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Bovine Spongiform Encephalopathy; Importation of Bovines and Bovine Products; Proposed Rule

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: Proposed rule.

SUMMARY: We are proposing to amend 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 proposing to base importation conditions on the inherent risk of BSE infectivity in specified commodities, as well as on the BSE risk status of the region from which the commodities originate. We are proposing to establish 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 proposing for the importation of specified commodities are based on internationally accepted scientific literature and, except in a few instances, are consistent with guidelines set out in the OIE's Terrestrial Animal Health Code. We are also proposing to classify certain specified countries as to BSE risk and are proposing to remove BSE restrictions on the importation of cervids and camelids and products derived from such animals. We are proposing to make these amendments after conducting a thorough review of relevant scientific literature and a comprehensive evaluation of the issues and concluding that the proposed changes to the regulations would 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. In this document we are also affirming the position we took in removing the delay of applicability of certain provisions of the rule entitled ''Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities,'' published in the **Federal Register** on January 4, 2005 (70 FR 460–553). The delay of applicability was removed in a final rule entitled ''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).

DATES: We will consider all comments that we receive on or before May 15, 2012.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2008-0010-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2008–0010, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0010* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

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) 851–3364.

For information regarding ruminant products and for other information regarding this proposed 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) 734–3277.

SUPPLEMENTARY INFORMATION:

I. Overview

Background

In order to guard against the introduction of animal diseases, the Animal and Plant Health Inspection Service (APHIS) 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 parts 92, 93, 94, 95, 96, and 98 of the U.S. Code of Federal Regulations (CFR) (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE), a chronic degenerative disease that affects the central nervous system of cattle. In this document we are proposing to amend the import regulations related to BSE.

Nature of BSE

BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. However, the distribution of infectivity in the body of the animal and mode of transmission differ according to the species and the TSE agent. In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease in deer and elk, and Creutzfeldt-Jakob disease in humans.

The agent that causes BSE has yet to be fully characterized. The theory that is most accepted in the international scientific community is that the agent is an abnormal form of a normal protein known as cellular prion protein. The BSE agent does not evoke a traditional immune response or inflammatory reaction in host animals. BSE is confirmed by post-mortem examination of an animal's brain tissue, which may include detection of the abnormal form of the prion protein in the brain tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is resistant to heat and to normal sterilization processes.

BSE is not a contagious disease, and therefore is not spread through casual contact between animals. Scientists believe that transmission is through ingestion of feed that has been contaminated with a sufficient amount of tissues or organs containing the BSE agent from an infected animal. This route of transmission can be prevented by excluding from ruminant feed tissues or organs that could potentially carry the BSE agent.

Other characteristics of the BSE agent, as evidenced by epidemiology, transmission studies, and pathogenesis are discussed in detail in a final rule APHIS published in the **Federal Register** on September 18, 2007 (72 FR 53314–53379, Docket No. APHIS–2006–0041) and in the supporting scientific

documentation that was prepared for this proposed rule. (The supporting scientific documentation can be accessed at the APHIS Web site at *http://www.aphis.usda.gov/newsroom/hot_issues/bse/downloads/RiskAssessment06–041–1%20.pdf).*

Roles of Different Agencies

APHIS, an animal health agency within USDA, promulgates its regulations regarding BSE under the authority of the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), which gives the Secretary broad discretion to regulate the importation of animals and animal products if necessary to protect the health of U.S. livestock.

Because variant Creutzfeldt-Jakob Disease (vCJD) in humans has been linked to exposure to the BSE agent, APHIS collaborates with other Federal agencies with regulatory responsibility for assuring food safety and the protection of human health to implement a comprehensive coordinated U.S. response to BSE. Within USDA, protecting human health from the risks of BSE is carried out by the Food Safety and Inspection Service (FSIS), the agency charged with responsibility for administering the Federal Meat Inspection Act, which was enacted to ensure that meat and meat food products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The USDA agencies carry out their programs in close coordination with the following Centers of the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services: The 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.

Rulemaking Regarding BSE

The protective measures the Federal Government has taken have evolved over the years, as scientific understanding of the disease has increased. In 1989, APHIS prohibited the importation of live cattle and other ruminants and certain ruminant products, including most rendered protein products, into the United States from countries where BSE is known to exist, and codified this prohibition in the CFR on April 30, 1991 (56 FR 19794–19796, Docket No. 90–252). The list of regions in which BSE is known to exist is set out in the current regulations in § 94.18(a)(1).

In June 1997, FDA prohibited the use of all mammalian protein—with the exception of pure pork and pure equine protein from single species processing plants and certain other materials—in animal feeds given to cattle and other ruminants, and established measures to protect against the contamination of ''allowable'' feed material with materials that could contain the BSE agent. We discuss this and other FDA actions regarding BSE in this document under the heading ''Evolution of U.S. Regulatory Response to BSE.''

In rulemaking made effective December 12, 1997, and published in the **Federal Register** on January 6, 1998, APHIS added to the regulations a category of regions that pose an undue risk of introducing BSE into the United States. In the rulemaking document establishing that category (63 FR 406–408, Docket No. 97–127–1), we explained that our decision to add the category was based on developments that led us to believe that, at the time, the BSE agent might have been present but as yet undetected throughout Europe. We noted that the Netherlands, Belgium, and Luxembourg had recently reported their first case of BSE in native-born cattle. Additionally, we noted that Belgium and Luxembourg had reported that cattle diagnosed with BSE had inadvertently been processed into the animal food chain. We concluded that, because of the movement of ruminants and ruminant products within Europe, the possibility existed that this potentially contaminated animal feed might have been moved to other European countries.

In our 1997 rulemaking, we applied the same import prohibitions and restrictions to regions of undue risk for BSE that were being applied to regions listed as those in which BSE is known to exist. The list of regions of undue risk for BSE is set out in the current regulations in § 94.18(a)(2). Imports from any region not listed in either of those two categories were not subject to any BSE prohibitions or restrictions.

In December 2000, APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species because of concern that cattle feed supposedly free of ruminant protein may have been cross-contaminated with the BSE agent (66 FR 42595–42601, Docket No. 00–121–1). FDA also issued import alerts on animal feed ingredients for APHIS-listed countries.

On November 4, 2003, APHIS published a proposed rule in the **Federal Register** (68 FR 62386–62405, Docket No. 03–080–1) in which we proposed to establish a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products and byproducts, and to add Canada to this category. The proposal also set forth conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions.

In the November 2003 proposal, we set forth factors that would be taken into account in determining whether a country qualified as a BSE minimal-risk region. According to our proposed definition of a BSE minimal-risk region, such measures would include importation restrictions, surveillance, and a feed ban. With regard to a feed ban, we proposed that, to be recognized as a BSE minimal-risk region, a country must have in place a ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

On December 25, 2003, less than 2 weeks before the close of the comment period for the proposed rule, a case of BSE in a dairy cow of Canadian origin in Washington State was verified by an international reference laboratory. Subsequently, both FSIS and FDA implemented significant additional measures in the United States to protect human health. In addition, APHIS commenced an enhanced BSE surveillance program to determine the incidence of the disease in the United States.

The measures taken by Federal agencies in January 2004 led to a change in APHIS' November 2003 proposed rule. Among the actions taken by FSIS to supplement its measures to prevent the BSE agent from entering the human food supply was to designate as specified risk materials (SRMs) certain tissues from cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, and to prohibit their use as human food. FSIS also required all slaughtering and processing establishments to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. FSIS did not restrict the age of cattle eligible for slaughter, because the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass

both ante-mortem and post-mortem inspections (i.e., apparently healthy cattle). (We discuss below additional BSE-related regulatory actions taken by FSIS and FDA under the heading ''Evolution of U.S. Regulatory Response to BSE.'')

The risk mitigation measures that FSIS implemented regarding slaughtered cattle had ramifications for the importation of bovine-derived meat from other countries. Pursuant to the Federal Meat Inspection Act, countries that export meat to the United States must implement food safety requirements that are equivalent to those in place in the United States. To be eligible to export beef to the United States, a country must have in place a system to effectively keep SRMs out of the production chain and to prevent cross-contamination of beef with SRMs. FSIS determined the SRM requirements implemented by Canada in July 2003 to be equivalent to FSIS' requirements. Additionally, FDA's feed ban prohibits most mammalian protein, including ruminant protein, from entering the ruminant feed chain in the United States.

On March 8, 2004, APHIS published a document in the **Federal Register** (69 FR 10633–10636, Docket No. 03–080–2) explaining the effects on our proposed rule of the detection of BSE in the State of Washington in a cow imported from Canada and of the additional measures taken by FSIS, APHIS, and FDA. That document explained why the detection of an imported BSE-infected cow did not alter the conclusions we had reached in our original risk assessment. It explained further that, in fact, the resulting additional measures put in place by FSIS provided a basis for removing from the proposed provisions an age restriction on cattle from which meat would be derived for export to the United States. Accordingly, we proposed to allow the importation of beef derived from cattle of any age. To give the public additional time to comment on the proposal in light of these developments, we reopened and extended the comment period for an additional 30 days.

On January 4, 2005, APHIS published in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) a final rule that established the criteria for BSE minimal-risk regions, listed Canada as a BSE minimal-risk region, and specified importation requirements for live animals, and meat products and byproducts. The final rule allowed the importation of meat from bovines of any age, as we had proposed on March 8, 2004. The final rule was scheduled to become effective on March 7, 2005.[1]

In January 2005, BSE was confirmed in two cows in Canada.

On March 11, 2005, APHIS published a document in the **Federal Register** (70 FR 12112–12113, Docket No. 03–080–6) that, pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, delayed the applicability of the provisions of the January 2005 final rule as they applied to the importation from Canada of certain commodities, including meat, meat food products, and meat byproducts other than liver when derived from bovines 30 months of age or older when slaughtered. We discuss the delay of applicability in more detail, below.

On August 18, 2005, APHIS published in the **Federal Register** (70 FR 48494–48500, Docket No. 05–004–1) a proposed rule to amend the regulations by allowing, under certain conditions, the importation of whole cuts of boneless beef from Japan.

On November 28, 2005, APHIS published in the **Federal Register** an interim rule (70 FR 71213–71218, Docket No. 03–080–8) that amended certain provisions established by the January 2005 final rule. The interim rule broadened the list of who is authorized to break seals on conveyances and allows transloading under supervision of products transiting the United States.

On December 14, 2005, APHIS published a final rule in the **Federal Register** (70 FR 73905–73919, Docket No. 05–004–2) that made final its August 2005 proposed rule regarding certain cuts of boneless beef from Japan. The risk assessment conducted for that rulemaking examined the evidence supporting the safety of this commodity. This evidence and APHIS' conclusions were consistent with those of the World Organization for Animal Health (OIE) for trade in meat derived from cattle from regions of controlled risk for BSE. (The risk document, ''Analysis of Bovine Spongiform Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan,'' can be accessed at *http://www.regulations.gov/#!documentDetail;D=APHIS-2005-0073-0002).* The OIE is the international standard-setting organization for guidelines related to animal health.

On March 14, 2006, APHIS published in the **Federal Register** a technical amendment (71 FR 12994–12998, Docket No. 03–080–9) that clarified our intent with regard to certain provisions in the January 2005 final rule and corrected several inconsistencies within the rule.

On August 9, 2006, APHIS published in the **Federal Register** a proposed rule (71 FR 45439–45444, Docket No. APHIS–2006–0026) that proposed to amend the provisions established by the January 2005 final rule by removing several restrictions regarding the identification of animals and the processing of ruminant materials from BSE minimal-risk regions, and by relieving BSE-based restrictions on hide-derived gelatin from BSE minimal-risk regions. We solicited comments concerning our proposal for 60 days ending October 10, 2006. On November 9, 2006, we published a document in the **Federal Register** (71 FR 65758–65759, Docket No. APHIS–2006–0026) reopening and extended the comment period until November 24, 2006.

On January 9, 2007, APHIS published a proposed rule in the **Federal Register** (72 FR 1101–1129, Docket No. APHIS–2006–0041) that proposed to establish conditions for the importation of the following commodities from BSE minimal-risk regions: Live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export;[2] blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines.

On September 18, 2007, APHIS published in the **Federal Register** (72 FR 53314–53379, Docket No. APHIS–2006–0041) a final rule that adopted the

[1] On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of APHIS' January 4, 2005, final rule be preliminarily enjoined. On July 14, 2005, the U.S. States Court of Appeals for the Ninth Circuit ordered that the preliminary injunction order be vacated and the case remanded to the District Court.

[2] Requiring that live bovines exported to the United States from BSE minimal-risk regions be born after the date of effective enforcement of a ruminant-to-ruminant feed ban is consistent with the OIE standards for the exportation of live bovines from countries classified by the OIE as having either a negligible or a controlled BSE risk. We consider effective enforcement to have been achieved after completion of the initial (or practical) period of implementation of a feed ban and after sufficient time has elapsed to allow most feed products to cycle through the system. The practical implementation period, which begins when the regulations are initially put in place, can be determined by evaluating implementation guidance and policies, such as allowing grace periods for certain aspects of the industry. In addition, the time necessary for initial education of industry and training of inspectors must be considered. After the practical implementation period is defined, we then consider the time necessary subsequent to practical implementation to allow most feed products to cycle through the system, given the management practices in the country. Effective enforcement does not necessarily mean that 100 percent compliance with the feed ban requirements will be achieved.

changes to the regulations we had proposed in January 2007. Additionally, the September 2007 final rule removed the partial delay of applicability of the January 2005 final rule with respect to meat and certain meat products and byproducts derived from cattle over 30 months of age.

On January 18, 2008, APHIS published in the **Federal Register** a final rule (73 FR 3379–3385, Docket No. APHIS–2006–0026) that made final the provisions of our August 9, 2006, proposed rule, with some changes.

On July 3, 2008, Judge Lawrence L. Piersol of the U.S. District Court for the District of South Dakota, in response to a motion filed in that Court, ordered USDA to provide the public with notice and a further opportunity to comment on the provisions of our January 2005 final rule regarding the importation of beef from bovines 30 months of age or older when slaughtered, to consider comments made by interested parties, and to revise the rule as USDA deems necessary.

On September 18, 2008, APHIS published a request for comments in the **Federal Register** (73 FR 54083–54089), in which we provided the public with such notice and further opportunity to comment. We solicited comments for 60 days ending November 17, 2008.

In this document, we discuss the issues raised by commenters in response to our September 2008 request for comments and provide our responses to those comments. Following that discussion, we describe and discuss changes we are proposing to make to the APHIS BSE regulations. However, in order to present our responses to the comments and the changes we are proposing in the context of the available scientific research and empirical data regarding the transmission of BSE, we consider it necessary to first discuss what is known regarding SRMs and the role of feed bans in reducing BSE risk.

Tissue Localization

Some bovine tissues have demonstrated infectivity, whereas others have not. Most of the information on the development and distribution of tissue infectivity in BSE-infected cattle has been derived from experimental pathogenesis studies conducted in the United Kingdom and Germany (Wells, *et al.,* 1994; 1996; 1998; 1999; 2005; EFSA 2007; Hoffman 2007; Hoffman 2011). In these studies, cattle were deliberately infected with BSE through oral exposure to the brain tissue of cattle with confirmed BSE. Subsets of the experimentally infected cattle were killed at regular intervals as the disease progressed. At each interval, the tissues of the infected cattle were examined for histopathological changes consistent with BSE and for abnormal prion proteins. Also, at each interval, a mouse assay was done—i.e., tissues of the BSE-infected cattle were injected intracerebrally and intraperitoneally into different types of mice (e.g., wild mice and mice genetically altered to be highly susceptible to BSE) to identify those tissues of cattle containing infectivity.

The first United Kingdom pathogenesis studies involved 30 animals, each of which received a single dose of 100g of infected brain at 4 months of age (Wells, *et al.,* 1994; 1996; 1998; 1999; 2005). This dose is probably 10–100 times greater than that associated with field exposure via feed (DEFRA, 2006). The studies demonstrate that in cattle infected with BSE, the total amount of infectivity in the animal, as well as the distribution of infectivity in the animal's body, changes over time (Wells, *et al.,* 1994; 1996; 1998; 1999; 2005). The highest levels of infectivity were detected in the brain and spinal cord at the end stages of disease. Some cattle exhibited clinical signs of BSE as early as 35 months after oral exposure to the BSE agent. By 37 months after oral exposure, all five animals that were still alive demonstrated clinical evidence of BSE. Infectivity was found in cattle with clinical signs of BSE in the brain, spinal cord, DRG,[3] trigeminal ganglia, and the distal ileum of the small intestine.

BSE infectivity was demonstrated in the brain, spinal cord, and DRG as early as 32 months after oral exposure to the BSE agent in some cattle (Wells, *et al.,* 1994; 1996; 1998; 1999; 2005). Infectivity was demonstrated in these tissues 3 months before animals began to develop clinical signs of the disease. Infectivity was demonstrated in the distal ileum of cattle 6 to 18 months after oral exposure to the BSE agent and again at 38 months and 40 months after oral exposure. A similar study (Espinosa, *et al.,* 2007) examined the infectivity of tissues from these same animals by intracerebral inoculation of highly sensitive transgenic mice overexpressing bovine PrP (prion protein). This study's findings were similar to those of Wells, *et al.,* described above. In addition, infectivity in the sciatic nerve was found at low levels only after 30 months from exposure. No detectable infectivity was found in the spleen, skeletal muscle, blood, or urine of asymptomatic cattle.

As explained by the United Kingdom's Department for Environment, Food and Rural Affairs (DEFRA) and by the European Commission's Scientific Steering Committee, a second phase of the pathogenesis studies, which used a cattle bioassay as an endpoint, was conducted to ensure that low levels of infectivity that may not have been detected in the first phase using the mouse bioassay were not missed (DEFRA, 2006; EC SSC 2002). This second phase of the study was completed in March 2007 (Gerald Wells, personal communication, 2008).

In the cattle bioassay, tissues from the same cattle orally exposed to BSE in the earlier pathogenesis studies were injected directly into the brain of BSE-free cattle (DEFRA, 2006). This method is considered to be several hundred-fold more sensitive in detecting BSE infectivity than the mouse bioassay (DEFRA, 2006). Preliminary results from the cattle bioassay study demonstrate that, in addition to the materials that were found to contain infectivity when the mouse bioassay was used, the tonsils of calves 10 months after oral exposure to the BSE agent also contain infectivity. However, because only one of five animals injected with tonsil material from infected animals developed clinical BSE at 45 months post-inoculation, the level of infectivity in the tonsils appears to be very low.

BSE infectivity has not been demonstrated in the muscle tissue of BSE-infected cattle examined in these studies through either the mouse bioassay or the cattle assays (Wells 1996; 2005; personal communication 2008). All assays of the skeletal muscle pools were completed in March 2007 (Wells, personal communication 2008).

A larger pathogenesis study conducted in Germany involved calves that were orally challenged with macerated brainstems from BSE-positive cattle (EFSA 2007; Hoffman 2007). Every 4 months, randomly selected animals are euthanized and necropsied, and more than 150 tissue and bodily fluid samples are collected from each animal and analyzed by immunohistochemistry, pure-tone average Western blot, and transgenic mouse bioassay (TgbovXV). The initial results from the German BSE pathogenesis study demonstrate that BSE prions can reach the brain as soon as 24 months after a massive oral challenge (Hoffman 2007).

In addition to these studies on experimentally infected cattle,

[3] DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. ''DRG'' as used in this document has the same meaning as the term ''dorsal spinal nerve root ganglia.'' Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.

distribution of tissue infectivity has also been studied in cattle exposed to BSE under field conditions. In these animals, at the end stages of the incubation period with demonstrated clinical signs, BSE infectivity has been confirmed by mouse bioassay only in the brain, spinal cord, and retina of the eye (EC SSC 2001).

