(4) of this section may be imported into the United States if the offal is derived from ovines or caprines from Canada that have not been in a region listed in paragraph (a)(4) of this section other than Canada, and the following conditions are met:

(1) 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.

(2) 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 exporting region, or issued by a veterinarian designated by the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (g)(1) of this section have been met; and

(3) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.25(c) of this subchapter.

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§§ 95.5 through 95.30 [Redesignated as §§ 95.16 through 95.41]

■ 31. Sections 95.5 through 95.30 are redesignated as §§ 95.16 through 95.41, respectively.

■ 32. New §§ 95.5 through 95.15 are added to read as follows:

Sec.

* * * * *

95.5 Processed animal protein derived from ruminants.

95.6 Offal derived from bovines.

95.7 Collagen derived from bovines.

95.8 Tallow derived from bovines.

95.9 Derivatives of tallow derived from bovines.

95.10 Dicalcium phosphate derived from bovines.

95.11 Specified risk materials.

95.12 Blood and blood products derived from bovines.

95.13 Importation from regions of negligible risk for BSE of processed animal protein derived from animals other than ruminants.

95.14 Importation from regions of controlled risk or undetermined risk for BSE of processed animal protein derived from animals other than ruminants.

95.15 Transit shipment of articles.

* * * * *

§ 95.5 Processed animal protein derived from ruminants.

The importation of ruminant-derived processed animal protein, or any commodities containing such products, is prohibited unless the conditions of this section are met:

(a) The exporting region is a region of negligible risk for BSE; and

(1) The product has not been commingled or contaminated with ruminant meat-and-bone meal or greaves from a region of controlled or undetermined risk for BSE; and

(2) The product must be derived from ruminants that were subject to a ban on the feeding of ruminants with meat-and-bone meal or greaves derived from ruminants if it is either:

(i) Exported from a region of negligible risk for BSE in which there has been at least one indigenous case of BSE; or

(ii) Derived from ruminants that were in a region of negligible risk for BSE in which there has been at least one indigenous case of BSE.

(b) The exporting region is a region of controlled or undetermined risk, the product is ruminant-derived processed animal protein other than ruminant meat-and-bone meal or greaves, and it has been demonstrated that the product has not been commingled or contaminated with ruminant meat-and-bone meal or greaves from a controlled or undetermined risk region.

(c) 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 exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state the exporting region and that the requirements of this section, as applicable, have been met.

(d) The person importing the processed animal protein obtains 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. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the processed animal protein and name and address of the consignee in the United States.

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§ 95.6 Offal derived from bovines.

Offal derived from bovines is prohibited importation into the United States unless it meets the requirements for the importation of meat, meat products, and meat byproducts in either § 94.19, § 94.20, or § 94.21, with the exception of the requirements in § 94.19(c), § 94.20(b), and § 94.21(b), respectively. The person importing the offal must obtain 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. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the offal and name and address of the consignee in the United States.

§ 95.7 Collagen derived from bovines.

(a) The importation of collagen derived from bovines is prohibited because of BSE unless:

(1) The collagen meets the requirements of either paragraph (b), (c), or (d), as well as the requirements of paragraph (e) of this section and all other applicable requirements of this part; or

(2) The collagen is authorized importation under paragraph (f) of this

section and meets all other applicable requirements of this part:

(b) The collagen is derived from hides and skins, provided the collagen has not been commingled with materials ineligible for entry into the United States.

(c) The collagen is derived from the bones of bovines that originated from a region of negligible risk for BSE.

(d) The collagen is derived from the bones of bovines that originated from a region of controlled or undetermined risk for BSE and meets the requirements of paragraphs (d)(1) through (d)(4) of this section:

(1) The bones from which the collagen was derived were derived from bovines that passed ante-mortem and post-mortem inspection;

(2) The bones from which the collagen was derived did not include the skulls of bovines or the vertebral column of bovines 30 months of age or older;

(3) The bones were subjected to a process that includes all of the following steps, or to a process at least as effective in reducing BSE infectivity:

(i) Degreasing;

(ii) Acid demineralization;

(iii) Acid or alkaline treatment;

(iv) Filtration; and

(v) Sterilization at 138 °C (280.4 °F) or greater for a minimum of 4 seconds; and

(4) The collagen has not been commingled with materials ineligible for entry into the United States.