In a 2005 study, mice genetically engineered to be highly susceptible to BSE and to overexpress the bovine prion protein were inoculated with tissues from an end-stage clinically affected BSE-infected cow (Buschmann and Groschup, 2005). The sensitivity of these mice to infection is significantly greater than other mice panels used in bio-assays, and the sensitivity is even greater than that of cattle by approximately tenfold. Using these highly sensitive mice, this study demonstrated low levels of infectivity in the facial and sciatic nerves of the peripheral nervous system of the cow. While this study, and the 2007 study by Espinosa, *et al.,* produced interesting findings that can help further characterize the pathogenesis of BSE, they cannot be extrapolated into the context of the risk presented by natural (i.e., field) exposure pathways. The findings may be influenced by the overexpression of prion proteins in these genetically engineered mice. Any apparent levels of infectivity are low in these extremely sensitive mice and would be even lower in other species such as cattle. Moreover, the route of administration to the mice was both intraperitoneal and intracerebral, both of which are very efficient routes of infection as compared to oral consumption.

Tissues that have demonstrated infectivity, and thus are likely to contain the infectious BSE agent in infected cattle, are brain, tonsil, spinal cord, eyes, trigeminal ganglia, DRG, and distal ileum. Approximately 90 percent of the infectivity is associated with the brain, spinal column, DRG, and trigeminal ganglia. The remaining 10 percent is associated with the infectivity in the distal ileum. In BSE, as with other TSEs, the total amount of infectivity in an animal increases throughout the incubation period, reaching the highest load at the end of that period, very close to the death of the animal. Infectivity is considered to increase exponentially, reaching 4.5 logs less than a clinical case at 50 percent of the incubation period and 3 logs less than a clinical case by 70 percent of the incubation period (Comer and Huntly, 2003).

All of this research has contributed to the definition of which tissues should be considered SRMs. Both the types of tissues and the understanding of the progression of the infectivity throughout the incubation period contribute to the definition of SRMs. Affiliated tissues or structures such as skull or vertebral column are also considered risk materials because of the difficulty in separating out small tissues such as DRG from the vertebral column. The risks associated with tissue localization can be mitigated by excluding SRMs from the food or feed chain or by excluding them completely from importation. FSIS and FDA regulations regarding SRMs, which we discuss below under the heading ''Evolution of U.S. Regulatory Response to BSE,'' are based on this scientific knowledge and an understanding of the mitigative effects of exclusion of SRMs (FSIS, 2004; 2004a; 2004b; 2005; 2007; FDA, 2004; 2005; 2007; 2008).

The measures taken by FSIS included declaring SRMs to be inedible and requiring their removal from cattle at slaughter. As noted above, even if a BSE-infected cow 30 months or older that was presented for slaughter were not exhibiting clinical signs of the disease and passed ante-mortem and post-mortem inspections, the removal of SRMs from the cow would effectively mitigate the BSE risk to humans.

Within USDA, APHIS and FSIS review and consider carefully, on an ongoing basis, all BSE research regarding the definition of SRMs, as do other countries that participate in the OIE. U.S. regulations regarding SRM removal are consistent with international guidelines.

Feed Bans

As noted, scientists believe that the route of field transmission in animals is through ingestion of feed that has been contaminated with tissues or organs containing the BSE agent from an infected animal. This route of transmission can be prevented by excluding potentially contaminated materials from ruminant feed.

Experience internationally in countries with BSE has demonstrated that feed bans are effective control measures and that the incidence of BSE worldwide continues to decline because of these measures (OIE, 2010). In the United States, prohibitions on the use of ruminant protein in ruminant feed are imposed by FDA to mitigate the risk of BSE transmission.

Because of the demonstrated efficacy of an effectively enforced feed ban in reducing the possibility of exposure of cattle to the BSE agent, the OIE provides guidelines for trade in live cattle from regions that have reported BSE if such regions have an effective feed ban in place, provided the cattle were born after the date when the feed ban was effectively enforced.

By eliminating transmission, an effective feed ban reduces the possibility of the existence of infected animals in a given cattle population, which in turn reduces further the chances of healthy animals being exposed to the BSE agent via subsequent recycling of infectivity.

September 2008 Request for Comments

As we discussed earlier in this document, the final rule that APHIS published in January 2005 to establish criteria for BSE minimal-risk regions, list Canada as a BSE minimal-risk region, and specify importation requirements for live animals, and meat products and byproducts was the outcome of a rulemaking process that APHIS initiated in 2003 to update its BSE regulations to reflect the latest scientific data and knowledge of the disease.

As discussed above, in our November 2003 proposal, we set forth factors that would be taken into account in determining whether a country qualified as a BSE minimal-risk region. According to our proposed definition of a BSE minimal-risk region, such measures would include importation restrictions, surveillance, and a feed ban. With regard to a feed ban, we proposed that, to be recognized as a BSE minimal-risk region, a country must have in place a ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

We explained the role a feed ban plays in reducing BSE risk, stating that the primary source of BSE infection is feed contaminated with the infectious agent, that scientific evidence shows that feed contamination results from the incorporation of ingredients that contain abnormal ruminant protein derived from specific tissues from infected animals, and that bans prohibiting incorporation of ruminant protein into ruminant feed are imposed to mitigate risk (Wilesmith, *et al.,* 1988; 1991; 1992).

In subsequent rulemaking documents, we elaborated further on the role and effect of a feed ban. In our January 2007 proposed rule, which we described earlier in this document, we discussed data associated with a ruminant-to-ruminant feed ban in the United Kingdom and indicated that experience in the United Kingdom demonstrates that implementation of a ruminant-to-ruminant feed ban causes BSE

prevalence to decrease. We noted that as a result of reducing the recycling of infectivity in the United Kingdom, the annual incidence of BSE fell by 99.4 percent, from 36,680 animals in 1992 to 203 in 2005 (DEFRA 2006a) and concluded that there is every reason to expect downward pressure on the prevalence of BSE in any country that implements a feed ban.

The conditions for the importation of ruminant products and byproducts from BSE minimal-risk regions that we proposed in November 2003 were proposed as changes to parts 94 and 95 of the regulations. The commodities addressed by the proposed changes to part 94 included meat and other edible products derived from ruminants. Part 95 addressed the importation of byproducts derived from ruminants.

Changes Regarding the Importation of Meat From Bovines Proposed in November 2003

As set forth in our November 2003 proposed rule, the provisions in part 94 for the importation of meat derived from bovines from BSE minimal-risk regions required that the following conditions be met:

- The meat is derived from bovines that were less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime;
- The bovines from which the meat is derived were slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the APHIS Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States;
- The intestines of the bovines were removed at slaughter; and
- The product qualifies as meat under the definition of *meat* in the FSIS regulations at 9 CFR 301.2.

As noted, one of the conditions for the importation of bovine-derived meat from BSE minimal-risk regions was that the bovines from which the meat is derived be less than 30 months of age when slaughtered. The relevance of the age of the animal to the risk of BSE, which we explained earlier in this document under the heading ''Tissue Localization,'' pertains to which tissues in a BSE-infected bovine have been demonstrated to contain BSE infectivity and the age at which a BSE-infected animal has been found to show infectivity in those tissues. In essence, as we stated in our November 2003 proposed rule, the proposed restriction on the age of the animals from which the commodity was derived was a measure to guard against the importation of, or contamination of meat through contact with, SRMs.

As noted above, after a BSE-infected cow of Canadian origin was discovered in Washington State in December 2003, both FSIS and FDA implemented significant additional measures in the United States to protect human health. Among the measures taken by FSIS and FDA was to declare SRMs to be inedible and require their removal from cattle at slaughter. FSIS 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 DRG of cattle 30 months of age or older, and the tonsils and distal ileum of the small intestine of all cattle. To ensure effective removal of the distal ileum, FSIS also required all slaughtering and processing establishments to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments were specifically required to implement procedures to address the potential contamination of edible materials with SRMs before, during, and after entry into the establishment. As noted above, FSIS did not restrict the age of cattle eligible for slaughter. Even if a BSE-infected cow 30 months or older that was presented for slaughter were not exhibiting clinical signs of the disease and passed ante-mortem and post-mortem inspections, the removal of SRMs from the cow would effectively mitigate the BSE risk to humans.

As discussed above, pursuant to the Federal Meat Inspection Act, implementation in the United States of those mitigation measures by FSIS meant that any country seeking to export beef to the United States would have to have equivalent mitigation measures in place. FSIS determined the SRM requirements implemented by Canada in July 2003 to be equivalent to FSIS' requirements.

As noted above, in March 2004, APHIS published a proposed rule and reopening of comment period in the **Federal Register** in which we explained why the detection of an imported BSE-infected cow did not alter the conclusions we had reached in the assessment of risk on which our November 2003 proposed rule was based. We explained further that, in fact, the resulting additional measures put in place by FSIS (i.e., declaring SRMs to be inedible and requiring their removal from cattle at slaughter) provided a basis for our removing from the provisions we had proposed in November 2003 the age restriction on cattle from which meat could be derived for export to the United States. In the March 2004 proposed rule and reopening of comment period, we stated that we did not believe it was necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided measures equivalent to those established by FSIS in the United States to ensure that SRMs are removed when the animals are slaughtered are in place in the exporting country and that such other measures as are necessary are in place.

As noted above, in January 2005 we published in the **Federal Register** a final rule that established the criteria for BSE minimal-risk regions, listed Canada as a BSE minimal-risk region, and specified conditions for the importation from BSE minimal-risk regions for live animals and meat, meat byproducts, and meat food products. For the reasons we discussed in our March 8, 2004, **Federal Register** document, the final rule did not limit the importation of bovine-derived meat from Canada to that derived from cattle younger than 30 months of age. In the final rule, we set forth in part 94 the following conditions for the importation from BSE minimal-risk regions of meat, meat byproducts, and meat food products derived from bovines:

- The bovines from which the meat, meat byproduct, or meat food product is derived have been subject to a ruminant feed ban equivalent to the requirements established by the U.S. Food and Drug Administration at 21 CFR 589.2000;
- The meat, meat byproduct, or meat food product is derived from bovines for which an air-injected stunning process was not used at slaughter; and
- The SRMs and small intestine of the bovines were removed at slaughter.

As noted above, in March 2005, APHIS published a document in the **Federal Register** that, pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, delayed the applicability of the provisions of the January 2005 final rule as they applied to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver; (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin

derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

In his February 9, 2005, announcement, the Secretary stated that, because ongoing investigations into the January 2005 finds of BSE in Canada in animals over 30 months of age were not complete, he felt it prudent to delay the effective date for allowing imports of meat from bovines 30 months of age and over. He also indicated that the delay of applicability would address concerns that the January 2005 final rule allowed the importation of meat from bovines 30 months of age or older while continuing to prohibit the importation of live cattle 30 months of age or older for processing in the United States. The Secretary stated that the Department would consider and develop a plan—based on the latest scientific information and with the protection of public and animal health as the highest priority—to allow imports of live bovines 30 months of age or older.

As discussed earlier in this document, in January 2007 we published a proposed rule in the **Federal Register** to, among other things, establish conditions for the importation from BSE minimal-risk regions of live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export.

As noted above, in September 2007, we published a final rule in the **Federal Register** that adopted the changes to the regulations we had proposed in January 2007. Additionally, the September 2007 final rule removed the partial delay of applicability of the January 2005 final rule with respect to meat and certain meat products and byproducts derived from cattle over 30 months of age that we addressed in our March 2005 notice. In our September 2007 final rule, we stated that, subsequent to implementation of the partial delay of applicability, ''we [had] obtained additional information regarding all aspects of the issues that prompted the delay of applicability and [had] conducted additional analyses'' as indicated by the Secretary in February 2005 to allow imports of live bovines 30 months of age or older (72 FR 53316).

As we concluded in our September 2007 final rule, the risk assessment for that final rule demonstrates the negligible BSE risk from the importation of additional classes of live bovines, including those 30 months of age or older.

II. Issues Raised in Response to Request for Comments

The September 2007 final rule, which included the removal of the partial delay of applicability of the provisions of the January 2005 rule relating to meat derived from cattle 30 months of age or older, became effective on November 19, 2007.

As noted above, on September 18, 2008, we published in the **Federal Register** a document that provided the public with notice and further opportunity to comment on the provisions of our January 2005 final rule regarding the importation from BSE minimal-risk regions of beef from bovines 30 months of age or older when slaughtered, for which the delay of applicability was removed in our September 2007 final rule. We solicited comments for 60 days ending November 17, 2008.

We received 12 comments by that date, including one submission that included a compilation of comments from a large number of individuals. The comments were from individual private citizens; associations of producers of livestock and other agricultural commodities, both in the United States and Canada; associations of meat processors; a consumer organization; and the Government of Canada. We carefully considered all comments received and we discuss in the following section the issues raised by the commenters and our response to those issues.

Comments in Support of the Removal of the Delay of Applicability

Five of the comments expressed support for the removal of the delay of applicability of provisions of our January 2005 final rule.

The remainder of the commenters opposed the removal of delay of applicability. Of those commenters, several provided no information to support their opposition. Others expressed general concern that allowing the importation of bovines and commodities derived from bovines from BSE minimal-risk regions would create an unacceptable disease risk. We discuss in the following section specific issues raised by commenters who opposed the removal of delay of applicability.

Meat Derived From Bovines Less Than 30 Months of Age

As noted above, one of the import conditions in the November 2003 proposed rule was that meat imported from bovines slaughtered in BSE minimal-risk regions be derived from bovines less than 30 months of age when slaughtered. Also as noted, in March 2004 we published a proposed rule and a reopening of the comment period for the November 2003 proposed rule. We explained in that document that we believed BSE risk mitigation measures implemented by FSIS subsequent to our November 2003 proposed rule provided a basis for removing from the proposed provisions the requirement that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, with the provision that equivalent measures are in place to ensure that SRMs are removed when the animals are slaughtered and that such other measures as are necessary are in place.

Issue: In our September 2008 request for comments, we included a chronology of the relevant rulemaking documents that had preceded the request for comments and referenced our March 2004 proposed rule and reopening of the comment period for the November 2003 proposed rule. One commenter stated that, in our September 2008 document, we mischaracterized our March 2004 proposed rule and reopening of the comment period as proposing to allow the importation from BSE minimal-risk regions of beef derived from cattle of any age. The commenter stated that the March 2004 proposed rule and reopening of the comment period 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.

Response: When we stated in our September 2008 request for comments that our March 2004 proposed rule and reopening of the comment period proposed to allow the importation of beef derived from cattle of any age, our intent was to explain that, under the provisions of the March 2004 proposed rule and reopening of the comment period, the fact that bovines from which meat and meat products intended for importation into the United States from a BSE minimal-risk region were 30 months of age or older when slaughtered would not in itself preclude the commodities from being imported. 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 (APHIS, 2004).

Issue: One commenter noted that the risk assessment APHIS conducted for its January 2005 final rule identified as a requirement for the importation of bovine-derived meat and meat products from a BSE minimal-risk country that veterinary officials in the exporting country certify that the animals from which the meat and meat products were derived were subject to a feed ban considered equivalent to that in place in the United States. The commenter also noted that APHIS' November 2003 proposed rule included a requirement that bovine-derived meat imported from a BSE minimal-risk region be derived from bovines that were not known to have been fed ruminant protein, other than milk protein, during their lifetime.

The commenter noted, further, that, in APHIS' September 2008 request for comments, we stated that, with respect to the importation of meat, the 30-month age restriction contained in our November 2003 proposed rule was a measure to guard against the importation of, or contamination of meat through contact with, tissues other than meat that have the potential of containing high levels of BSE infectivity. According to the commenter, that wording mischaracterized APHIS' rationale in the November 2003 proposed rule regarding the 30-month age restriction on bovines from which meat and meat products were derived. The commenter stated that APHIS' true intention regarding the 30-month age restriction was to prevent the importation of products derived from Canadian cattle that had been exposed to BSE infectivity.

The commenter cited text from the risk assessment conducted for APHIS' 2005 final rule that stated that the risk of introducing BSE infectivity can be reduced by requiring that animals presented for export and animals from which meat or meat products intended for export were derived were subject to a ruminant feed ban. Additionally, the commenter cited text from (1) APHIS' November 2003 proposed rule that stated that animals, and the products derived from those animals, will present a lower risk if the animals were born after the implementation of an effective feed ban and (2) from the risk assessment APHIS conducted for its January 2005 final rule that stated that, in addition, Canadian cattle less than 30 months of age would have been born and raised during a time when the Canadian feed ban had been in place for more than 5 years, and, based on evidence of a high level of compliance with the feed ban, are unlikely to have been exposed to the BSE agent.

The commenter discussed APHIS' provisions regarding two specific products derived from bovines—tongues and liver—to support the commenter's contention that APHIS' true intent regarding the 30-month age restriction on bovines from which meat and meat products are derived was to prevent the importation of products derived from Canadian cattle that had been exposed to BSE infectivity, rather than to guard against the importation of, or contamination of meat through contact with, tissues other than meat that have the potential of containing high levels of BSE infectivity.

With regard to tongues, the commenter stated that APHIS' November 2003 proposed rule would have allowed the importation of bovine tongues, even tongues derived from cattle 30 months of age or older, despite the fact that APHIS acknowledged that tongues are connected to and bear the risk of contamination by tonsils, which the commenter stated have the potential of containing high levels of BSE infectivity. The commenter stated that, to mitigate this risk, APHIS proposed to require that tongues be derived from cattle from which the tonsils were removed at slaughter and that were born after the implementation of an effective feed ban and were not known to have been fed ruminant protein, other than milk protein, during their lifetime.

The commenter pointed to a similar situation regarding bovine-derived liver from BSE minimal-risk regions. The commenter stated that APHIS' November 2003 proposed rule would have allowed the importation of liver that was not subject to the 30-month age restriction, even though, according to APHIS, it was susceptible to contamination by brain emboli, tissues that have the potential of containing high levels of BSE infectivity. The commenter noted that, in APHIS' November 2003 proposed rule, the only mitigation of the potential for the contamination of liver by the BSE agent was the requirement that the liver not be derived from cattle for which an air-injected stunning process was used at slaughter. The commenter noted that in APHIS' January 2005 final rule, however, the importation of liver from BSE minimal-risk regions was governed by the same conditions as those set forth for other types of meat from bovines, including the requirement that liver be derived from bovines that were subject to a ruminant feed ban.

Response: We consider the commenter's assertion to be inconsistent with APHIS' stated intent in its rulemaking documents and supporting risk analyses, with the regulatory provisions of previous rulemaking documents, and with internationally accepted scientific literature.

In presenting the issues noted above, the commenter seems to be incorrectly concluding that two separate risk mitigation measures we included in our November 2003 proposed rule—(1) a prohibition on the importation from BSE minimal-risk regions of bovine-derived meat and meat products from animals that were 30 months of age or older when slaughtered, and (2) a requirement that the animals from which the commodities were derived were subject to a ruminant feed ban—were intended to mitigate BSE risk in the same way, i.e., by preventing the importation of products derived from Canadian cattle that had been exposed to BSE infectivity.

The commenter's characterization of APHIS' rationale for the 30-month age restriction is inconsistent with the explanation we provided in our November 2003 proposed rule. In the November 2003 proposed rule, we explained in detail the likelihood that specific tissues in a BSE-infected bovine of a certain age will contain the disease agent and how that likelihood influences the risk of BSE transmission from an infected animal. We stated in the proposed rule that ''levels of infectious agent in certain tissues vary with the age of an animal, so the age of the animal influences risk'' (68 FR 62390), then discussed in detail the research findings supporting that statement. We concluded our discussion of the influence of the age of the animal on BSE risk by stating that ''because BSE infectivity has not been found in most bovine tissues until at least 32 months post-exposure, we believe that by requiring that bovines imported into the United States from BSE minimal-risk regions be less than 30 months of age, the risk of the BSE agent being present at infectious levels in most tissues in the animal is minimized.'' (62 FR 62391)

As we discuss earlier in this document, in our March 2004 proposed rule and reopening of the comment period, we explained that, in light of the SRM removal requirements implemented in the United States by FSIS following the diagnosis of BSE in Washington State in December 2003 in a cow imported from Canada, we did not believe it would be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRMs are removed

when the animals are slaughtered, and that such other measures as are necessary are in place. In our September 2007 final rule, we emphasized that the removal and disposal of SRMs is the key factor in the food safety of products from bovines used for human consumption.

The ''other measures'' regarding the importation of bovine-derived meat, meat byproducts, and meat food products and meat products from BSE minimal-risk regions set forth in our January 2005 final rule were that (1) the commodity be derived from bovines that have been subject to a ruminant feed ban equivalent to the requirements established by FDA in the United States and (2) the commodity be derived from bovines for which an air-injected stunning process was not used at slaughter.

As the commenter noted, effective enforcement of a ruminant-to-ruminant feed ban reduces the risk that an animal will be exposed to the BSE agent. However, the removal of SRMs from bovines is an effective means of mitigating the risk of BSE transmission to humans from meat, meat products, and meat byproducts derived even from an exposed animal. In comparison, the BSE regulations for live bovines imported from a BSE minimal-risk region require that the animals were born after the date of effective enforcement of a ruminant-to-ruminant feed ban to reduce the likelihood that a BSE-infected live animal is imported into the United States.

Requiring that SRMs be removed from bovines from which meat and meat products are derived, as is required in both the United States and Canada, ensures that tissues containing BSE infectivity are removed even from a BSE-infected animal that might be presented for slaughter showing no visible signs of BSE. We note that the OIE Code for trade in fresh meat and meat products from cattle from countries of controlled BSE risk (both Canada and the United States are classified as countries of controlled BSE risk by the OIE) recognizes the negligible risk presented by such products as long as SRMs are removed. Therefore, the Code does not recommend that the date of birth of the animal from which the commodity was derived be a condition for such trade, or that the commodity be accompanied by certification that the animal was subject to a feed ban.

APHIS' confidence in the effectiveness of SRM removal in reducing BSE risk was demonstrated in a final rule that APHIS published in December 2005 to allow the importation, under certain conditions, of boneless beef from Japan. Although that rulemaking differs from the rulemaking APHIS conducted regarding BSE minimal-risk regions in the sense that the only commodity addressed in the Japan rulemaking was boneless beef—whereas a more extensive list of commodities was made eligible for importation into the United States from BSE minimal-risk regions—it is significant to note that the conditions in § 94.27 of the regulations for the importation of boneless beef from Japan do not include the requirement that the bovines from which the beef was derived were subject to a feed ban. The requirements for the importation of boneless beef from Japan are that it be prepared in an establishment eligible to have its products imported into the United States under the Federal Meat Inspection Act and the FSIS regulations in 9 CFR 327.2, that it meet all other applicable requirements of the Federal Meat Inspection Act and regulations thereunder (9 CFR chapter III), including the requirements for the removal of SRMs and the prohibition on the use of air-injection stunning devices prior to slaughter on cattle from which the beef is derived, and that it be derived from cattle that were not subjected to a pithing process at slaughter.

Although a ruminant-to-ruminant feed ban reduces the possibility of exposure of bovines to the BSE agent and is an important measure in mitigating the risk that BSE will be transmitted in a region, it serves a different role in BSE mitigation than does SRM removal.

Issue: One commenter stated that APHIS, in its September 2008 request for comments, explained that the conclusion reached in the risk assessment for the September 2007 final rule regarding the negligible BSE risk from the importation of cattle from Canada, even those 30 months of age older, gave further support to the conclusion of the risk analysis conducted for APHIS' 2005 final rule that the importation of meat and meat products derived from bovines from BSE minimal-risk regions posed a low BSE risk, provided certain conditions were met.

The commenter stated that both the risk assessment for APHIS' 2007 final rule regarding the importation of live older bovines and the risk assessment for APHIS' 2005 final rule were predicated on a bovine's being subject to a feed ban during its entire lifetime and that neither the January 2005 final rule nor the risk analysis that accompanied that rule addressed the risk of BSE contamination in meat or meat products derived from cattle that were born prior to the date of effective enforcement of Canada's feed ban. Therefore, stated the commenter, APHIS had no basis to lift its restriction on the importation of beef from Canadian cattle that were over 30 months of age when slaughtered.

The commenter stated further that APHIS, in its September 2007 final rule, deleted from the regulations without explanation the requirement that bovine-derived meat and meat products imported from a BSE minimal-risk region be derived from an animal that had been subject to a feed ban.

Response: The commenter is incorrect in stating that the September 2007 final rule removed the requirement that bovine-derived meat and meat products, and certain byproducts, imported from a BSE minimal-risk region be derived from animals that had been subject to a feed ban.

With regard to the commenter's discussion of the wording we used in our September 2008 request for comments in referring to our risk assessments, although we acknowledge that the wording we used in that document could be interpreted in several ways, our intent was to compare the likelihood of BSE introduction into the United States through the importation of live bovines from Canada with the likelihood of BSE introduction through the importation of bovine-derived meat and meat products from Canada. In making such a comparison, we referred to the risk assessments for our January 2005 and September 2007 final rules, in which we explained in detail the role of SRMs in BSE transmission and the effectiveness of reducing the likelihood of BSE transmission through the removal of SRMs at slaughter. Our point was that, if, as we concluded in our September 2007 final rule, the risk of BSE exposure in the United States from the importation of live bovines—with SRMs intact—from Canada is negligible, then the importation of bovine-derived meat and meat products from Canada would present even less of a risk, because the SRMs from the bovines from which the meat and meat products were derived would have been left behind in Canada.

Effectiveness of Canadian Inspection System

As discussed above, one of the required risk mitigation measures for bovine-derived meat and meat products imported from Canada is that the SRMs of the bovines from which the commodities are derived were removed at slaughter.

Issue: Several commenters expressed concern about the ability of Canadian food inspectors to ensure that meat products are free from SRMs. One commenter stated that, in a 2007 audit of Canadian food establishments eligible to export to the United States, FSIS reported the following: ''Inspection system controls at all levels were not fully developed and implemented. There were many instances of deficiencies both in the documentation reviews and in the operations audits that should have been addressed prior to the FSIS audit. Some inspection personnel were not well-trained in the performance of their inspection tasks.'' (The commenter cited ''Food Safety and Inspection Service, United States Department of Agriculture, ''Final Report of an Audit Carried Out in Canada Covering Canada's Meat, Poultry, and Egg Products Inspection System, May 1 through June 6, 2007'', *http://www.fsis.usda.gov/OPPDE/FAR/Canada/Canada2007.pdf.''*)

Response: In addressing this issue, FSIS has stated that, with respect to the FSIS audit of Canada in 2007, FSIS specifically assessed controls for SRM removal in Canada and identified no related deficiencies. With regard to the other deficiencies identified in the 2007 audit, FSIS stated that none caused FSIS to question whether the Canadian inspection system was adequate with regard to SRM control. FSIS has included a review of controls for SRM removal in its audits since 2005. In each review—including audits conducted in February 2005, April-May 2006, May-June 2007, and May-June 2008—no deficiencies were noted in relation to SRM removal and other BSE-related requirements.

Issue: One commenter stated that the Canadian Food Inspection Agency (CFIA) is considering weakening government food inspection and turning the inspection process over to industry and that further deregulation of meat inspection in Canada would endanger U.S. public health.

Response: In addressing this issue, FSIS has informed APHIS that FSIS has been in contact with CFIA, including follow-up discussions about possible changes to the inspection system in Canada. FSIS is not aware of any substantive planned changes at this time. Any changes affecting meat, poultry, or processed egg product destined for the United States would require discussion related to equivalency to the U.S. inspection system.

Issue: One commenter stated that, although APHIS' September 2008 request for comments indicated that FSIS has determined that Canada has implemented food safety requirements that are equivalent to those in the United States, including Canada's July 2003 requirements regarding SRMs, there is a disparity between what FSIS is supposed to require of foreign plants that ship products to the United States and what is actually practiced.

Response: In 2005, FSIS conducted an enforcement audit to evaluate Canada's implementation of SRM controls for products destined for the United States. FSIS concluded that SRM controls had been effectively implemented, in accordance with FSIS regulatory requirements, in Canadian establishments certified to export beef to the United States. The audit led to no delistments of eligible establishments, nor to any notices of intent to delist eligible establishments.[4]

Issue: One commenter cited a December 2005 report by the USDA's Office of Inspector General (OIG) that stated, in part:

> In July 2003, FSIS found that Canadian inspection officials were not enforcing pathogen reduction and HACCP system regulations. These same types of concerns were identified again in June 2005, almost 2 years later. However, as of September 2005, FSIS has not made a determination whether the identified concerns are serious enough to limit the import of Canadian products. As a result, FSIS has allowed the importation of almost 700 million pounds of meat and poultry from plants that did not receive daily inspection, a requirement for all U.S. meat and poultry plants. Additionally, FSIS allowed the import of over 261 million pounds of ready-to-eat meat and poultry that had not been subjected to finished product testing for *Listeria monocytogenes,* as is required of U.S. plants. (The commenter cited ''Audit Report Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System, U.S. Department of Agriculture, Office of Inspector General, Northeast Region, Report No. 24601–05–Hy, December 2005, at 4.'')

The commenter stated that, according to the OIG, FSIS does not have protocols or guidelines for evaluating deficiencies in a country's inspection system that could jeopardize a country's overall equivalence determination and that FSIS did not institute compensating controls to ensure that public health was not compromised while deficiencies were present.

Response: As noted in the OIG report, FSIS addressed audit deficiencies with CFIA officials during and immediately following the 2003 and 2005 audits. For those deficiencies that had potential impact on public health, FSIS auditors required the establishments to take immediate corrective actions. In some instances, FSIS also required enforcement action to be taken by Canadian authorities. These enforcement actions included immediate delistment of the establishment or the issuance of a warning letter requiring specific corrective actions within 30 days. FSIS' analysis of the audit reviews have identified and resolved all potential public health concerns.

Issue: One commenter stated that, in a follow-up report issued by the OIG in August 2008, the OIG reported that FSIS could not demonstrate that the number of intensified inspections for physical and laboratory failures provided the appropriate level of protection to ensure the safety and wholesomeness of imported products.

Response: In response to Recommendation #8 of OIG audit 24601–08–Hy, FSIS agreed with OIG's findings and stated that FSIS would determine the appropriate number of intensified inspections needed following physical and laboratory failures to ensure the safety and wholesomeness of imported products.[5] After further analysis of available data, FSIS determined that the current number of intensified inspections for laboratory and physical failures is sufficient and appropriately established. Thus, according to FSIS, further revisions to the FSIS procedures for intensified inspections are unnecessary.

Issue: One commenter stated that the OIG found that FSIS could not demonstrate that it performed an adequate sampling of foreign establishments to validate that the country's inspection system is equivalent to that in the United States. The commenter stated, further, that the OIG found that FSIS did not visit the minimum number of establishments necessary to validate that inspection systems were equivalent to that in the United States in three of the four countries it reviewed and questioned whether FSIS had sufficient data to conclude that these countries' inspection systems were equivalent to the U.S. system.

[4] Delistment of an establishment removes it from the list of establishments authorized to export meat and meat products to the United States. A notice of intent to delist is issued to an establishment that conducts marginally acceptable practices, and puts it on notice that it will be delisted unless specified improvements are made.

[5] Intensified inspections are triggered after a product fails to pass reinspections for physical and laboratory testing. If the level of inspection is increased, FSIS management officials have decided to perform reinspection activities above the normal level of inspection for a lot, based on problems associated with the specific product, foreign establishment, or country.

Response: In response to Recommendation #2 of OIG audit 24601–08–Hy, FSIS has developed and implemented a process to document the reasons for the number of establishments selected for an on-site country audit as part of the agenda for the pre-audit conference between FSIS and the foreign country. In addition, FSIS has implemented a statistically based sampling plan using a country's recent history of overall compliance with FSIS requirements, as well as information provided by the country on a continuous basis, in determining that the foreign country's inspection system is performing adequately.

Efficacy of SRM Removal in Mitigating the Risk of BSE

Issue: One commenter stated that the risk modeling the commenter said APHIS relies on to support its claim that SRM removal alone is sufficient to mitigate the potential BSE risk to humans shows otherwise. The commenter stated that the risk modeling shows that there are two significant factors that contribute to the reduction in potential BSE risk to humans: (1) The amount of BSE infectivity in circulation (based on the number of BSE-infected cattle), and (2) compliance with SRM removal requirements. The commenter stated that the influence of the amount of BSE infectivity is demonstrated by the fact that when the 2005 risk model was updated to include the presence of BSE-contaminated poultry litter, resulting in more BSE-infected cattle, the effectiveness of SRM removal in reducing potential BSE risk to humans was decreased by nearly half (from 20 oral ID_{50}s to 11oral ID_{50}s) [6] even with perfect compliance with SRM removal requirements.[7] (BSE infectivity is expressed in terms of cattle oral ID_{50}s. A cattle oral ID_{50} is defined as the amount of infectivity required to cause infection in 50 percent of an exposed cattle population).

The commenter stated that the authors of the risk models further substantiated that the amount of circulating infectivity impacts human health even with perfect compliance by explaining why the potential risk to humans was reduced following a simulation that prohibited SRMs from being used in both human food and animal feed. The commenter quoted the authors of the risk model as stating:

> Removing infectious tissues from both human food and animal feed, assuming that the ban effectively covers dead stock, and assuming perfect compliance, together have a substantial impact on both the potential human exposure and the spread of BSE * * *. Potential human exposure decreases both because there are fewer BSE cases and because the measures remove infectious tissues from the human food supply. Average human exposure decreases by more than 99 percent from 3,800 cattle oral ID_{50}s to 10 oral ID_{50}s.'' [8]

Response: The commenter appears to be attempting to use various model results to suggest that the SRM restrictions simulated in the models are not sufficient to mitigate the public health risk when there are higher numbers of infected animals present. However, the model results themselves do not support this conclusion. To discuss the commenter's statements in meaningful context, it is necessary to first provide a history of the models and model runs referred to.

In 2001, Harvard University provided USDA with the results of an extensive model that simulated the results of introducing BSE-infected cattle into the United States. This model has since been used and updated by both FSIS and APHIS at various times. These uses and updates include the following that are of significance and/or referenced in this docket:

- 2004—FSIS used model runs as part of their ''Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent from Entering the U.S. Food Supply.''
- October 2005—FSIS asked Harvard to update the model and run several simulations, and these were published for public comment ''Harvard Risk Assessment of BSE Update; Phase IA, October 31, 2005.''
- December 2006—FSIS/Harvard incorporated changes based on public comment from the October 2005 simulations. This was made public, along with the responses to the public comments as ''Harvard Risk Assessment of BSE Update; Phase IA; Supplemental Simulation Results, December 26, 2006.''
- September 2007—APHIS used the model, with amendments, as part of the risk assessment supporting its September 2007 final rule. The quantitative model was used to support the exposure assessment of the risk assessment.

In each of these instances, the assumptions used, the scenarios examined, and even the model itself differed from those in the others. It is therefore challenging to compare results from different instances of using the model without understanding the changes in the assumptions and the simulations. In the following paragraphs, we summarize these different model runs in chronological order and provide selected results from each, to help clarify the interpretation of the results.

2004: In this instance, FSIS used a modified version of the 2001 Harvard BSE risk assessment model (as revised by Harvard in response to peer review comments). The baseline estimate assumed that five BSE-infected animals were imported into the United States in 2003. The model then simulated the spread of BSE infectivity until 2020. The analysis assumed that measures implemented in the United States to prevent the spread of BSE—e.g., the FDA feed ban—were in place at the time that infectivity was introduced. FSIS simulated the introduction of public health risk mitigation options—i.e., restrictions on SRMs and advanced meat recovery (AMR)—and assumed that these were implemented in 2004, 1 year after the infectivity was introduced. Therefore, because of these assumptions, the simulated mitigation options could never remove all of the infectivity that could be available for human consumption over the model simulation timeframe. In other words, BSE infectivity could enter the human food supply for 1 year before FSIS mitigations took effect. In the baseline analysis, with five infected animals introduced into the United States, over the 17-year simulation a mean of slightly less than two additional animals were affected. The baseline level of potential human exposure for the introduction of 5 infected animals—with no SRM risk mitigation options in place during the 17-year simulation—was an average of 22 cattle oral ID_{50}s over the 17-year timeframe. With the introduction of SRM and AMR requirements (essentially the same requirements as those established by the FSIS regulations), the potential human exposure was an average of 7.5 cattle oral ID_{50}s over the 17-year simulation. This was an 80 percent reduction in this simulation. Again, it is important to note that the public health assumptions used in these simulations could never remove more than 90 percent of the potential human exposure from the simulation.

[6] BSE infectivity is expressed in terms of cattle oral ID_{50}s. A cattle oral ID_{50} is defined as the amount of infectivity required to cause infection in 50 percent of an exposed cattle population.

[7] The commenter cites Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA, Supplemental Simulation Results, December 26, 2006, Appendix 2A, Section 2.1.2c, line 15 (AR 17464); *see also* Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA, October 31, 2005, Appendix 2A, Section 2.1.2, line 15 (AR 17109).

[8] The commenter cites the Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA, October 31, 2005, at 29 (AR 17086).

In 2005 and 2006, FSIS again used the model to simulate a variety of risk mitigation options. The original simulations were published in October 2005 and public comment on the model and the assumptions used was invited. In response to the public comments received, some changes were made to the model and the assumptions, and the final results were published in December 2006. The base case in each of these simulations represented the circumstances in the United States prior to December 2003—i.e., with an FDA feed ban in place prior to the introduction of infected animals. In each scenario, 500 infected animals were introduced at one time and the model ran a total of 50,000 simulation runs for each scenario. The scenarios considered included various food safety measures, animal health measures (changes to the feed ban), and combinations of both.

The October 2005 model included the following results. The results of the base case simulation—500 infected animals and a simulation timeframe of 20 years—indicated a mean of 680 total infected animals over the 20 years (500 imported animals and 180 domestic animals) and a mean of 3,800 cattle oral ID_{50}s potentially available for human consumption. In comparison, the scenario that modeled a comprehensive ban from human food of SRMs from cattle 30 months of age or older (which we refer to below as ''30-month SRM restrictions'') yielded similar results for the number of infected animals, but with a mean of only 11 cattle oral ID_{50}s potentially available for human consumption over the entire 20-year timeframe. The authors noted that they found that the food safety measures enacted by USDA all reduce potential human exposure to BSE infectivity but have little effect on spread of BSE in the cattle population. They also specifically noted that the results of the food safety measures enacted were relative reductions to what is already a small risk in absolute terms, especially in light of the fact that these simulations reflect the assumed introduction of 500 infected cattle into the United States. One other scenario modeled in this report was a removal of SRMs of animals 12 months and older (which we refer to below as a ''12-month SRM restrictions'') from both the human and the animal food chain. This scenario decreased the number of infected animals to a mean of 540 total infected animals over the 20 years (including both imports and domestic cases) and indicated a mean of 9.8 cattle oral ID_{50}s potentially available for human consumption. The authors conclude that this scenario indicates potential human exposure decreases both because there are fewer BSE cases and because the measures remove infectious tissues from the human food supply, although the amount of infectivity potentially available for human consumption (9.8 oral ID_{50}s) was not significantly different from the simulation that modeled SRM removal (30 months of age and older) from only the human food supply. In other words, the number of BSE cases (680 total in the simulation with SRM removal from only human food as compared to 540 total in the simulation with SRM removal from both human and animal food chain) did not appear to significantly impact the potential human exposure.

The December 2006 model provided similar results in many ways. This report included a change to explicitly model contamination of cattle feed as a result of the recycling of poultry litter. The base case again simulated 500 infected animals introduced, with 50,000 simulation runs of 20-year timeframes. The base case results indicated a mean of 700 total infected animals over the 20 years (500 imported animals and 200 domestic animals), with a mean of 6,600 cattle oral ID_{50}s potentially available for human consumption. Modeling a requirement for removal from the human food supply of SRMs from cattle 30 months of age or older, with 100 percent compliance, indicated a mean of 20 oral ID_{50}s potentially available for human consumption over the 20-year time period. This same requirement, with an assumption of 99 percent compliance, indicated a mean of 83 oral ID_{50}s potentially available for human consumption.