(e) The collagen is accompanied to the United States by an original certificate signed by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (b), (c), or (d) of this section, as applicable, have been met and, for collagen other than that described in paragraph (b) of this section, must indicate the BSE risk classification of the exporting region.

(f) The Administrator determines that the collagen will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the collagen has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the collagen and the name and address of the consignee in the United States.

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§ 95.8 Tallow derived from bovines.

(a) The importation of bovine-derived tallow is prohibited unless:

(1) The requirements of either paragraph (b), (c), or (d), as well as the requirements of paragraph (e) of this section are met; or

(2) The requirements of paragraph (f) of this section are met.

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

(c) The tallow originates from a region of negligible risk for BSE; or

(d) The tallow originates from a region of controlled risk for BSE, is derived from bovines that have passed ante-mortem and post-mortem inspections, and has not been prepared using SRMs as defined for regions of controlled risk for BSE in § 92.1 of this subchapter.

(e) The tallow is accompanied to the United States by an original certificate signed by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (b), (c), or (d) of this section, as applicable, have been met and, for tallow other than that described in paragraph (b) of this section, must indicate the BSE risk classification of the exporting region.

(f) The Administrator determines that the tallow will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the tallow has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the tallow and the name and address of the consignee in the United States.

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§ 95.9 Derivatives of tallow derived from bovines.

(a) The importation of derivatives of tallow from bovines is prohibited unless the commodity meets the conditions of either paragraph (b), (c), (d), or (e) of this section as well as paragraph (f) of this section, or, alternatively, meets the conditions of paragraph (g) of this section.

(b) The commodity meets the definition of tallow derivative in § 95.1.

(c) The derivative is from tallow composed of a maximum level of insoluble impurities of 0.15 percent in weight.

(d) The derivative is from tallow that originates from a region of negligible risk for BSE.

(e) The derivative is from tallow that originates from a region of controlled risk for BSE, is derived from bovines that have passed ante-mortem and post-mortem inspections, and does not contain SRMs as defined for regions of controlled risk for BSE in § 92.1 of this subchapter.

(f) The tallow derivative is accompanied to the United States by an original certificate signed by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (b), (c), (d), or (e) of this section, as applicable, have been met and, for tallow derivatives other than those described in paragraph (b) or (c) of this section, must indicate the BSE risk classification of the exporting region.

(g) The Administrator determines that the tallow derivative will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the tallow derivative has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services,

National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the tallow derivative and the name and address of the consignee in the United States.

(Approved by the Office of Management and Budget under control number 0579–0393)

§ 95.10 Dicalcium phosphate derived from bovines.

(a) The importation of dicalcium phosphate derived from bovines is prohibited unless:

(1) The requirements of either paragraph (b), (c), or (d) and the requirements of paragraph (e) of this section are met; or

(2) The requirements of paragraph (f) of this section are met.

(b) The dicalcium phosphate contains no trace of protein or fat; or

(c) The dicalcium phosphate originates from a region of negligible risk for BSE; or

(d) The dicalcium phosphate originates from a region of controlled risk for BSE, is derived from bovines that have passed ante-mortem and post-mortem inspections, and does not contain SRMs as defined for regions of controlled risk for BSE in § 92.1 of this subchapter.

(e) The dicalcium phosphate is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must indicate the BSE risk classification of the exporting region and state that the requirements of paragraph (b) (c), or (d) of this section, as applicable, have been met.

(f) The Administrator determines that the dicalcium phosphate will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the dicalcium phosphate has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the dicalcium phosphate and the name and address of the consignee in the United States.