APHIS used a modified version of the Harvard model as part of the risk assessment that supported the September 2007 final rule. Specifically, we used the quantitative model in our exposure assessment to consider less likely scenarios. The model simulated BSE release and exposure in the United States over 20 years, with the introduction of infected animals from Canada at a constant rate over the entire period. We assumed that the existing FDA feed ban requirements were in place throughout the 20 years, and that FSIS and FDA restrictions on SRMs in human food were the same as implemented in 2004. The base case scenario results indicated that the importation of approximately 19 infected animals leads to approximately 2 U.S. cases as secondary spread, for a total of 21 infected animals over the 20-year period. The base case indicated a mean of 45 cattle oral ID_{50}s potentially available for human consumption.

As noted above, the model results themselves do not support what seems to be the commenter's conclusion that the SRM restrictions simulated are not sufficient to mitigate the public health risk when there are higher numbers of infected animals present. Specifically, in the October 2005 model, both the base case and the 30-month SRM restrictions from human food indicated the same number of total infected animals—680 infected animals over the 20-year timeframe. Yet, the simulation modeling the 30-month SRM restrictions from human food reduced the mean amount of cattle oral ID_{50}s available for human consumption from 3,800 to 11. In the scenario where 12-month SRM restrictions were applied in both human and animal food, although the number of total BSE cases changed (540 total infected animals), the amount of oral ID_{50}s potentially available for human consumption (9.8 oral ID_{50}s) stayed essentially the same as those in the 30-month SRM restriction scenario (11 oral ID_{50}s). It should be noted that the assumptions used in the APHIS base case exposure assessment provided a total of only 21 infected animals over a 20 year time period—significantly less than the approximately 700 total infected animals in the FSIS simulations.

It is important to place some context around the results of the amount of infectivity potentially available for human consumption. The significance of cattle oral ID_{50}s to human exposure and susceptibility is not known; however, various studies suggest that the infectious agent may be 10 to 10,000 times less pathogenic in humans than in cattle because of a species barrier (EC SSC, 2000). Thus, if the cattle-human species barrier were 100, it would mean that 100 times more infective material would be required in order to have a similar probability of infecting a human as a bovine. Comer and Huntly (2003) estimated, after an evaluation of available literature, that 54,000,000 (54 million) bovine oral ID_{50}s were available for human consumption in Great Britain from 1980 to 2003. This extremely large amount of available infectivity has resulted in 168 cases of vCJD identified or suspected in the United Kingdom through March 2009, plus a few additional cases identified in other countries but attributed to exposure in the United Kingdom. When compared to the United Kingdom's BSE experience and the associated estimate of available bovine oral ID_{50}s, the mean values of 11 potentially available cattle oral ID_{50}s—

or even 20 oral ID_{50}s or 83 oral ID_{50}s—over a 20-year period are miniscule.

Issue: One commenter stated that the prevalence of BSE in Canada is significantly higher than BSE prevalence in the United States and that APHIS has no basis to claim that measures implemented in the United States to mitigate the prevalence of BSE in this country are sufficient to mitigate a much higher prevalence in Canada. The commenter referenced a statement by the Centers for Disease Control (CDC) that the prevalence of BSE in Canada has been 90 percent likely to be between 18-fold and 48-fold higher than the previously published best estimate of the prevalence of BSE in the United States. The commenter stated that CDC notes that, nonetheless, a BSE prevalence in Canada 23-fold higher than that in the United States continues to be used in the Harvard Risk Assessments' ''worst case'' analysis when evaluating the risk of imported Canadian cattle's causing BSE to spread among U.S. animals.

Response: In comparing the estimate of the prevalence of BSE in the United States with the estimated prevalence of BSE in Canada, it should be noted that the estimated number of BSE-infected animals per million is very low in either case—0.167 cases per million in the United States and 3 to 8 cases per million in Canada.

The commenter states that prevalence of disease has a significant impact on the effectiveness of mitigation measures, but provides no evidence to support this claim. Evidence in countries with significant outbreaks of BSE indicates that the animal health and public health mitigation measures are effective, even in the face of significantly higher prevalence levels. The primary animal health mitigation measure is a feed ban to prevent the inclusion of potentially infective tissues from being fed to cattle. This measure has demonstrably worked in the United Kingdom, a country with a significantly higher prevalence level relative to other countries. The number of BSE cases identified in birth year cohorts (all cattle born in a given year) in the United Kingdom has continued to decline since peaking in 1987. The United Kingdom established its initial feed ban requirement in 1988. This continuous decline clearly demonstrates the effectiveness of a feed ban as an animal health mitigative measure in the face of an outbreak with high prevalence. Similarly, on the public health side, SRM restrictions are an effective public health measure, even in a high prevalence situation. Experience in the United Kingdom and elsewhere in Europe demonstrates this effectiveness. The models used by FSIS that are discussed above continue to indicate the effectiveness of this measure, even when simulating relatively high numbers of infected animals present in the system. Given all of these points, APHIS has no reason to believe that the effectiveness of these mitigation measures is impacted by differences in prevalence levels.

Issue: One commenter stated that it is important to note that APHIS' estimate of the prevalence of BSE in Canada is based on the detection of 11 cases of BSE, and that since that estimate was made, additional cases of BSE in Canadian cattle have been diagnosed. The commenter stated that APHIS should not rely on outdated prevalence estimates to evaluate Canada's BSE risk.

Response: In conducting our assessment of the risk of importing live bovines from Canada under the provisions of the 2007 final rule, we took into account, among other factors, the estimated prevalence of BSE in Canada. In discussing our estimate of BSE prevalence in Canada in that final rule, we explained that the number of BSE cases detected through surveillance understates the disease prevalence because exposed animals may be incubating disease and carrying infectious material in their tissues without presenting clinical symptoms. We noted, additionally, that surveillance will miss a proportion of detectable cases. Therefore, as we explained in our 2007 final rule, we applied statistical methods to the available epidemiologic and surveillance data to estimate, with attendant uncertainty, the prevalence of BSE in Canada. Even taking into account this attendant uncertainty, our qualitative and quantitative assessments of release of BSE into the United States via the import of live bovines from Canada demonstrate an extremely low likelihood of release, and that, because of the comprehensive mitigations already in place in the U.S., the likelihood of establishment is negligible.

Issue: One commenter noted that the epidemiological investigation conducted by Canada regarding an animal born in 2003 indicated that the most likely source of infection was consumption of commercial cattle feed produced in Canada. The commenter concluded that such information demonstrates that what the commenter termed ''Canada's widespread BSE exposure'' occurred because the August 1997 feed ban in Canada failed to address the cross-contamination of cattle feed with feed produced for other animals.

The commenter stated that APHIS' statement that its 2005 evaluation of the feed ban in Canada revealed that overall compliance with the feed ban is good and that the feed ban was reducing the risk of transmission of BSE in the Canadian cattle population has been disproven by subsequent outbreaks of BSE in cattle that were born years after the implementation of Canada's feed ban. The commenter stated further that the CDC has reported that occurrence of BSE in Canada has risen in recent years.

The commenter stated that there is no evidence that the prevalence of BSE in Canada is decreasing at this time. The commenter noted that most of the animals diagnosed with BSE in Canada were born after Canada implemented its 1997 feed ban and that over half of those cases were born after March 1, 1999, the date that APHIS determined to be the date of effective enforcement of the feed ban in Canada. The commenter also noted that more animals determined to be infected with BSE—two—were born in 2000 than in any other year. Other commenters also expressed opposition to the removal of the delay of applicability of the provisions described above because of the diagnosis of BSE in a number of Canadian-born cows since the diagnosis of BSE in a Canadian-born cow in May 2003. Some commenters expressed particular concern regarding the discovery of BSE in Canadian cattle within the past several years. One commenter stated that Canada's feed ban was not made whole until July 2007, when Canada took steps to ban ruminant protein from all animal feed and fertilizer. The commenter concluded that USDA should withdraw the September 2007 final rule and initiate a rulemaking to determine if Canada's feed ban is likely to have become effectively enforced after July 2007.

Response: We disagree with the commenters' conclusions. The commenters suggest that, in order for the Canadian feed ban to be considered effective, BSE surveillance data would have to demonstrate that the likelihood of BSE transmission in that country has been eliminated. However, as noted in the risk assessment for our September 2007 final rule, Canadian BSE surveillance data do not provide a statistical basis for distinguishing BSE prevalence among birth year cohorts (APHIS, 2007); the overall prevalence is so low that distinguishing any difference is nearly impossible. In other words, the data cannot distinguish any significant difference in prevalence among animals born in different years, which would have been one way to demonstrate the effect of a feed ban

(e.g., if the feed ban were implemented at the beginning of 1997, surveillance data showing a higher BSE prevalence in animals born in 1996 than in animals born in 1997 would support the effectiveness of the feed ban). However, in the absence of a feed ban that reduced exposure to BSE, we would expect the prevalence of the disease to increase over time. We have no evidence that such an increase has occurred but we do have data that the feed ban is being enforced.

Furthermore, as we discussed in the risk assessment for our September 2007 final rule, detection of BSE in an animal born after the date a feed ban was implemented does not indicate an overall failure of the measures in place to stem transmission of the disease in that country. Most other countries that have experienced cases of BSE have reported similar cases. Human error is expected, which is why the feed ban is comprised of a number of interrelated measures that have a cumulative effect. Our risk assessment does not assume 100 percent compliance with all measures all of the time. We discussed factors related to the feed ban in Canada since before its implementation in 1997. We considered activities related to inspection and compliance with the feed ban, the rendering industry, the risk of cross-contamination, education activities and industry awareness, and on-farm practices that might contribute to the efficacy of the feed ban. In addition, we highlighted the fact that since the implementation of the feed ban on August 4, 1997, Canada has continued to revise and strengthen its processes and procedures to further enhance the effectiveness of the feed ban.

With regard to the commenter's recommendation that a date in July 2007 be considered as the date of effective enforcement of a feed ban in Canada, as we discussed in our September 2007 final rule, we consider the July 2007 expansion of the Canadian feed ban to be an enhancement of an already effective ban. In July 2007, Canada modified its feed ban to remove SRMs from all animal feeds, pet food, and fertilizer. CFIA, in explaining its rationale for the enhanced ban, emphasizes that although surveillance results and investigations of BSE cases indicate that the feed ban in Canada has effectively reduced the spread of BSE since being implemented in 1997, even compliance with the ban's requirements left limited opportunities for contamination during manufacture, transportation, and storage that CFIA considered worth eliminating. In addition, the accidental misuse of feed on farms with multiple species could not be discounted. With the enhanced ban, CFIA projects that the eradication of BSE in Canada will be accelerated. Following such a regulatory path does not indicate that the feed ban in Canada prior to July 2007 was not effective or effectively enforced.

Issue: One commenter stated that APHIS, in its September 2007 final rule, established that SRM removal requirements are approximately 19 percent less effective in preventing human exposure to the BSE agent when those requirements are applied to cattle born before effective BSE mitigation measures were in place, such as in cattle born before the Canadian feed ban became effective.

The commenter discussed analyses that were conducted by FSIS to estimate the likely reduction of potential human exposure to BSE given the SRM removal requirements established by that Agency. The commenter stated that, in its 2004 evaluation, FSIS estimated that the SRM removal policy adopted by that Agency could reduce potential human exposure to BSE by 80 percent, based on the assumption that five BSE-infected animals had been introduced into the United States 12 months before FSIS implemented its BSE mitigation measures, including SRM removal. In 2005, stated the commenter, FSIS re-analyzed the likely reduction in potential human exposure, this time assuming that U.S. risk mitigation measures were implemented before the introduction of BSE-infected cattle in the United States. Using that assumption, said the commenter, FSIS indicated that the mitigation measures implemented by FSIS in 2004 would reduce potential human exposure by more than 99 percent on average. APHIS discussed the results of this re-analysis in its September 2007 final rule, stating:

> ''Since all scenarios [evaluated by FSIS] included at least some time in which the mitigations were not implemented, under the simulations, a certain amount of potential infectivity was allowed into inappropriate channels, such as human food. Because none of these scenarios incorporated the more realistic assumption that the mitigations were implemented (even imperfectly) throughout the simulation period, it is inappropriate to use this analysis as a citation for the level of public health protection provided by risk mitigation measures in place in the United States.
>
> A more appropriate analysis for understanding the role of SRM removal in potential human exposure to BSE infectivity would be the FSIS update of the same Harvard simulation model that was available for public comment in 2006 * * *. This updated model used the ''base case'' as the circumstances in the United States prior to December 2003, and simulated the response of the U.S. system for 20 years following the import of BSE-infected cattle. FSIS' updated model estimated the impact of various risk management measures, including measures that were adopted, considered, or proposed by various agencies and groups. These simulations, where the risk mitigation was applied during the entire simulation, as opposed to the simulation in the [2004] analysis * * * (in which it was not), indicated that removing SRMs, as currently defined by FSIS, reduced potential human exposure by more than 99 percent, on average. This report also stated that ''[i]t is worth noting that these measures reduce what is already a small exposure in absolute terms.'' (72 FR 53335–53336)

The commenter stated that the latter FSIS analysis is irrelevant to the issue of risk related to the importation of beef from Canada derived from cattle 30 months of age or older, because Canada is known to have had at least three generations of BSE infectivity in its native cattle herd prior to the time that Canada implemented its BSE mitigation measures, including SRM removal.

Response: The commenter states that APHIS established that SRM removal requirements are approximately 19 percent less effective in preventing human exposure to the BSE agent when those requirements are applied to cattle born before effective BSE mitigation measures were in place, such as in cattle born before the Canadian feed ban became effective. However, APHIS did not establish or suggest such a conclusion. In our September 2007 final rule, we responded to a commenter who raised the issue of the FSIS 2004 model, where the potential human exposure was reduced by only 80 percent. APHIS explained that this specific use of the model was not appropriate in completely evaluating the role of SRM removal in potential human exposure and noted that the FSIS 2005/2006 simulations provided a better analysis for understanding potential human exposure. APHIS noted that the FSIS 2004 model included ''* * * at least some time in which the mitigations were not implemented * * *'' (72 FR 53336). The commenter appears to have interpreted this to include all mitigations, including animal health mitigations such as the feed ban. This is inaccurate, as the FSIS 2004 model assumed that the feed ban requirements were in place throughout the 17-year time period of the simulations.

The commenter suggests that use of the FSIS 2005 model is inappropriate in an evaluation of the risk of imported beef from Canada, because Canada had infectivity in its cattle herd for at least three generations prior to implementing SRM restrictions. The commenter is

correct that the timeframe of implementing SRM restrictions is important for public health considerations. However, the commenter's conclusion that the presence of infectivity in animals prior to the implementation of SRM restrictions affects the effectiveness of those SRM restrictions is inaccurate. Requirements to prevent the inclusion of SRMs in the human food supply provide an immediate public health impact, regardless of the length of time infectivity may have been present in animals. These restrictions prevent infectious tissues from any animal—born before or after a feed ban—from entering the human food supply. As demonstrated in the FSIS 2005 and 2006 models, they provide significant public health protection, even over a 20-year timeframe.

Issue: The commenter stated that APHIS has provided no basis for an assertion that the rate of compliance with SRM removal requirements for Canadian cattle slaughtered in either the United States or Canada is adequate to protect human health. The commenter stated that the influence of the extent of compliance with SRM removal requirements is demonstrated by that fact that, all else being equal, when compliance with SRM removal requirements drops by only 1 percent, the potential risk to human health is more than quadrupled (increasing from 20 oral ID_{50}s to 83 oral ID_{50}s).

Response: We disagree that APHIS has not provided a basis for its conclusion that SRM removal in the United States or Canada constitutes an effective safeguard of human health with regard to BSE. In our September 2007 final rule, we established conditions for the importation into the United States of live bovines born on or after the date of effective enforcement of a ruminant-to-ruminant feed ban in a BSE minimal-risk region, as well as conditions for the importation of other bovine-derived commodities. As part of that rulemaking, we conducted an assessment of the potential BSE risk of implementing the provisions of the final rule. The exposure model used for the risk assessment assumed that SRMs are effectively removed 99 percent of the time in the United States. This assumption was based on FSIS summaries of Noncompliance Records performed from January 2004 to May 2005 in about 6,000 federally inspected meat and poultry establishments. Based on these records, FSIS estimated that noncompliance with respect to SRM-related regulations had a frequency of less than 1 percent.

In our September 2007 final rule, we explored the possible impact of assuming an arbitrary decrease (compared to the results of our exposure model) in SRM removal compliance in the United States on the availability of infectivity for human consumption. The model was for the United States, not Canada, but based on similarities in slaughterhouse practices in the United States and Canada, we can make a broad general assumption that the results in Canada would be the same as those in the United States. As discussed earlier in this document, in a 2007 audit in Canada, FSIS specifically assessed controls for SRM removal in Canada and identified no related deficiencies.

In our September 2007 final rule, we discussed the significance of an order-of-magnitude increase in available infectivity compared to our model's findings. First, we considered the results of that model, which uses the unlikely assumption that prevalence in Canada (and thus the proportion of infected animals imported from Canada) remains constant over the next 20 years. In the model's scenario, the total amount of infectivity potentially available for human consumption over the 20 years of the analysis is 45 cattle oral ID_{50}s.

As discussed above, if the cattle-human species barrier were 100, it would mean that 100 times more infective material would be required in order to have a similar probability of infecting a human as a bovine. As noted, the extremely large amount of infectivity available for human consumption in Great Britain from 1980 to 2003—estimated by Comer and Huntly (2003) as 54 million bovine oral ID_{50}s—resulted in 168 cases of vCJD identified in the United Kingdom through March 2009, plus a few additional cases identified in other countries but attributed to exposure in the United Kingdom. As discussed above, when compared to the United Kingdom's BSE experience and the associated estimate of available bovine oral ID_{50}s, the expected or average value of 45 cattle oral ID_{50}s indicates that only a miniscule amount of the BSE infective agent could possibly be available for potential human exposure in the United States over a 20-year period. (The potential for human exposure under this scenario is estimated at 1,200,000 times less in the United States than what the United Kingdom experienced during its BSE epidemic.) Even if compliance with the SRM ban were not as high as the 99 percent estimated in our exposure model, and we were to assume that the infectivity available for human consumption were increased by an order of magnitude (10x), it would still be far less than that estimated to have circulated in the United Kingdom and, we conclude, not be of significance to human health.

Issue: One commenter noted that APHIS stated in its September 2007 final rule that effective enforcement of a ruminant-to-ruminant feed ban does not necessarily mean 100 percent compliance with the feed ban will be achieved. The commenter stated that, although APHIS concludes that removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections, FSIS states that this conclusion regarding the effectiveness of SRM removal is valid only if compliance is perfect. The commenter stated that it is arbitrary and capricious for APHIS to conclude that a feed ban is effective and effectively enforced even without perfect compliance, while at the same time concluding that SRM removal requirements provide effective mitigation to human health, even though such a level of protection is predicated on perfect compliance.

Response: We disagree with the commenter's logic. There are multiple mitigation measures that contribute to reduction of BSE risk. Each has its own degree of importance in a systemic reduction in risk. As we discuss above, enforcement of an effective feed ban in a region has the effect of reducing the amount of circulating BSE infectivity in that region. This makes it less likely that any one animal in that region will be infected with BSE. SRM removal is a method of removing and disposing of tissues that present a high likelihood of containing BSE infectivity if an animal were infected. In effect, countries such as the United States, Canada, and other countries worldwide that require SRM removal are making the assumption that any one animal presented for slaughter could be infected with BSE, even though the presence of an effective feed ban in that country reduces the likelihood of that to a minimal level.

With regard to the text from the FSIS document regarding perfect compliance, it is important to review the wording cited by the commenter in context. In the FSIS interim rule referred to by the commenter, FSIS refers to the December 2006 model we describe above, and states the following:

> However, although both the number of BSE cases and the level of human exposure increased in the post-public comment runs, conclusions with regard to prohibiting the use of SRMs for human food remain the same. More specifically, even with the revised base case, the post-public comment

runs show that excluding the materials designated as SRMs in this final rule almost completely eliminates potential human exposure to the BSE agent if compliance is perfect. Similarly, the post-public comment runs found that neither lowering the age classification for SRMs from cattle 30 months of age and older to 12 months of age and older, nor from 30 months of age and older to 24 months of age and older, provides additional benefits in reducing the level of potential human exposure to the BSE agent. Thus, the results of the 2005 model, regardless of the base case used, have not led the Agency to change its conclusion that the measures adopted in this final rule are prudent for preventing potential human exposure to the BSE agent. (72 FR 38726)

In addition, in the same rule, FSIS refers to the October 2005 model we described above, and states the following: ''The pre-public comment runs found that removing SRMs from cattle 30 months of age and older almost completely eliminates potential human exposure, reducing it to 11 cattle oral ID_{50}s * * *. It is worth noting that these are relative reductions to what is already a small risk in absolute terms, especially in light of the fact that these simulations reflect the assumed introduction of 500 infected cattle into the U.S.'' (72 FR 38725)

FSIS considered all of the information from the modeling simulations, including those runs where compliance was assumed to be less than 100 percent. Evaluating all of these results and statements together demonstrates the overall conclusion that SRM removal effectively mitigates the BSE risk to humans.

We also note that APHIS did not assume 100 percent compliance with SRM removal in the exposure assessment of our risk assessment. As noted elsewhere, we assumed a 99 percent compliance rate, acknowledging that no regulatory effort can ever ensure 100 percent compliance.

Specified Risk Materials

One of the requirements for the importation of meat, meat byproducts, and meat food products derived from bovines in BSE minimal-risk regions is that the SRMs of the bovines were removed at slaughter. In §§ 94.0 and 95.1 of the regulations, SRMs are defined as ''[t]hose bovine parts considered to be at particular risk of containing the bovine spongiform encephalopathy (BSE) agent in infected animals, as listed in the FSIS regulations at 9 CFR 310.22(a).'' With some limited exceptions, the FSIS regulations list the following tissues as SRMs: (1) The 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 DRG from cattle 30 months of age and older, and (2) the distal ileum of the small intestine and the tonsils from all cattle. If the small intestine is to be used for human food, the distal ileum must be removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum, or must be otherwise removed by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

Issue: One commenter stated that central to APHIS' September 2008 request for comments is the Agency's assumption that SRM removal will effectively protect consumers from exposure to BSE. The commenter stated that such an assumption is called into question by numerous studies demonstrating the limitations on mitigating the risk of BSE exposure via SRM removal. The commenter stated that the CDC has acknowledged that the risk of humans developing vCJD from eating muscle meat from cattle potentially infected with BSE cannot be precisely determined. The commenter stated that APHIS should have, but has not, explained why this uncertainty does not undermine what the commenter termed APHIS' almost-exclusive reliance on SRM removal requirements to protect American public health from potentially hazardous Canadian imports.

The commenter stated that the current inability to detect BSE prions in certain tissues does not mean that there is insufficient infectivity to be a hazard and that, while BSE prions have been found only in a solitary bovine muscle of a single cow, that likely is a function of the current limited analytical sensitivity of the test. The commenter stated that all the other information points to the likelihood that prions are present in such tissues.

The commenter stated that APHIS ignores the significance of recently detected BSE variations and dismisses the relevance of new studies that have detected BSE infectivity in new tissues. The commenter stated that in its September 2008 request for comments, APHIS stated that the new findings could be the result of more sensitive tests and of detection tools that may over-express the BSE agent. The commenter stated that APHIS incorrectly argued in its September 2008 request for comments that, because demonstrating the presence of PrP does not necessarily indicate the presence of BSE infectivity, studies that have detected abnormal PrP in the facial and sciatic nerves do not warrant new mitigation measures. The commenter stated that the World Health Organization (WHO) has found both the presence of Prp^{TSE} and BSE infectivity in the peripheral nerves of cattle. The commenter stated that the WHO has identified two classifications of BSE tissue infectivity, ''high infectivity'' and ''lower infectivity,'' and that the WHO includes peripheral nerves (e.g. sciatic and facial nerves) in the category of lower infectivity.

The commenter stated that, in its request for comments, APHIS specifically cited research that detected BSE infectivity in the sciatic nerve of cattle, but only after 30 months after exposure. Despite this, stated the commenter, APHIS does not require mitigation measures regarding the sciatic nerve in cattle 30 months of age or older. The commenter stated that facial and sciatic nerves are the only bovine tissues scientifically determined by multiple studies to harbor BSE infectivity for which APHIS requires no risk mitigations, not even the mitigation of requiring that beef imported from Canada be derived only from cattle that were subject to a feed ban during their lifetimes. The commenter stated that this policy is inconsistent with APHIS' consideration of tonsils in cattle of any age as an SRM tissue, even though APHIS cites only one study that found what appears to be a very low level of infectivity in the tonsils of BSE-infected cattle.

The commenter disagreed with this policy, stating that (1) BSE infectivity is known to exist in non-SRM tissues; (2) BSE infectivity is known to have been circulating in Canadian cattle for years, leading up to and including 2003; and (3) APHIS does not know the minimum dosage necessary to cause BSE infectivity in either humans or cattle. The commenter cited 2006 WHO guidelines as stating: ''It remains unknown whether tissues containing such very small amounts of infectious material [detected by novel techniques] would transmit infection to humans.'' (The commenter cites WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies, World Health Organization, 2006, at 10.) Based on this uncertainty, stated the commenter, APHIS should take precautionary steps to avoid human exposure to meat and meat products from Canadian cattle that pose the highest risk of infection—cattle 30 months of age or older—particularly those born before the Canadian feed ban was effective.

Response: A similar issue was raised by the commenter in response to our January 2007 proposed rule. We are aware of the studies cited by the commenter and do not agree that they question the efficacy of SRM removal. In our September 2007 final rule, we acknowledged that studies using new methods that provide increased sensitivity will probably demonstrate the presence of PrP^{BSE} (the abnormal form of the prion protein) in various tissues. However, demonstrating the presence of PrP^{BSE} does not necessarily indicate the presence of BSE infectivity, especially if no infectivity is demonstrated via the most sensitive method available: Cattle-to-cattle exposure via intracerebral transmission. Therefore, one cannot automatically assume that a finding of PrP^{BSE} in a tissue means the tissue should be defined as an SRM. The OIE made this particular point in the *Terrestrial Animal Health Standards Commission Report, October 2006—Supporting Document for Chapter 2.3.13. Of the Terrestrial Animal Health Code on Bovine Spongiform Encephalopathy,* as follows:

> The availability of experimental infectivity data has significantly increased in recent years. During the same interval, extremely sensitive tests have been developed, including those employing highly sensitive transgenic mice strains and potentially more sensitive laboratory PrP detection methods. With the development of such highly sensitive methods, the probability of detection of PrP^{BSE} in tissues that are not currently listed as infectious is increasing. However, such findings need to be considered in context, and their relevance to establishing risk to consumers evaluated carefully when the quantity of PrP^{BSE} detected is potentially below the limit of detection of intracerebral (i.c.) cattle to cattle bioassay. By April 2007, 165 variant Creutzfeldt-Jakob Disease (vCJD) cases had been detected in the United Kingdom, a country where most probably the majority of the population was exposed to the BSE-agent. The latest models of the vCJD epidemic estimate that the potential scale of the clinical epidemic arising from food-borne exposure is unlikely to exceed 400 future cases in the United Kingdom (Clarke and Ghani, 2005). The relatively low number of predicted vCJD cases in relation to the massive exposure to the BSE agent is suggested to be due mainly to a significant species barrier between cattle and humans (Comer and Huntley, 2004; Bishop *et al.,* 2006).

APHIS is familiar with the results of the study (Buschmann, 2005) in which tissues from a BSE-diseased cow were inoculated into genetically engineered (transgenic) mice that are highly susceptible to BSE and that overexpress the bovine prion protein. Using this extremely sensitive mouse assay, the study demonstrated low levels of infectivity in the peripheral nervous system (e.g., facial and sciatic nerves) of the infected cow. APHIS discussed these findings in the risk assessment it made available with its September 2007 final rule and concluded that ''[g]iven all these factors there is not sufficient information to alter our understanding of the epidemiologically significant distribution of BSE infectivity in cattle.'' (APHIS, 2007). APHIS also acknowledges the results of Japanese studies in which PrP^{BSE} has been reported in the peripheral nerves of a case of BSE (Iwamaru *et al.,* 2005) and in some peripheral nerves of cattle slaughtered at abattoirs in Japan (Iwata *et al.,* 2006) by Western blot analyses. APHIS has also reviewed the German study in which infectivity was detected in the brainstem of an animal at 24 months post-infection (Hoffman, 2007). We have carefully considered all of these findings. USDA reviews and takes into consideration all BSE research for the definitions of SRMs, as do Canada and other countries internationally. As noted in the quote above, international policies regarding SRM removal have not changed based on the results of the studies discussed. Both the U.S. and Canadian policies regarding SRM removal are consistent with international standards.

Finally, we consider the quote the commenter provides from the WHO 2006 report to be of little use when presented out of context. In the report referenced by the commenter, the WHO was discussing in a hypothetical fashion the possibility of advances in techniques to detect PrP^{TSE} not limited to PrP^{BSE}. The WHO statement reads as follows:

> Several new methods attempting to detect PrP^{TSE} using novel techniques * * * if successfully developed, might eventually offer sufficient sensitivity to demonstrate amounts of agent below the level of detection of currently validated tests. It has been speculated that such methods might find small amounts of agent in some tissues currently thought to be free of infectivity. It remains unknown whether tissues containing such very small amounts of infectious material would transmit infection to humans. (WHO, 2006)

Issue: One commenter stated that APHIS' assumption that removal of the tonsils removes the potential for BSE transmission is unjustified given that APHIS has not evaluated the potential for contamination of tongue with tonsil tissue. The commenter stated that, although APHIS claims the possibility of such contamination is eliminated by current slaughter techniques, scientists who examined over 250 bovine tongues intended for human consumption found tonsillar tissue in the vast majority; in some cases, even after the most rigorous trimming of the root of the tongue.[9]

Response: We are making no changes based on the comment. As we discussed in our September 2007 final rule, Wells *et al.* (2005) state the following:

> However, the trace level of infectivity so far detected in tonsillar tissue and the localization of the lingual tonsillar lymphoid tissue, together with the current SRM legislation for the removal of tonsil from cattle carcasses and the low and diminishing prevalence of BSE in the UK suggest that the risk of human exposure to infected tonsil is now remote. It seems likely that under these circumstances any additional trimming of the tongue would result in an immeasurable reduction in the risk * * *

In other words, the study cited by the commenter does not present a strong case for additional risk measures, and, in fact, points to the opposite conclusion.

Moreover, even before the SRM requirements were implemented in January 2004, FSIS did not consider tonsil to be edible tissue—it was previously required to be removed. As noted in FSIS Notice 50–04:

> In the preamble to 9 CFR 310.22, FSIS stated that tonsils of all livestock species, including cattle, were already required to be removed and were prohibited for use as ingredients in meat food products under 9 CFR 318.6(b)(6). The accepted practice for removing the tonsils from livestock has been to remove all visible tonsils. In cattle, this includes separation of the palatine tonsils and lingual tonsils from the tongue (in establishments that harvest the tongue for human food) by a transverse cut caudal (just behind) the last vallate papillae * * * FSIS expected that establishments would continue to remove tonsils from cattle in accordance with the procedures that they had implemented to comply with 9 CFR 318.6(b)(6) * * * Establishments that slaughter cattle should have been following these practices before tonsils were designated as SRMs. (FSIS, 2004c).

APHIS' quantitative exposure model conducted for the September 2007 final rule included an update that acknowledged the potential infectivity in tonsils and clearly added these as an SRM, with the acknowledgment that they could still be potentially available for human consumption. In fact, the output tables from the model runs show the potential oral ID_{50}s derived from tonsils and available for human consumption over the 20-year period of

[9] The commenter cites Wells, G., Spiropoulos, J., Hawkins, S., and Ryder, S., Pathogenesis of Experimental Bovine Spongiform Encephalopathy; Preclinical Infectivity in Tonsil and Observations on the Distribution of Lingual Tonsil in Slaughtered Cattle, *Veterinary Record* (2005) 156, 401–407.

the analysis. These values are obviously very low, ranging from 0.026 oral ID_{50}s in the base case scenario to 0.16 oral ID_{50}s in sensitivity analysis 6 (in which all uncertain parameters were simultaneously set to their corresponding pessimistic level). Such very small values are not surprising given the low likelihood of infectivity in the tissue itself. Moreover, although our model predicts a vanishingly low level of possible human exposure via tonsils, we have not stated that the risk is ''eliminated,'' as was suggested in the comment.

Issue: One commenter stated that it is not yet possible to demonstrate how effective SRM removal is in mitigating the risk of BSE, because SRM removal requirements have not been in place long enough for an effect to be evident, particularly in light of the lengthy incubation periods assumed for vCJD in humans. The commenter stated that any human who consumed beef from a BSE-infected animal slaughtered after SRM removal requirements were implemented would not be expected to show signs of vCJD for about 17 years. The commenter stated that, if there has been a reduction in the number of cases of vCJD infection—which the commenter said is unclear—it is much more likely that that the reduction resulted from decreases in the number of infected cattle in the past decade due to feed bans, rather than to what the commenter termed the much more recent implementation of SRM removal.

Response: The commenter raised a similar issue in response to our January 2007 proposed rule. In response to the comment, we acknowledged in our September 2007 final rule that there has been no specific controlled study that clearly and unequivocally demonstrates the effectiveness of SRM restrictions on protecting public health. However, the absence of such a study does not negate the fact that substantial epidemiological and case evidence clearly indicate the success of such control measures. As we stated in our September 2007 final rule, it is widely and generally accepted internationally, including by such international bodies as the WHO and the OIE, that the primary public health protective measure regarding BSE is the removal of SRMs from the human food supply (WHO, 2002).

The OIE Scientific Revue notes the following: ''Excluding SRM from the human food chain effectively minimizes the risk of human exposure and is the most important measure taken to protect consumers. Failure to remove SRMs would probably expose a large number of consumers to an unnecessary risk.'' (Heim and Kihm, 2003). This point is also widely acknowledged in scientific literature. For example, Bradley and Liberski (2004) conclude that ''risks to humans from infected cattle are now remote so long as the [bans on the use of SRMs in human food] are rigorously enforced.'' Fox and Peterson (2004) conclude that ''[a]doption of the human [specified bovine offal] ban in the United Kingdom in 1989 is probably the only example in the BSE story of a government going beyond expert opinion in taking a precautionary measure. It turned out to be the correct decision, and likely saved thousands of people from exposure to the disease.''

Simulation models and analysis conducted in the United Kingdom support the assumption that primary exposure sources for people were SRMs in the food supply prior to imposed restrictions. These models have been updated and revised repeatedly since the original identification of vCJD and the link to BSE in cattle (Ghani *et al.,* 1998, 2000, 2001, 2003). They incorporate assumptions for all the parameters that could influence the course of vCJD in the United Kingdom—including assumptions about primary exposure from dietary sources, calculations about how many infected cattle may have been slaughtered at different points in time, what tissues from those animals were available for consumption, and what restrictions were imposed on the tissues and types of products available for consumption. The models are updated routinely to incorporate new information about vCJD cases as they are reported.

These models have been used to predict the course of the vCJD epidemic in the United Kingdom. Initially, the projections were fairly high with considerable uncertainty. As more information is incorporated into the models, these projections continue to decline and the uncertainty levels also decrease. The number of clinical cases of vCJD in the United Kingdom has continued to decline since an apparent peak in 2000 (Andrews, 2007). This decline is consistent with projections made from the models, thus validating some of the assumptions used in the models. As an example, Cooper and Bird (2003) assume that the primary sources of exposure are the consumption of meat products—including mechanically separated meat and head meat–that were most likely contaminated with SRMs such as spinal cord, DRG, and brain. Restrictions on the inclusion of spinal cord and brain, among other tissues, were initially imposed in the United Kingdom in 1989. Restrictions on the production of mechanically separated meat, which included a significant level of infectivity from DRG, were imposed in the United Kingdom in 1995. Cooper and Bird (2003) concluded that ''[t]here is remarkable similarity between the age distribution and gender of simulated and observed vCJD patients, which supports (but does not prove) our assumption about the primary sources of exposure to BSE.''

The commenter noted the ''exceedingly long incubation periods assumed for humans.'' More recent updates of the models described previously have included estimates of the mean incubation period for vCJD (Ghani *et al.,* 2003), estimating the mean incubation period at 12.6 years when using the accumulated case data from confirmed vCJD cases. When additional information was added from results of a screening study performed on appendix and tonsil tissues, the mean incubation period was 16.7 years when fitted to this data. From this evidence, we can conclude that even the longer mean incubation period of 16.7 years would allow sufficient time to demonstrate the effect of SRM restrictions on the outbreak, since the initial SRM restrictions were imposed in 1989. We note that all vCJD cases that have been genotyped to date, with one exception, have been of the homozygous methionine (MM) genotype at codon 129 of the human prion protein gene. In describing the methodology used for their 2003 update of projections of future vJCD cases in the United Kingdom, Ghani *et al.* indicated that approximately 40 percent of the Caucasian population is homozygous methionine, with approximately 10 percent valine homozygous, and the remaining 50 percent heterozygous. While the effect of genotype on vCJD is still unknown, we can evaluate scenarios in the MM genotype as an example of epidemic progression, because this genotype may be the most susceptible and/or have shorter incubation periods than other genotypes.

Issue: One commenter stated that, in its September 2008 request for comments, APHIS misguidedly relied on OIE recommendations to justify its decision not to strengthen SRM removal requirements and to allow the importation from Canada of live cattle 30 months of age or older. The commenter stated that APHIS should base its assessment of the effectiveness of BSE mitigation measures on empirical data from countries that have imposed BSE restrictions, rather than on empirically unproven standards such as those recommended by the OIE.

The commenter stated that Japan allows the importation of beef only from cattle 20 months of age or younger and that the European Union limits imports of beef to that derived from cattle under 30 months of age.

The commenter stated that all countries in which BSE has been diagnosed, except for Canada, remove the brain, spinal column, etc., at slaughter from all bovines 12 months and over, rather than just from all bovines 30 months of age or older, as is required by APHIS for the importation of meat, meat byproducts, and meat food products from BSE minimal-risk regions. The commenter noted that Japan requires the removal of SRMs from cattle of any age. Therefore, stated the commenter, the experience with SRM removal in those countries is inapplicable for predicting risk in the United States and APHIS lacks a basis for stating that the SRM removal it requires has been demonstrated to be highly effective.

Response: We disagree with the commenter in several ways. First, contrary to the commenter's statement, the European Union has determined that its policies regarding the importation of beef are consistent with the OIE Code. Second, the commenter failed to list the United States as a country in which BSE has been diagnosed in a native animal that requires removal of the brain, spinal column, etc., at slaughter from bovines 30 months of age or older. Finally, the commenter's recommendations are inconsistent with scientific findings regarding BSE transmission generally accepted internationally.

As we noted in our September 2007 final rule, in the past few years, significant consideration has been given to the age limits on SRMs and their appropriateness. Additional information obtained from new research findings has contributed to these evaluations. Scientists in Europe have specifically examined these findings as part of their consideration of the age limit in cattle for the removal of SRMs (EFSA Journal, 2005; 2007). In each of these opinions, they conclude that any likely detectable infectivity in the central nervous system (CNS)—including the SRMs in question—appears at about 75 percent of the incubation time. These opinions also note that the experimental low-dose scenarios are more likely to resemble the actual field exposure. The low-dose research scenarios are those in which calves were exposed orally to 1 gram of highly infective brain tissue, rather than the 100 grams used in the high-dose scenario. Experimental attack rate studies indicate that the incubation period for the low-dose scenario has a mean of 60 months, with a range of 45 to 73 months (Wells *et al.,* 2007). Using the low end of this range of incubation period, and assuming that infectivity is present in the CNS at 75 percent of the incubation period, they predict that infectivity would be sub-detectable or still absent in CNS in cattle aged 33 months.