(Approved by the Office of Management and Budget under control number 0579–0393)

§ 95.11 Specified risk materials.

Notwithstanding any other provisions of this part, the importation of specified risk materials from controlled-risk regions or undetermined-risk regions for BSE, and any commodities containing such materials, is prohibited, unless the Administrator determines that the materials or other commodities will not come into contact with ruminants in the United States and can be imported under conditions that will prevent the introduction of BSE into the United States, and the person importing the materials or other commodities has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*). The application for such a permit must state the intended use of the materials and other commodities and the name and address of the consignee in the United States.

§ 95.12 Blood and blood products derived from bovines.

The importation of bovine blood and products derived from bovine blood is prohibited unless the following conditions and the conditions of all other applicable parts of this chapter are met:

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

(1) The blood was collected in a hygienic manner, as determined by the Administrator, that prevents contamination of the blood with SRMs; and

(2) 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.

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

(1) The blood was collected in a hygienic manner, as determined by the Administrator, that prevents contamination of the blood with SRMs; and

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

(c) The blood and blood products are accompanied to the United States by an original certificate that states that the conditions of this section have been met. The certificate must be issued by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so.

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§ 95.13 Importation from regions of negligible risk for BSE of processed animal protein derived from animals other than ruminants.

The importation from regions of negligible risk for BSE of processed animal protein derived from animals other than ruminants is prohibited importation into the United States unless the following conditions are met:

(a) The processed animal protein is not prohibited importation under § 95.4;

(b) The processed animal protein imported into the United States in accordance with this section is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so, that indicates that the material is derived from animals other than ruminants.

(c) 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. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*).

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§ 95.14 Importation from regions of controlled risk or undetermined risk for BSE of processed animal protein derived from animals other than ruminants.

The importation from regions of controlled risk or undetermined risk for BSE of processed animal protein derived from animals other than ruminants is prohibited importation into the United States unless the following conditions are met:

(a) The processed animal protein is not prohibited importation under § 95.4;

(b) Except as provided in paragraph (c) of this section, the processed animal protein does not contain and was not commingled with material derived from ruminants originating in a BSE controlled- or undetermined-risk region;

(c) For blood meal, blood plasma, and other blood products, the material does not contain and was not commingled with ruminant blood or blood products prohibited importation into the United States under this part.

(d) Inspection of the facility for compliance with the provisions of this section is conducted at least annually by a competent authority of the government agency responsible for animal health in the region, unless the region chooses to have such inspections conducted by APHIS. The inspections must verify either that:

(1) All steps of processing and storing the material are carried out in a facility that has not been used for the processing or storage of materials derived from ruminants originating in a BSE controlled- or undetermined-risk region; or

(2) The material is produced in a manner that prevents contamination of the processed animal protein with materials prohibited importation into the United States.

(e) If APHIS conducts the inspections required by paragraph (d) of this section, 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.

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

(g) The processed animal protein imported into the United States in accordance with this section is accompanied by an original certificate signed by a full-time, salaried veterinary officer of the national government of the exporting region, or issued by a veterinarian designated by the national government of the exporting region and endorsed by a full-time, salaried veterinary officer of the national government of the exporting region, representing that the veterinarian issuing the certificate was authorized to do so, that states that the processed animal protein is not of ruminant origin and that conditions of this section have been met.

(h) 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. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*).

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§ 95.15 Transit shipment of articles.

Articles that are otherwise prohibited importation into the United States in accordance with §§ 95.4 through 95.14 may transit air and ocean ports in the United States for immediate export if the conditions of paragraphs (a) through (c) of this section are met. Articles are eligible to transit the United States by overland transportation if the requirements of paragraphs (a) through (e) of this section are met.

(a) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed during the entire time that it is in the United States.

(b) Before such transit, the person moving the articles must notify, in writing, the inspector at both the place in the United States where the articles will arrive and the port of export. The notification must include the:

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

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

(3) Serial numbers of the sealed containers.

(c) The articles must transit the United States under Customs bond.