In the United Kingdom, even including cases from the height of the BSE epidemic there, which are believed to have had shorter incubation periods than more recent cases, the peak age at onset of clinical signs was 5 to 6 years. This age of clinical onset is consistent with an assumption that the average incubation period in the United Kingdom has been about 60 months. The average age of animals identified with disease in the European Union is higher than this–the average was 86 months in 2001 and has increased since then. This evidence indicates that considering certain tissues in bovines 30 months of age or older to be SRMs, and removing and disposing of those tissues, would eliminate the majority of infectivity present, and removing and disposing of these same tissues from bovines between 12 and 30 months of age would not provide any significant additional protection.

This same point is illustrated in various models. Comer and Huntly (2003) modeled the potential human exposure available in the United Kingdom from 1980 through 2002. They concluded that an estimated total of 54 million bovine oral ID_{50} units could have been consumed in that timeframe. This period included both the beginning of the epidemic in cattle, before the disease was recognized and public health control measures were established, and later in the epidemic when control measures were developed and instituted. Comer and Huntly also concluded that 99.4 percent of this estimated exposure was from animals older than 30 months of age. Therefore, SRM restrictions from animals greater than 30 months would reduce the vast majority of potential exposure.

Also, as discussed above in this document, in 2006, FSIS/Harvard incorporated changes based on public comment on an October 2005 simulation that used a modified version of the 2001 Harvard BSE risk assessment model. This was made available to the public, along with the responses to the public comments, as ''Harvard Risk Assessment of BSE Update; Phase IA; Supplemental Simulation Results, December 26, 2006.'' The base case simulated 500 infected animals introduced, with 50,000 simulation runs of 20-year timeframes. The base case results, which assumed no removal of SRMs, indicated a mean of 700 total infected animals over the 20 years (500 imports and 200 domestic), with a mean of 6,600 cattle oral ID_{50}s potentially available for human consumption. In comparison, modeling a requirement for removal from the human food supply of SRMs from cattle 30 months of age or older, assuming 100 percent compliance, indicated a mean of 20 oral ID_{50}s potentially available for human consumption over the 20-year time period. The update also modeled requirements for removal from the human food supply of SRMs from cattle 12 months of age and older and 24 months of age and older. There was no significant difference between the results of those models and that which modeled a requirement for removal from the human food supply of SRMs from cattle 30 months of age and older—*viz.,* 17 oral ID_{50}s each when SRM removal from cattle 12 months of age and older and 24 months of age and older were modeled, compared to 20 oral ID_{50}s when removal of SRMs from cattle 30 months of age was modeled.

In summary, we agree with the conclusion that has been widely reached and that has generally been accepted internationally, that the primary public health protective measure regarding BSE is the removal of SRMs from the human food supply, and we concur that the OIE recommendations address those tissues that have been shown to contain BSE infectivity.

Issue: Several commenters stated that our September 2007 final rule should be withdrawn because the USDA's OIG reported in 2008 that APHIS' import controls are not sufficient to prevent, detect, or address the entry of animals that do not meet import requirements. The commenters expressed concern about APHIS' ability to prevent the introduction of a BSE-infected animal from Canada and concluded that the OIG report demonstrates that APHIS is incapable of adequately enforcing import restrictions necessary to protect the health of U.S. cattle and U.S. consumers.

One commenter stated that the OIG report dealt with, among other things, APHIS' enforcement of requirements in its January 2005 final rule during the period between August 2006 and July 2007. The commenter stated that the report concluded that APHIS' import procedures were not sufficient to prevent unauthorized shipments of live animals into the United States. The commenter stated, further, that according to the OIG report, the

problems that the OIG found regarding compliance with APHIS' January 2005 final rule raise concerns with APHIS' controls over live animal imports and whether the controls are adequate to ensure compliance with import restrictions contained in APHIS' September 2007 final rule. The commenter stated that the OIG audit also referenced other findings regarding APHIS enforcement of its regulations.

The commenter stated that the OIG report contradicts APHIS' statement in its September 2007 final rule that there were only individual instances of errors or violations regarding the provisions of APHIS' January 2005 final rule. The commenter stated that OIG found the errors and violations to be pervasive and stated that the OIG report concluded that problems associated with inaccurate health, age, identification, and pregnancy status on Canadian cattle certificates that were used to import more than 7,000 cattle were not isolated occurrences because they involved at least 52 different Canadian veterinarians and 40 CFIA officials. The commenter stated that APHIS was aware, while preparing its September 2007 final rule, that OIG was auditing its import controls and finding what the commenter termed serious violations of APHIS' enforcement of the January 2005 final rule.

Response: We agree that the OIG audit referenced by the commenter identified several areas where APHIS could improve its management controls and documentation regarding import procedures. Our response to the audit agrees with many of the recommendations and identifies actions to address them. In many instances, these actions will assist APHIS in documenting issues to provide sufficient information for an analysis to determine the true significance of the reported issues. The report itself acknowledges that OIG had ''difficulty assessing the significance of import noncompliance * * *.'' (Audit Report, USDA's Controls Over the Importation and Movement of Live Animals, Department of Agriculture, Office of Inspector General, Midwest Region, Report No. 50601–0012–Ch, March 2008). The commenter stated that OIG found errors in certificates to be pervasive, yet the report does not reach this conclusion. OIG identified a total of 211 cattle that were imported with inaccuracies on the health certificate—86 animals inaccurately certified for pregnancy status, 105 animals allegedly inaccurately certified for age, and 21 with inaccurate identification. These inaccuracies are out of a total of 1.1 million animals imported in that year. While we agree with the recommendations in the report and are taking actions to improve our processes, we disagree with the commenter's conclusion that this level of inaccuracies is pervasive and that this demonstrates that APHIS is incapable of enforcing its import regulations.

Issue: One commenter stated that, in its September 2007 final rule, APHIS relied on disproven findings to support its decision to remove the delay of applicability of those provisions of its January 2005 final rule governing the importation of meat and meat byproducts from BSE minimal-risk regions. The commenter stated that, as justification for its decision to lift the ban on the importation of such commodities from Canada, APHIS asserted that its 2005 evaluation of the epidemiology of BSE cases identified at that time suggested that Canada's BSE outbreak was only a local exposure, based on the relatively small geographical location, temporal association, and the clustering of cases. The commenter stated that this conclusion has been disproven by subsequent outbreaks of BSE that occurred prior to APHIS' publication of its September 2007 final rule.

Response: The commenter is incorrect that, in its September 2007 final rule, APHIS cited the results of the 2005 evaluation of the epidemiology of BSE cases identified in Canada as justification for lifting the delay of applicability of certain provisions of its January 2005 final rule. In its September 2007 final rule, APHIS explained its rationale for the lifting of the delay of applicability as follows:

> Since the date of the partial delay of applicability of our January 2005 final rule, we have obtained additional information regarding all aspects of the issues that prompted the delay of applicability and have conducted additional analyses in line with the plan as described. The risk assessment for this final rule demonstrates the negligible BSE risk from the importation of additional classes of live cattle, including those 30 months of age or older. This includes acknowledging the potential risk pathway that could be available if the SRMs from infected imported cattle entered the ruminant feed supply in contravention of current feed regulations. The negligible risk from the importation of live older cattle therefore gives further support to the conclusion of the risk analysis conducted for our January 2005 final rule regarding meat and meat products derived from bovines of any age in BSE minimal-risk regions. Specifically, the risk is even lower for the importation of meat and meat products, as the SRMs will be removed in accordance with the regulations, than for live bovines. (72 FR 53316)

APHIS' description of the 2005 epidemiological investigation referred to by the commenter appeared in its September 2008 request for comments on the removal of the delay of applicability, and was included, for the sake of completeness, in a chronological list of events that occurred since APHIS' November 2003 proposal to establish the category of BSE minimal-risk regions. In the September 2008 request for comments, APHIS did not point to the 2005 epidemiological investigation as the rationale for removing the delay of applicability.

Issue: One commenter stated that, in its September 2007 final rule, APHIS projected that 75,000 cull cattle 30 months of age and older would be imported from Canada. However, stated the commenter, USDA data showed that by November 8, 2008, the United States had imported approximately 167,224 cull cattle 30 months of age or older from Canada. The commenter stated that APHIS has explained that projected imports are a key component of the likelihood of BSE infectivity. Thus, stated the commenter, APHIS' estimate that the implementation of the September 2007 final rule could lead to the introduction of between 19 and 105 BSE-infected cattle into the United States—which could, in turn, produce BSE infections in 2 to 75 U.S.-born cattle, lasting over a 20-year period—understates the actual level of BSE infectivity that has likely entered the United States in 2008.

Response: The commenter is correct that, in analyzing the potential economic effects of its September 2007 final rule, APHIS projected that 75,000 cull cattle 30 months of age and older would be imported into the United States from Canada in 2008. That number was a decrease from the 657,000 head that APHIS had originally projected in its January 2007 proposed rule, and took into account information supplied by commenters on the proposed rule. However, the risk analysis for the September 2007 final rule continued to use a projected importation of 657,000 head. Therefore, the number of cull cattle actually imported under the provisions of the final rule was less than that assumed in the risk analysis.

Issue: One commenter stated that APHIS' promulgation of its September 2007 final rule violates the Agency's Congressional mandate to take the action necessary to prevent the introduction into or dissemination within the United States and to take the steps necessary to detect, control, and eradicate animal disease. The commenter stated that APHIS acknowledged that the September 2007 final rule could result in the importation

of some BSE-infected cattle from Canada. For this reason, stated the commenter, APHIS should withdraw its September 2007 final rule.

Response: We disagree that the Secretary acted outside his broad authority under the Animal Health Protection Act (AHPA) (7 U.S.C. 8301 *et seq.*) in promulgating the September 2007 final rule. The applicable section of the AHPA provides that ''the Secretary may prohibit or restrict * * * the importation or entry of any animal, article, or means of conveyance * * * if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock'' (7 U.S.C. 8303 (a)(1)). The United States Court of Appeals for the Ninth Circuit held that this section confers ''wide discretion'' on the Secretary in dealing with imports and ''does not impose any requirement on USDA that all of its actions carry no associated increased risk of disease'' (R-*CALF* v. *USDA,* 415 F.3d 1078, 1094). The court found that open borders are a default under the AHPA and that the Secretary can close them only when he has determined that it is necessary. The court noted that the statute's use of the word ''may'' suggests that the Secretary has broad discretion to decide whether to close the borders at all (*id.* at 1094–1095). We do not believe that the September 2007 final rule violates our statutory mandate and we deny the commenter's request to withdraw the rule on this basis.

Issue: One commenter stated that the United States should prohibit the importation of beef or cattle from any country known to have BSE. Another commenter stated that beef and cattle trade with Canada should not be expanded until, among other actions pertaining just to live animals, Canada can verify 100 percent compliance with its ruminant feed ban and that its cattle herd and beef products are BSE-free.

Response: The actions recommended by the commenter are not supported by scientific evidence or empirical data, nor are they consistent with internationally accepted animal health standards. Such action, if taken in turn by U.S. trading partners with regard to U.S. beef and cattle, would eliminate the export of beef and cattle from the United States.

In a series of documents published from November 2003 through September 2008, which we discuss above in this document, APHIS provides the scientific rationale for classifying Canada as a BSE minimal-risk region and allowing the importation of certain ruminants and ruminant products from Canada under specified conditions.

The regulatory conditions for the importation into the United States of beef and cattle from a BSE minimal-risk region such as Canada are consistent with the OIE Code for trade in beef and live animals from a country recognized by the OIE as having controlled risk for BSE. Both Canada and the United States are recognized as BSE controlled risk countries.

The OIE, of which the United States is a Member country, is the internationally recognized standard-setting body that develops science-based recommendations for the safe trade of animals and animal products. The World Trade Organization has recognized 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.

The OIE facilitates intergovernmental cooperation to prevent the spread of contagious diseases in animals by sharing scientific research among its members. The major functions of the OIE are to collect and disseminate information on the distribution and occurrence of animal diseases and to ensure that science-based standards govern international trade in animals and animal products. The OIE carries out its function through the development and revision of international standards for diagnostic tests, vaccines, and the safe international trade of animals and animal products.

The OIE develops risk-based standards, which, if agreed upon by Member countries through consensus, are published in the OIE Terrestrial Animal Health Code (Code). However, each OIE Member country is obligated to review and comment on proposed OIE standards, and make decisions regarding the adoption of those standards, strictly on their scientific merits.

As an OIE Member country, the United States reviews and, where appropriate, comments on all draft OIE chapters and revisions. As part of the U.S. 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.

In addition, each year, prior to formulating its comments for the OIE annual meeting, APHIS makes available on its Web site those potential changes to the Code that the OIE has submitted to Member countries for comment, and accepts information and recommendations from the public regarding those proposed changes. Through its OIE Reference Laboratories and Collaborating Centers, APHIS also provides OIE Member countries with technical assistance and expert advice on disease surveillance and control and risk analysis, as well as diagnostic assistance, evaluation, and consultation.

Over the years, the OIE Member countries, including the United States, have agreed by consensus to amend the OIE Code based on increased scientific evidence regarding the disease. The OIE Code reflects the current understanding that, depending on multiple factors, there can be gradations in the risk of the BSE agent being moved from one country to another, and gradations in the risk of BSE transmission and amplification within any particular country. As a member of the OIE, 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.

Issue: One commenter stated that beef and cattle trade with Canada should not be expanded until U.S. international beef export markets are firmly established. The commenter also urged that, if the restrictions on importations from Canada are removed, American cattle producers be compensated for economic disadvantages that might arise from such importations. Another commenter stated that U.S. exports are suffering because the United States requirements for imports from Canada are consistent with OIE standards but less stringent than the requirements imposed by other countries for the importation into those countries of beef from the United States.

Another commenter stated that, as noted above, in its September 2007 final rule, APHIS projected that 75,000 cull cattle 30 months of age older would be imported from Canada. However, stated the commenter, USDA data showed that by November 8, 2008, the United States had imported approximately 167,224 cull cattle 30 months of age or older from Canada. The commenter stated that although APHIS had projected revenue losses of over $66 million for U.S. cattle producers due to the importation from Canada of cattle 30 months of age or older, the larger number of such cattle actually imported will make those losses significantly higher.

Response: As we stated in our September 2007 final rule, APHIS does

not have the statutory authority to restrict trade based purely on its potential economic impact, market access effects, or quantity of products expected to be imported. Under the AHPA, the Secretary of Agriculture may prohibit or restrict the importation or entry of any animal or article when the Secretary determines it is necessary to prevent the introduction or dissemination of a pest or disease of livestock. This authority has been delegated to APHIS.

We note that neither our January 2005 final rule nor our September 2007 final rule made any commodities eligible for importation from Canada that were not already allowed importation prior to May 2003, when a BSE-infected cow was diagnosed in Canada. One difference between the current situation and pre-May 2003, however, is that certain of the commodities that are now eligible for importation are subject to risk-mitigating importation conditions appropriate to the fact that BSE has been detected in Canada and that we consider that country a minimal-risk region for BSE. Both Canada and the United States have been classified as controlled-risk countries for BSE under the OIE Code. Nonetheless, there are some commodities (e.g., cattle born before March 1, 1999) that continue to be ineligible for importation into the United States. Even taking into account such restrictions, however, the current regulations represent to a great extent a return to trade patterns that existed between the United States and Canada for many years previously.

Issue: One commenter stated that during the period 2004–2007 the United States lost a total of $11 billion in the sale of U.S. beef abroad, including $5.7 billion in lost sales to Japan and $3.7 billion in lost sales to Korea. The commenter stated that restrictions on the importation of U.S. beef by other countries shows that those countries view OIE BSE risk mitigation standards—which the commenter stated the United States applies to imports of Canadian cattle and beef—as inadequate to protect their consumers from exposure to BSE.

Response: The reduction in export sales that the commenter cites occurred during a 3-year period that began following the diagnosis of BSE in a cow of Canadian origin in Washington State in December 2003, prior to the publication of APHIS' final rule recognizing the category of BSE minimal-risk regions. As we stated in our September 2007 final rule, U.S. Government agencies are actively negotiating with trading partners to reestablish our export markets. After the December 2003 detection of an imported BSE-infected cow in Washington State, many of the 114 nations that imported U.S. beef banned our beef and live animals, despite the apparent lack of scientific basis for such measures. The efforts of multiple U.S. Government agencies have succeeded in removing bans in over half of those markets, including our largest export market, Japan. U.S. Government agencies continue to work to reopen or further open markets where restrictions remain.

Issue: One commenter stated that beef and cattle trade with Canada should not be expanded until mandatory country of origin labeling (COOL) is fully implemented and enforced.

Response: On May 13, 2002, President Bush signed into law the Farm Security and Rural Investment Act of 2002, more commonly known as the 2002 Farm Bill. One of its many initiatives requires country of origin labeling (COOL) for beef, lamb, pork, fish, perishable agricultural commodities and peanuts. The COOL program became fully effective as of March 16, 2009. However, as USDA's Agricultural Marketing Service noted in its October 30, 2004 proposal in discussing Section 10816 of Public Law 107–171 (7 U.S.C. 1638–1638d), the ''intent of the law is to provide consumers with additional information on which to base their purchasing decisions. It is not a food safety or animal health measure. COOL is a retail labeling program and as such does not address food safety or animal health concerns.''

Affirmation of Position Regarding Removal of Delay of Applicability

After closely considering the issues raised by commenters in response to our September 2008 request for comments, for the reasons given in our September 2007 final rule and in this document we are affirming the position we took in removing the delay of applicability of certain provisions of our January 2005 final rule.

III. Proposed Changes

Although APHIS has amended its BSE regulations in recent years consistent with increased scientific understanding of the disease, we believe that the regulations contain certain provisions that are not yet fully consistent with the latest scientific literature. Therefore, in this document we are proposing to establish conditions for the importation of live bovines and products derived from bovines that we believe are more reflective of current scientific understanding of BSE.

We are proposing to base importation conditions on the inherent risk of BSE infectivity in specified commodities, as well as on the BSE risk status of the region from which the commodities originate. We are proposing to establish a system for classifying regions as to BSE risk that is consistent with the system employed by the OIE. The conditions we are proposing for the importation of specified commodities are based on internationally accepted scientific literature and, except in a few instances, are consistent with the OIE Code. We are also proposing to classify certain specified countries as to BSE risk and are proposing to remove BSE restrictions on the importation of cervids and camelids and products derived from such animals. We are proposing to make these amendments after conducting a thorough review of relevant scientific literature and a comprehensive evaluation of the issues and concluding that the proposed changes to the regulations would 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.

Evolution of U.S. Regulatory Response to BSE

As discussed earlier in this document, the Federal Government conducts a coordinated response to protect humans and livestock from BSE. The protective measures APHIS has taken have evolved over the years, as scientific understanding of the disease has increased. From 1997 until 2005, the only two categories of regions listed in the CFR with regard to BSE were regions in which BSE is known to exist and regions of undue risk for BSE. The regulations prohibit the importation from such regions of live cattle and other ruminants and certain ruminant products, including most rendered protein products. Imports from any region not listed in either of those two categories are not subject to any BSE prohibitions or restrictions. While this approach has been successful in protecting against the risk of BSE, advances in scientific understanding of the disease now allow the United States to take a more focused approach.

In terms of method of transmission, BSE differs from most other livestock diseases. Oral ingestion of feed contaminated with the BSE agent is the only documented route of field transmission of the disease. This understanding of the disease made it increasingly evident that preventing material potentially infected with the BSE agent from being fed to ruminants is a key to preventing introduction and amplification of the disease within a

livestock population. Scientific research also found that some bovine tissues have demonstrated infectivity, whereas others have not, and that levels of infectious agent in certain tissues vary with the age of an animal.

This scientific evidence regarding the most likely method of transmission of BSE was the basis for measures taken by Federal agencies to protect the U.S. human and livestock populations from BSE. As noted above under the heading ''Rulemaking Regarding BSE,'' in June 1997 FDA prohibited the use of all mammalian protein, with the exception of pure pork and pure equine protein from single species processing plants, in animal feeds given to cattle and other ruminants, and established measures to protect against the contamination of ''allowable'' feed material with materials that could contain the BSE agent (62 FR 30936; codified at 21 CFR 589.2000). The rule also allows exceptions for certain products believed to present a low risk of transmitting BSE: blood and blood products; gelatin; inspected meat products that have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings, referred to below as ''plate waste''); and milk products (milk and milk protein).