(d) The person moving the articles must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors. To apply for a permit, file a permit application on VS Form 16–3 (available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *http://www.aphis.usda.gov/animal_health/permits/*).

(e) The commodities must be eligible to enter the United States in accordance with §§ 95.4 through 95.14 and must be accompanied by the certification required by that section. Additionally, the following conditions must be met:

(1) The shipment must be exported from the United States within 7 days of its entry;

(2) The commodities may not be transloaded while in the United States, except for direct transloading under the supervision of an authorized inspector, who must break the seals of the national government of the exporting region 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; and

(3) A copy of the import permit required under paragraph (d) of this section must be presented to the inspector at the port of arrival and the port of export in the United States.

§ 95.16 [Amended]

■ 33. In newly redesignated § 95.16, footnote 1 is amended by removing the citation ''§ 95.30'' and adding ''§ 95.41'' in its place.

§ 95.17 [Amended]

■ 34. In newly redesignated § 95.17, the introductory text is amended by removing the citation ''§ 95.5'' and adding the citation ''§ 95.16'' in its place.

§ 95.18 [Amended]

■ 35. In newly redesignated § 95.18, the introductory text is amended by removing the citation ''§ 95.8'' and adding the citation ''§ 95.19'' in its place, and footnote 3 to paragraph (c) is amended by removing the citation

''§ 95.5'' and adding the citation ''§ 95.16'' in its place.

§ 95.19 [Amended]

■ 36. In newly redesignated § 95.19, the introductory text is amended by removing the citation ''§ 95.7'' and adding the citation ''§ 95.18'' in its place.

§ 95.20 [Amended]

■ 37. In newly redesignated § 95.20, the introductory text is amended by removing the citation ''§ 95.10'' and adding the citation ''§ 95.21'' in its place, and footnote 4 to paragraph (c) is amended by removing the citation ''§ 95.5'' and adding the citation ''§ 95.16'' in its place.

§ 95.21 [Amended]

■ 38. In newly redesignated § 95.21, the introductory text is amended by removing the citation ''§ 95.9'' and adding the citation ''§ 95.20'' in its place.

§ 95.23 [Amended]

■ 39. In newly redesignated § 95.23, the introductory text is amended by removing the citation to ''§ 95.11'' and adding the citation ''§ 95.22'' in its place.

§ 95.25 [Amended]

■ 40. In newly redesignated § 95.25, the introductory text is amended by removing the citation ''§ 95.16'' and adding the citation ''§ 95.27'' in its place.

§ 95.26 [Amended]

■ 41. Newly redesignated § 95.26 is amended by removing the citation ''§ 95.16'' and adding the citation ''§ 95.27'' in its place.

§ 95.27 [Amended]

■ 42. In newly redesignated § 95.27, the introductory text is amended by removing the citation ''§ 95.15'' and adding the citation ''§ 95.26'' in its place.

§ 95.28 [Amended]

■ 43. In newly redesignated § 95.28, the introductory text is amended by removing the citation ''§ 95.18'' and adding the citation ''§ 95.29'' in its place.

§ 95.29 [Amended]

■ 44. Newly redesignated § 95.29 is amended by removing the citation ''§ 95.17'' and adding the citation ''§ 95.28'' in its place.

§ 95.32 [Amended]

■ 45. Newly redesignated § 95.32 is amended by removing the citation ''§ 95.28'' and adding the citation ''§ 95.39'' in its place, and by removing the citation ''§ 95.22'' and adding the citation ''§ 95.33'' in its place.

§ 95.33 [Amended]

■ 46. Newly redesignated § 95.33 is amended by removing the citation ''§ 95.28'' and adding the citation ''§ 95.39'' in its place, and by removing the citation ''§ 95.21'' and adding the citation ''§ 95.32'' in its place.

§ 95.36 [Amended]

■ 47. In newly redesignated § 95.36, paragraphs (a) and (b) are amended by removing the citation ''§ 95.26'' both times it appears and adding the citation ''§ 95.37'' in their place.