FSIS, in a series of three interim final rules published in the **Federal Register** on January 12, 2004, established provisions to supplement its measures to prevent the BSE agent from entering the human food supply. As discussed above, in one of the interim final rules (FSIS Docket No. 03–025IF; 69 FR 1861–1874), FSIS, among other actions, designated 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 DRG of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle as SRMs, and prohibited their use as human food. To ensure effective removal of the distal ileum, the SRM rule required establishments to remove the entire small intestine and dispose of it as inedible. FSIS also required all slaughtering and processing establishments to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments were specifically required to implement procedures to address the potential contamination of edible materials with SRMs before, during, and after entry into the establishment. FSIS did not restrict the age of cattle eligible for slaughter, because the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections (i.e., apparently healthy cattle). The rule also declared mechanically separated beef (MS beef)) to be inedible and prohibited its use for human food, and prohibited all non-ambulatory disabled cattle for use as human food.

The second interim final rule (FSIS Docket No. 03–038IF; 69 FR 1874–1885) prohibited products produced by advanced meat recovery systems from being labeled as ''meat'' if, among other things, they contain central nervous system (CNS) tissue.

The third interim final rule (FSIS Docket No. 01–0331IF; 69 FR 1885–1891) prohibited the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle because they may force large fragments of CNS tissue into the circulatory system of stunned cattle where they may become lodged in edible tissues.

On July 14, 2004, FDA published in the **Federal Register** an interim final rule (69 FR 42255–42274, Docket No. 2004N–0081), consistent with the January 2004 FSIS rulemaking, that prohibited the use of certain cattle material in human food, including dietary supplements, and cosmetics.

On September 7, 2005, FSIS published in the **Federal Register** an interim final rule (70 FR 53043–53050, Docket No. 03–025IFA) that allowed for use as human food, under certain conditions, beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments or in certified foreign establishments in countries listed by FSIS in 9 CFR 327.2(b) as eligible to export meat products to the United States.

Also on September 7, 2005, FDA published an interim final rule (70 FR 53063–53069, Docket No. 2004N–0081) and request for comments in which it provided that small intestine is not considered a prohibited cattle material if the distal ileum is removed by a qualifying procedure. FSIS imposed a similar requirement in its interim rule.

On July 13, 2007, FSIS published an interim final rule (72 FR 38199–38730, Docket No. 03–025F) that affirmed its January 2004 interim final rules with some changes.

In its September 2007 final rule (discussed above under the heading ''Rulemaking Regarding BSE,'') APHIS, among other things, made its BSE regulations consistent with the FSIS and FDA changes regarding the small intestine.

On April 25, 2008, FDA published a final rule (73 FR 22718–22758, Docket No. 2002N–0273) to prohibit the following in the food or feed of all animals: The entire carcass of BSE-positive cattle; the brains and spinal cord from cattle 30 months of age and older; the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not removed; tallow that is derived from BSE-positive cattle; tallow that is derived from other materials prohibited by the April 2008 final rule that contains more than 0.15 percent insoluble impurities; and mechanically separated beef that is derived from the materials prohibited by the April 2008 final rule.

International Standards

The science upon which U.S. Federal agencies have based their rulemaking has also been the basis for internationally accepted BSE-related standards governing the trade of ruminants and ruminant products. Much of the information that follows regarding the OIE and the United States' role in international standard setting is set out above in our response to a comment from the public on our September 2008 request for comments. We repeat it here because of its relevance to the changes we are proposing in this document. As noted above, the OIE, of which the United States is a Member country, is the internationally recognized standard-setting body that develops science-based recommendations for the safe trade of animals and animal products. The OIE is currently composed of 174 Member nations, each of which is represented by a delegate who, in most cases, is the chief veterinary officer of that country. The World Trade Organization has recognized the OIE as the international forum for setting animal health standards, reporting global animal disease events, and presenting guidelines and recommendations on sanitary measures related to animal health.

As noted above, the OIE facilitates intergovernmental cooperation to prevent the spread of contagious diseases in animals by sharing scientific research among its members. The major functions of the OIE are to collect and disseminate information on the distribution and occurrence of animal diseases and to ensure that science-based standards govern international trade in animals and animal products. The OIE aims to achieve these through

the development and revision of international standards for diagnostic tests, vaccines, and the safe international trade of animals and animal products.

The OIE develops risk-based standards, which, if agreed upon by Member countries through consensus, are published in the OIE Terrestrial Animal Health Code (Code). The OIE Code chapters are drafted (or revised) by either the Terrestrial Animal Health Standards Commission or by *ad hoc* groups composed of technical experts nominated by the Director General of the OIE by virtue of their subject-area expertise. Once a new chapter is drafted or an existing one is revised, the chapter is distributed to Member countries for review and comment.

Generally, if a country has concerns with a particular draft standard, and supports those concerns with sound technical information, the pertinent OIE Code Commission will revise that standard accordingly, circulate the revised standard to OIE Member countries for comment, and present the revised draft for adoption at the General Session in May. In the event that a country's concerns regarding a draft standard are not taken into account, that country may refuse to support the standard when it comes up for adoption at the General Session. However, each Member country is obligated to review and comment on proposed standards, and make decisions regarding the adoption of those standards, strictly on their scientific merits.

Through APHIS, the United States plays on ongoing role in the development and revision of the OIE Code. The science upon which APHIS has based its regulations has also been the basis for APHIS' recommendations regarding and response to BSE-related changes in the OIE Code. APHIS maintains a data base of disease and subject matter experts to review specific Code chapters; monitors and evaluates reports and scientific data produced by the OIE; and conducts meetings with staff members, pertinent industry groups, and subject matter experts to review and develop positions for the safe movement of animal and animal products.

As an OIE Member country, the United States reviews and, where appropriate, comments on all draft OIE chapters and revisions. As part of the U.S. 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.

In addition, each year, prior to formulating its comments for the OIE annual meeting, APHIS makes available on its Web site those potential changes to the Code that the OIE has submitted to Member countries for comment, and accepts information and recommendations from the public regarding those proposed changes. (The proposed changes can be accessed at *http://www.aphis.usda.gov/import_export/animals/oie/*). Through its OIE Reference Laboratories and Collaborating Centers, APHIS also provides OIE Member countries with technical assistance and expert advice on risk analysis and disease surveillance and control, as well as diagnostic assistance, evaluation, and consultation.

Over the years, the OIE Member countries, including the United States, have agreed by consensus to amend the OIE Code based on increased scientific evidence regarding the disease. The OIE Code reflects the current understanding that, depending on multiple factors, there can be gradations in the risk of the BSE agent being moved from one country to another, and gradations in the risk of BSE transmission and amplification within any particular country. As a member of the OIE, 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.

This recognition of varying levels of BSE risk is the underpinning for OIE's system of classifying countries according to different levels of BSE risk. Currently, the OIE categorizes countries as either negligible risk, controlled risk, or undetermined risk for BSE. For live cattle and for many products derived from cattle, the trade conditions recommended by the OIE Code are based on the BSE risk classification of the exporting country.

Changes to APHIS' Regulations Regarding BSE

In recent years, APHIS has amended its regulations consistent with scientific evidence and BSE risk management that allow the United States to take a more focused approach to categorizing regions and establishing import prohibitions and restrictions with regard to BSE. As discussed above, in January 2005, APHIS amended its regulations to recognize a category of regions that present a minimal risk of introducing BSE into the United States, even though BSE may have been diagnosed in the region. In evaluating the BSE risk from a region to determine whether to classify it as a minimal-risk region, APHIS considers a combination of factors, focusing on overall effectiveness of control mechanisms in place (e.g., surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). In its 2005 rule, APHIS also established conditions for the importation of certain live ruminants and ruminant products and byproducts from such regions and recognized Canada as a BSE minimal-risk region. We based our recognition of Canada as a BSE minimal-risk region on an analysis we conducted of the conditions considered for such a designation and the information available to us regarding how Canada meets those conditions. (The risk document, ''Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities.'' which also identified measures necessary to mitigate any BSE risk that specific commodities imported from Canada might present to the United States, can be accessed at *http://www.aphis.usda.gov/peer_review/downloads/risk_assessment_final9-2007.pdf*)

As noted above, in December 2005, APHIS amended its regulations to allow the importation of certain cuts of boneless beef from Japan. The risk assessment conducted for that rulemaking examined the evidence supporting the safety of this commodity. This evidence and APHIS' conclusions were consistent with OIE for trade in meat derived from cattle from regions of controlled risk for BSE. (The risk document, ''Analysis of Bovine Spongiform Encephalopathy (BSE) Risk to the U.S. Cattle Population from Importation of Whole Cuts of Boneless Beef from Japan,'' can be accessed at *http://www.regulations.gov/#!documentDetail;D=APHIS-2005-0073–0002*).

As discussed above, in September 2007, APHIS again amended the BSE regulations to allow the importation of additional commodities from BSE minimal-risk regions. As part of this rulemaking, APHIS conducted a risk assessment that was peer reviewed by recognized experts in the field. (The risk assessment, peer review, and APHIS responses to peer review comments can be accessed at *http://www.aphis.usda.gov/peer_review/downloads/risk_assessment_%20final9-2007.pdf*).

BSE Categories in Current APHIS Regulations

With the 2005 addition to the regulations of the BSE minimal-risk category, the three categories of regions

with regard to BSE set forth in APHIS' regulations became: (1) Those in which BSE is known to exist (listed in § 94.18(a)(1) of the regulations); (2) those that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance (listed in § 94.18(a)(2) of the regulations); and (3) those that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products and byproducts (listed in § 94.18(a)(3) of the regulations). These are the categories set forth in the current regulations.

How APHIS categorizes a region with regard to BSE risk determines which ruminants and products derived from ruminants from that region are eligible for importation into the United States. Of the three categories listed in § 94.18(a), those regions listed in § 94.18(a)(1) (regions in which BSE is known to exist) and in § 94.18(a)(2) (regions that present an undue risk of introducing BSE into the United States) are subject to the most restrictive BSE-related regulatory provisions. The prohibitions and restrictions on the importation of live ruminants and commodities derived from ruminants are the same for regions in either of those categories.

The importation of live ruminants of any kind is prohibited from regions listed in either § 94.18(a)(1) or § 94.18(a)(2). Additionally, with certain exceptions, regions listed in either § 94.18(a)(1) or § 94.18(a)(2) are not eligible to import into the United States the following commodities derived from ruminants that have been in the regions: Meat; meat products; and edible products other than meat. Also, with certain limited exceptions, the following commodities are prohibited importation into the United States if they are derived from ruminants that have been in any region listed in § 94.18(a)(1) or § 94.18(a)(2), or if the commodities themselves have been in such regions (and, in some cases, if they are derived from nonruminant species that might have been commingled with products derived from ruminants): Processed animal protein; tankage; offal; tallow other than tallow derivatives (unless, in the opinion of the Administrator, the tallow cannot be used in feed); glands and unprocessed fat tissue; processed fats and oils; derivatives of processed animal protein, tankage, and offal; derivatives of glands; casings, other than stomachs; and serum and related materials.

Under the regulations regarding BSE minimal-risk regions, specified live ruminants and products derived from ruminants are eligible for importation from such regions, provided certain conditions are met. Factors governing the eligibility of and conditions for importation of such commodities from BSE minimal-risk regions include the following: The species of animal intended for importation or from which products were derived; whether an animal intended for importation has been properly identified; whether the animal had been subject to a ruminant-to-ruminant feed ban; and, in the case of products derived from bovines, whether specified BSE risk materials were removed from the animal at slaughter.

APHIS does not restrict the importation into the United States of ruminants and ruminant products from any region that is not listed in one of the three categories included in § 94.18(a) (regions in which BSE is known exists, regions of undue risk for BSE, and regions of minimal risk for BSE), but their importation might be prohibited or restricted due to other animal diseases.

Proposed Changes

Refining science-based regulations for safe trade in bovines and meat and other products derived from bovines has been and continues to be a high priority for APHIS. As noted above, although APHIS' regulatory changes in recent years with regard to BSE have been consistent with increased scientific understanding of the disease, we believe that further refinement of the regulations is in order given the latest scientific literature regarding BSE. In this document, we are proposing to amend the regulations to establish importation requirements based on our current scientific understanding of the risk of BSE. In many instances these changes, while still protecting livestock in the United States from BSE, would allow the importation into the United States of additional commodities. In a few cases, this proposal would make BSE-related import conditions more restrictive.[10]

OIE Code

APHIS is closely familiar with the development of the OIE Code and considers it to be based on sound science. The scientific literature upon which we are basing our proposed regulations includes literature that has been considered by OIE subject matter experts and Member countries in developing and updating the OIE Code, as well as other scientific literature reviewed by APHIS. One result of implementing these science-based changes would be to make the APHIS regulations more consistent with the 2010 OIE Code. In those few instances where our proposed provisions differ from the guidelines in the 2010 OIE Code, we provide a science-based rationale for those differences, either in this document or in the supporting scientific documentation.

The OIE Code reflects the scientific understanding of the nature of BSE and appropriate risk mitigation measures. Two of the most important risk mitigation measures are the control of SRMs and feed bans. Most of the OIE guidelines rest on these two significant mitigation measures. An additional risk mitigation measure can be the application of certain production processes that can achieve a level of inactivation of the BSE agent. In some instances, industrial production methods—such as those for gelatin production—are sufficient to provide varying levels of inactivation of the BSE agent. These are described in more detail in this document in the relevant sections for these products. The use of these mitigation measures as outlined in the OIE Code significantly reduces the risk that the BSE agent might be present in the animals or products presented for trade.

The same mitigation measures are applied domestically, thus minimizing the risk that BSE will become established in the United States if the BSE agent is present in an imported animal or product. Using the importation of live cattle as an example, we can consider the risk pathway for transmission of BSE. Several steps must take place for BSE to be transmitted to cattle in the United States from a bovine imported live from another country. A BSE-infected bovine must be imported into the United States; the infected bovine must die or be slaughtered; tissues from that animal that contain sufficient levels of the infectious agent must be sent to a rendering facility; the infectivity present in these tissues must survive inactivation in the rendering process; the resulting processed animal protein containing the abnormal prion protein must be incorporated into feed; and this feed must be fed to cattle at a level adequate to infect the cattle. (The amount of infectious material required in feed for cattle to become infected is dependent on the age of the cattle; younger cattle are more susceptible to BSE and require less BSE-contaminated feed to become infected.) The nature

[10] For example, ruminant-derived MBM and greaves, and products containing such, sourced from regions of controlled and undetermined risk would be prohibited.

and likelihood of these pathways depend in large part on mitigations—such as SRM controls and a feed ban—acting in series and in parallel that reduce the likelihood that BSE will be established in the United States.

The combined OIE requirements and additional APHIS requirements would serve to prevent the introduction and spread of the BSE agent from imported commodities regardless of a country's BSE prevalence.

Classification of Regions as to BSE Risk

One of the structural changes this proposed rule would make to the current BSE regulations would be to change the current § 94.18(a) categories of regions in which BSE is known to exist, regions of undue risk for BSE, and BSE minimal-risk regions to the system used by the OIE of classifying areas as being either of negligible risk, controlled risk, or undetermined risk for BSE.[11] Whether a live bovine or a bovine-derived product would be eligible for importation into the United States, and under what conditions, would in many cases be determined by the BSE category of the region from which the animal or product originates.[12]

BSE Classification of Regions

We are proposing to base APHIS' classification of the BSE risk status of a region on the results of an evaluation of BSE risk posed by that region. Under this proposed rule, that evaluation could have been conducted either by APHIS or by the OIE. The process the OIE uses in conducting such an evaluation and the information it considers are equivalent to the process and information APHIS considers necessary to arrive at an appropriate determination of BSE risk. The process and information considered are discussed at greater length, below, under the heading ''Process for Determining BSE Risk Classification.''

Scope of This Proposed Rule

The current APHIS regulations regarding BSE encompass all ruminants and products from all ruminants. Under the current regulations in 9 CFR parts 93, 94, and 98, *ruminants* are defined as ''all animals that chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.'' Included among ruminants are bovines (e.g., cattle), ovines (e.g. sheep), caprines (e.g., goats), cervids (e.g., deer and elk), and camelids (e.g., llamas and alpacas). Bovines are defined in the regulations as *bos taurus, bos indicus,* and *bison bison*—cattle and bison. In the following paragraphs, we discuss how this proposed rule applies to each of these groups of ruminants.

Cervids and Camelids

In prohibiting the importation of all ruminants from regions listed in § 94.18(a)(1) and (a)(2), the current regulations prohibit the importation from such regions of cervids and camelids, and products derived from such animals, from such regions. However, live cervids and camelids and products derived from cervids and camelids are eligible for importation from BSE minimal-risk regions without restriction regarding BSE.

In this document, we are proposing to remove all restrictions with regard to BSE from the importation of live cervids and camelids and their products from any region of the world. Although BSE has been shown to be naturally and experimentally transmitted to a wide range of ruminants, natural transmission of BSE has not been reported in cervids or camelids. One ongoing study shows that red deer (*cervus elaphus)* developed clinical signs similar to chronic wasting disease upon intracerebral inoculation of BSE-infected brain (Martin, *et al.,* 2007); however red deer challenged intra-gastrically with BSE-infected brain developed neither clinical signs of disease nor presence of PrPsc at post-mortem examination. In addition, surveillance in the United Kingdom and European cervid population did not show any evidence of any TSEs (*http://www.cdc.gov/Ncidod/eid/vol12no02/pdfs/05–0970.pdf; http://www.defra.gov.uk/animalh/bse/othertses/index.html*). Therefore, APHIS considers the BSE risk from removing import restrictions on cervids and camelids and their products to be very low. The OIE Code with respect to BSE does not address trade in cervids or camelids.

Ovines and Caprines

In this proposal, we continue to apply the current import prohibitions and restrictions regarding ovines and caprines (e.g., sheep and goats) and their products. 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 such animals. Upon completion of such a proposal, we will publish it in the **Federal Register** for public comment.

Because this proposed rule contains no substantive changes to the import regulations regarding ovines and caprines, any comments we receive in response to this proposed rule that pertain to ovines and caprines will not be addressed in this rulemaking, but will be considered as we develop our proposed rule regarding the importation of ovines and caprines and products from such animals.

Although we are not proposing at this time to make any substantive changes to the regulations regarding the importation of ovines and caprines and products derived from such animals with regard to BSE, we are proposing certain formatting and wording changes to those regulations. We discuss these proposed changes below under the heading ''Provisions Regarding Ovines and Caprines.''

Bovines

As noted above, we are proposing to amend our import regulations with regard to bovines and BSE in a way that would result in our regulations being more consistent with the current scientific understanding of BSE, which is also reflected in the recommendations regarding trade in cattle and cattle products set forth in Chapter 11.5 of the OIE Code.[13]

[11] Although the OIE Code refers to categorization of ''countries, zones, or compartments,'' the only areas that have been classified by OIE with regard to BSE risk to date have been entire countries. In discussing animal diseases in its regulations, APHIS uses the term ''region'' to refer to foreign areas. Under the APHIS regulations, a region can consist of any of the following: (1) A national entity (country); (2) part of a national entity (zone, county, department, municipality, parish, Province, State, etc.); (3) parts of several national entities combined into an area; or (4) a group of national entities combined into a single area. In our proposed rule, we would continue to use the term ''region'' in order to be consistent with our current animal import regulations, and will refer to the geographic and political entities considered by the OIE as ''regions.'' However, when considering BSE risk classification, we do not anticipate dealing with any entities other than individual countries in their entirety. Considering the BSE risk status of entire individual countries would be consistent with past APHIS practice, as well as OIE practice.