■ 48. Newly redesignated § 95.40 is revised to read as follows:

§ 95.40 Certification for certain materials.

(a) In addition to meeting any other certification or permit requirements of this chapter, the following articles, if derived from ovines or caprines, may be imported into the United States from any region not listed in § 95.4(a)(4) 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;

(2) Glands and unprocessed fat tissue;

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

(4) Derivatives of glands; 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 § 95.4(a)(4), with the regions listed in § 95.4(a)(4) specifically named;

(4) That the material did not originate in, and was never stored, rendered, or processed in, or otherwise associated with, a facility in a region listed in § 95.4(a)(4); 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 § 95.4(a)(4).

(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.

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PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

■ 49. The authority citation for part 96 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.4.

■ 50. In § 96.2, paragraph (b) is revised and paragraph (c) is added to read as follows:

§ 96.2 Prohibition of casings due to African swine fever and bovine spongiform encephalopathy.

* * * * *

(b) *Casings from ovines or caprines.* The importation of casings, except stomachs, derived from ovines or caprines that originated in or were processed in any region listed in § 95.4(a)(4) are prohibited, unless the following conditions are met:

(1) The casings are derived from sheep that were slaughtered in Canada at less than 12 months of age and that were from a flock subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000; and

(2) The casings are accompanied by an original certificate that meets the requirements of § 96.3 and:

(i) States that the casings meet the conditions of this section;

(ii) Is written in English;

(iii) Is signed by an individual eligible to issue the certificate required under § 96.3; and

(iv) Is presented to an authorized inspector at the port of entry.

(c) *Casings from bovines.* The importation of casings derived from bovines is prohibited, unless the following conditions are met:

(1) If the casings are derived from bovines from a region of negligible risk for BSE, as defined in § 92.1 of this subchapter, the certificate required under § 96.3 indicates the APHIS BSE risk classification of the region in which the bovines were slaughtered and the casings were collected.

(2) If the casings are derived from bovines from a region of controlled risk for BSE or a region of undetermined risk for BSE, as defined in § 92.1 of this subchapter, the casings are not derived from the small intestine or, if the casings are derived from the small intestine, the casings are derived from that part of the small intestine that is eligible for use as human food in accordance with the requirements established by the Food Safety and Inspection Service at 9 CFR 310.22 and the Food and Drug Administration at 21 CFR 189.5.

(3) The casings are accompanied by an original certificate that meets the requirements of § 96.3 and paragraphs (b)(2)(i) through (b)(3)(iv) of this section.

* * * * *

■ 51. In § 96.3, paragraph (d) is revised to read as follows:

§ 96.3 Certificate for animal casings.

* * * * *

(d) In addition to meeting the requirements of this section, the certificate accompanying sheep casings from Canada must state that the casings meet the requirements of § 96.2(b) and the certificate accompanying bovine casings must state that the casings meet the requirements of either § 96.2(c)(1) or (c)(2) as applicable.

* * * * *

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

■ 52. The authority citation for part 98 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 53. Section 98.11 is amended by adding definitions of *camelid* and *cervid,* in alphabetical order, to read as follows:

§ 98.11 Definitions.

* * * * *

Camelid. All species of the family *Camelidae,* including camels, guanacos, llamas, alpacas, and vicunas.

Cervid. All members of the family *Cervidae* and hybrids, including deer, elk, moose, caribou, reindeer, and related species.

* * * * *

■ 54. In § 98.15, the introductory text of paragraph (a) is revised to read as follows:

§ 98.15 Health requirements.

* * * * *

(a) The donor dam is determined to be free of communicable diseases based on tests, examinations, and other requirements, as follows, except that, with regard to bovine spongiform encephalopathy, the following does not apply to bovines, cervids, or camelids.

* * * * *

Done in Washington, DC, this 19th day of November 2013.

Max T. Holtzman,

Acting Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2013–28228 Filed 12–3–13; 8:45 am]

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