[12] The current regulations regarding BSE minimal-risk regions apply to bison as well as cattle. In current §§ 93.400, 94.0, and 95.1 of the regulations, *bovine* is defined as *Bos taurus, Bos indicus,* and *Bison bison.* Although the research and other data cited in this proposed rule refer to bovines other than bison (i.e., to ''cattle''), there is no evidence to indicate that the BSE susceptibility of bison differs from that of cattle. We therefore assume that our conclusions based on cattle-specific evidence discussed in this proposed rule are also applicable to bison. The provisions of this proposed rule would apply to bovines as defined in the current regulations, which include bison.

[13] The current regulations regarding BSE minimal-risk regions apply to bison as well as cattle. In current §§ 93.400, 94.0, and 95.1 of the regulations, *bovine* is defined as *Bos taurus, Bos indicus,* and *Bison bison.* Although the research and other data cited in this proposed rule refer to bovines other than bison (i.e., to ''cattle''), there is no evidence to indicate that the BSE susceptibility of bison differs from that of cattle. We therefore assume that our conclusions based on cattle-specific evidence discussed in this proposed rule

Continued

As discussed above, commodities from regions not listed in any of the categories set forth in § 94.18(a) (regions in which BSE is known to exist, regions of undue risk for BSE, and regions of minimal risk for BSE) are currently not subject to import restrictions because of BSE. Imports from BSE-affected regions and those that present an undue risk are governed by the same set of restrictions, which prohibit the importation of live ruminants and most products derived from ruminants. Imports from BSE minimal-risk regions are governed by their own set of restrictions, which allow for the importation of more commodities than do the regulations regarding BSE-affected regions and those that present an undue risk.

As noted above, the 2010 OIE Code chapter regarding BSE provides for three possible BSE risk classifications: Negligible risk, controlled risk, and undetermined risk. APHIS has thoroughly reviewed the peer-reviewed scientific literature on BSE that the OIE uses to support its guidelines for risk evaluations (discussed in ''Supporting document for Chapter 2.3.13 of the Terrestrial Animal Health Code on Bovine Spongiform Encephalopathy'' (OIE TAHSC, 2006)) and, with certain limited exceptions, agrees with the OIE's recommendations and guidelines. We discuss below the factors the OIE takes into account in making its classifications.

Under the OIE Code for live cattle and many products derived from cattle, many of the recommended measures to mitigate any BSE risk from the trade of such commodities depend on the risk classification of an exporting region. The OIE takes many factors into account in determining whether the BSE risk in a particular country is negligible, controlled, or undetermined. These factors include: The history of BSE in the country; whether BSE-infected animals in the country were imported or were indigenous; if indigenous, how long ago an infected animal was born; identification and destruction of infected animals and potentially exposed animals; the level of surveillance for BSE carried out in the country and the length of time the surveillance has been carried out; whether, and for how long, appropriate awareness and notification programs and laboratory diagnostic procedures have been in place; whether, and for how long, a ban on the feeding of ruminant materials to other ruminants has been effectively enforced. These are the same factors that APHIS took into account when determining that Canada qualified as a BSE minimal-risk region.

In this proposal, we are proposing to amend our BSE regulations to structure classification of regions for BSE risk in the same way as does the OIE. Such classification is based on an overall evaluation of the BSE risk of a region, including a risk assessment. Because the data and process for a BSE risk evaluation that APHIS would conduct are equivalent to those employed by the OIE in making its own evaluations, we are proposing that APHIS' classification of the BSE risk status of an exporting region could be based on either an evaluation of the BSE risk of a country that is conducted by the OIE, or, for regions not yet classified by OIE, on an evaluation conducted by APHIS following a request.

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

We are proposing to add definitions of a region of negligible risk for BSE, a region of controlled risk for BSE, and a region of undetermined risk for BSE to the regulations in § 92.1. The definitions we are proposing to add are substantively the same as those used by the OIE in its Code. However, stylistically, our proposed definitions are, in some places, worded differently from the wording used in the OIE Code.

Regions of Negligible Risk for BSE

There are multiple criteria that must be met for a region to qualify as a region of negligible risk for BSE. Our proposed definition of a region of negligible risk for BSE appears in § 92.1 and includes the following conditions. We are proposing that a region of negligible risk for BSE is one for which a risk assessment has been conducted that is sufficient to identify the historical and existing BSE risk factors in the region and that:

- Has demonstrated that appropriate BSE risk mitigation measures have been taken for at least as long as indicated in this definition;
- Has demonstrated that Type B surveillance in accordance with Article 11.5.22 of the OIE Code, 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 (OIE guidelines for surveillance are discussed below under the heading ''Epidemiological situation concerning BSE in the country.'')
- Has, for at least the past 7 years:

1. Conducted an ongoing awareness program for veterinarians, farmers, and workers involved in the transportation, marketing and slaughter of bovines to encourage reporting of all bovines showing clinical or behavioral signs that could be indicative of BSE.
2. Required notification and investigation of all bovines showing clinical signs consistent with BSE; and
3. 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 system;

- Has demonstrated through an appropriate level of control and audit that, for at least the past 8 years, neither meat-and-bone meal (MBM) nor greaves derived from ruminants have been fed to ruminants. In the OIE Code, the 8-year requirement regarding a feed ban applies to MBM and greaves derived from ruminants. Even though the OIE recommends that regions that are considered controlled risk or undetermined risk should not trade in MBM and greaves derived from ruminants, or in any commodities containing such, APHIS is proposing that the recommendation apply to processed animal protein derived from ruminants or commodities containing processed animal protein derived from ruminants. In part 95 of the current regulations, *processed animal protein* is defined as ''meat meal, bone meal, MBM, blood meal, dried plasma and other blood products, hydrolyzed proteins, hoof meal, horn meal, poultry meal, feather meal, fish meal, and any other similar products.'' Like MBM, each of the other products in the definition is a rendered product, and, except for blood and blood products, we have not yet done an assessment of the BSE risk of the products. Additionally, we believe it is necessary to take into account the risk that the other products could become commingled with MBM, which, if derived from infected ruminants, may contain the infectious agent. APHIS would allow the importation of those processed animal proteins derived from ruminants or commodities containing such after an assessment of the risk has determined that these products are not commingled or contaminated with ruminant MBM or greaves.

In addition to meeting the criteria listed above, for a region to qualify as a region of negligible risk for BSE, one of the following conditions must apply; either:

- There has been no case of BSE in the region; or

are also applicable to bison. The provisions of this proposed rule would apply to bovines as defined in the current regulations, which include bison.

• There have been one or more cases, but each case has been demonstrated to have been imported and has been completely destroyed; or

• There has been at least one indigenous case, but every indigenous case was born more than 11 years ago. If there has been one or more indigenous cases, all bovines included in either of the following two categories must, if still alive, be 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, be completely destroyed:

1. 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 feed that potentially contained SRM material as the infected animal during that period; or

2. 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.

Regions of Controlled Risk for BSE

If a region does not qualify as a region of negligible risk for BSE, we are proposing that it could be classified as a region of controlled risk for BSE if specified conditions are met, as set forth in § 92.1 of this proposed rule and described below. We are proposing that a region of controlled risk for BSE is one for which a risk assessment has been conducted sufficient to identify the historical and existing BSE risk factors in the region and that:

• Has demonstrated that appropriate mitigations are being taken to manage all identified risks, but has not taken every mitigation measure for the length of time that would be necessary to qualify as a region of negligible risk for BSE;

• Has demonstrated that Type A surveillance in accordance with Article 11.5.22 of the OIE Code, 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 equivalent guidelines recognized by the Administrator has been met. Type B surveillance, or equivalent surveillance recognized by the Administrator, is sufficient in place of Type A surveillance once the relevant points target for Type A surveillance has been met;

• Meets the conditions of one of the two following sets of conditions:

Conditions Set 1. There has been no case of BSE in the region, or, if there have been one or more cases of BSE, every case has been demonstrated to have been imported and has been destroyed. In addition, both of the following conditions apply:

• The following conditions have been met and continue to be met:

a. The region has conducted an ongoing awareness program for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of bovines to encourage reporting of all bovines showing clinical signs that could be indicative of BSE;

b. The region has required notification and investigation of all bovines showing clinical signs consistent with BSE; and

c. The region 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 required surveillance and monitoring system;

and:

• The feeding to ruminants of MBM and greaves derived from ruminants is prohibited in the region.

However, the requirements described above regarding awareness, notification, and examination have not been met for at least the past 7 years and/or it cannot be demonstrated that controls over the feeding of ruminant protein to ruminants have been in place for at least the past 8 years.

Conditions Set 2. There has been an indigenous case of BSE, and either or both of the following applies; either:

• The following conditions have been met and continue to be met, but not for at least the past 7 years:

a. The region has conducted an ongoing awareness program for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of bovines to encourage reporting of all bovines showing clinical signs that could be indicative of BSE;

b. The region has required notification and investigation of all bovines showing clinical signs consistent with BSE;

c. The region 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 required surveillance and monitoring system;

or:

• The feeding to ruminants of MBM or greaves derived from ruminants is prohibited in the region, but it cannot be demonstrated through an appropriate level of control and audit that the prohibited material has not been fed to ruminants for at least the past 8 years.

• Additionally, in either of the situations described in this second set of conditions, for a region to qualify as a region of controlled risk for BSE, the following condition must be met: If alive in the region, bovines that are included in either of the following categories 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 feed that potentially contained SRM material 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 the BSE-infected bovine either within 12 months before or 12 months after the birth of the infected animal.

Regions of Undetermined Risk for BSE

A region of undetermined risk for BSE is defined by the OIE, and would be defined by APHIS in § 92.1, as a region that does not meet the criteria for being classified as either a region of negligible risk for BSE or a region of controlled risk for BSE.

Incorporation by Reference of OIE Code Standards for BSE Surveillance

The proposed definitions of *region of negligible risk for BSE* and *region of controlled risk for BSE* include the criteria that the region has demonstrated that specified surveillance in accordance with Article 11.5.22 of the OIE Code, or with equivalent guidelines recognized by the Administrator, is in place and that the relevant points target, in accordance with Table 1 of Article 11.5.22 of the OIE Code or equivalent guidelines recognized by the Administrator has been met.

As discussed above, the OIE, of which the United States is a member country, is the internationally recognized standard-setting body that develops science-based recommendations for the safe trade of animals and animal products. We are proposing to incorporate into the regulations by reference at § 92.7 Article 11.5.22 of the

OIE Code. The OIE surveillance standards are discussed in more detail, below, under the heading ''Epidemiological situation concerning BSE in the country.'' Section 92.7 would also state that the incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and that the OIE maintains a copy of its standards on its internet homepage at *http://www.oie.int/eng/normes/Mcode/en_sommaire.htm.* Additionally, § 92.7 would state that copies of the OIE standards are available for inspection at the National Archives and Records Administration (NARA) and that information on the availability of this material at NARA can be obtained by calling 202–741–6030 or by going to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Process for Determining BSE Risk Classification

In the following paragraphs, we discuss the process followed by the OIE in conducting its evaluation of a country for BSE risk. As noted above, APHIS recognizes the scientific validity of the process used by the OIE and employed an equivalent process in classifying Canada as a BSE minimal-risk region and, in subsequent rulemaking, allowing additional imports of live bovines and bovine products from Canada.

In carrying out its evaluation process, the OIE refers to risk factors as they involve ''cattle.'' Therefore, when discussing the OIE process in this proposed rule, we use the term ''cattle.'' However, as we note above in this document, the provisions of this proposed rule would apply to bovines as defined in the current regulations, which include bison.

As described in the questionnaire for BSE status recognition (*http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/A_BSE quest.pdf*) that is based on Articles 11.5.3 and 11.5.4 of the OIE Code, countries requesting classification from the OIE as a country of negligible risk for BSE or a country of controlled risk for BSE must submit a dossier containing BSE historical data to support a risk assessment and overall evaluation. The information in the dossier is evaluated by BSE experts who are leading specialists regarding the disease.

In the following paragraphs we discuss the OIE procedure for recommending the BSE classification of a country and the rationale behind the considerations taken. As noted above, APHIS considers the approach taken by the OIE to be based on the current scientific understanding of BSE. In its own evaluations of the BSE risk in other countries, APHIS has taken, and will continue to take, an equivalent approach.

For purposes of discussion of the classification process, we will follow the OIE terminology in discussing the country being evaluated for BSE risk as the exporting country or exporting region. In proposed §§ 92.1, 93.400, 94.0, and 95.1, we define *exporting region* as a region from which shipments are sent to the United States.

The risk classification of an exporting country may be influenced by commodities the country has imported from another country. For purposes of discussion, we will follow the OIE terminology and refer to a country that sends commodities to the ''exporting country'' as a ''country of origin.''

Components of a Risk Assessment

A risk assessment is the primary tool used by the OIE in determining whether to recognize a country as either a country of negligible risk for BSE or a country of controlled risk for BSE, and would be the primary tool used by APHIS in making such a determination. An assessment of BSE risk includes at least two components: A release assessment and an exposure assessment. A release assessment assesses the likelihood that BSE has been introduced into the exporting country through live animals, processed animal protein, or other animal products. An exposure assessment assesses the likelihood that cattle within the exporting country could have been exposed to the BSE agent.

Under the OIE Code, in addition to the information necessary to allow OIE to conduct a risk assessment, a country requesting OIE classification as a country of negligible risk or controlled risk for BSE must also submit information regarding the country's BSE awareness program, its notification requirements for BSE, its diagnostic capabilities, and its BSE surveillance program. This type of information was also considered by APHIS in conducting its evaluation of the BSE disease risk of Canada.

Release Assessment Component of a Risk Assessment

As noted above, a release assessment assesses the likelihood of release of the BSE agent into a country through the importation of potentially infected live cattle, processed animal protein, or other products of animal origin potentially infected with BSE. In the following paragraphs, we discuss the significance of these commodities with regard to BSE risk.

Potentially Infected Live Cattle

An assessment of the risk of the release of the BSE agent in the exporting country includes consideration of whether potentially infected live cattle were imported into that country. The risk of the release of the BSE agent in the exporting country is dependent on:

- The BSE status of the country of origin of the potentially infected live cattle;
- The feeding and management of the cattle in the country of origin;
- Whether the cattle are dairy or beef breeds, if there are differences in exposure due to feeding practices in the country of origin;
- The date at which imports occurred, relative to the BSE mitigation in the country of origin; and
- The volume of potentially contaminated imports.

Products of Animal Origin That Could Pose a BSE Risk

A release assessment also considers the importation of animal products that could pose a BSE risk. As with importation of potentially infected live cattle, there are various factors that can affect the potential risk presented by products of animal origin.

- The risk of the release of the BSE agent in the exporting country due to the importation of animal products is dependent on:
- Whether products from cattle contain tissues of the type known to contain BSE infectivity (i.e., SRMs);
- The country of origin of the products and the BSE status of that country;
- The feeding and management of the animals in the country of origin;
- Whether the cattle from which the products are derived in the country of origin are dairy or beef breeds, if there are differences in exposure due to feeding practices in the country of origin; and
- The age at which the cattle from which the products were derived were slaughtered in the country of origin.

For both live animals and animal products, some of the risk factors identified can be mitigated through import requirements. These are evaluated as part of the OIE process. For example, if a country prohibited the importation of any cattle products containing or derived from SRMs, the risk would be mitigated. Therefore, imports meeting those conditions would not necessarily result in an elevated risk as noted in the risk assessment.

For most animal products, the OIE evaluates the information described above regarding products of animal origin that have been imported during the previous 7 years into the potential exporting country (i.e., the country seeking a BSE risk classification from the OIE).

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 if originating from low-risk countries.

Because of the relatively greater BSE risk posed by processed ruminant protein compared to other animal products, the required reporting period for MBM and greaves is greater than for other animal products, and countries seeking BSE risk classification must inform the OIE whether MBM, greaves, or feedstuffs containing either, have been imported into that country within the past 8 years, and, if so, from what country and in what quantities. (In the OIE Code, MBM is defined as ''the solid protein products obtained when animal tissues are rendered, including any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino acids.'' Greaves are the protein-containing residue obtained after the partial separation of fat and water during the rendering process.) Eight years are associated with the incubation period of BSE, and represent a time period longer than the one representing the 95th percentile of the normal distribution of the age of clinical BSE cases detected at the peak of the United Kingdom and Swiss epidemic—i.e., 95 percent of clinical cases of BSE would be expected to be detected in some period of time less than 8 years after exposure to MBM or greaves contaminated with the BSE agent.

Exposure Assessment of the Exporting Country

The exposure assessment assesses the likelihood of exposure to the BSE agent of cattle in the exporting country, given the release of the BSE agent into the country. The exposure assessment evaluates the entire risk pathway for the transmission of BSE in the country. This includes all aspects of the cattle feed production and management systems.

Evidence indicates that field transmission of BSE requires that cattle ingest feed that has been contaminated with tissues or organs containing the BSE agent from an infected animal. Several steps in the risk pathway must take place consecutively for this to happen. An infected animal, carrying significant amounts of the infectious agent, must die or be slaughtered; tissues from that animal that contain the infectious agent must be sent to a rendering facility; the infectivity present in these tissues must survive inactivation in the rendering process; the resulting protein must be incorporated into feed, and this feed must be fed to at least one bovine at an adequate level.

The exposure assessment conducted by the OIE carefully evaluates all of these steps in the pathway as they consider the potential for the exposure of cattle to the BSE agent through consumption of MBM or greaves of bovine origin. This incorporates an evaluation of the implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed. It includes all aspects of the potential for recycling and amplification of the BSE agent—whether the origin and use of bovine carcasses (including fallen stock), byproducts, and slaughterhouse waste presented a risk of recycling or amplification of the BSE agent; the parameters of the rendering processes; and the methods of producing feed for cattle and other animals. The OIE evaluates information addressing each of the factors listed above.

The rendering industry is crucial in reducing the risk of transmitting BSE infectivity, not only because of its role in inactivation of the BSE agent, but also because it serves as a critical control point for the redirection of ruminant protein away from cattle feeds. The OIE evaluates all aspects of the rendering industry. These include what types of tissues and/or carcasses are used as inputs in the rendering process. If SRMs are excluded from the input tissues or carcasses, this reduces the risk. It also includes the parameters of the rendering processes. Certain rendering processes can inactivate a proportion of the BSE agent present. If a fraction of the BSE infectivity were to escape in activation at the rendering facility, it would need to bypass controls imposed to prevent cross-contamination and ensure proper labeling of rendered materials (at the renderer) and feeds produced using prohibited MBM (at the feed mill).

The OIE also evaluates any feed ban or feed controls that are in place in the country. As noted above, it is widely accepted that BSE is caused by the consumption of processed animal protein of ruminant origin carrying and/or contaminated with the BSE agent. For potential exporting countries requesting a classification of BSE risk, the OIE evaluates information on whether MBM or greaves of ruminant origin have been fed to cattle in the country within the previous 8 years, including information regarding the implementation and enforcement of a feed ban and measures to prevent cross-contamination of animal feed. This evaluation includes consideration of the regulations imposing a feed ban, the veterinary infrastructure used to enforce and audit all aspects of the feed ban, and results of all audits or enforcement activities.

The overall risk of BSE in the cattle population of a country is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For a risk assessment to conclude that the cattle population of a country is of negligible or controlled risk for BSE, it must have been demonstrated that appropriate measures have been taken for a set period of time to manage any risks identified. The risk assessment evaluates information, within the context of the risk described above, regarding all aspects of the feeding practices over the previous 8 years in the country.

Additional Factors To Be Considered in the Determination of BSE Risk Status

Epidemiological Situation Concerning BSE in the Country

Surveillance programs generate a picture of the epidemiological situation of BSE in a country. The more targeted the surveillance activities, the greater the power of the information. Surveillance targeted at high-risk populations for BSE provides more powerful information than generic animal disease surveillance for the entire cattle population.

Depending on the characteristics of the country, the goal of BSE surveillance could be to:

- Detect cases at a predetermined design prevalence;
- Monitor the evolution of the disease (i.e., introduction and/or spread);
- Monitor the effectiveness of a feed ban and/or other risk mitigation measures; or
- Provide supporting evidence for claimed BSE status or for maintaining status or advancing to a higher BSE status.

Targeted sampling for BSE surveillance focuses on two factors that

have been shown to be relevant to determining the risk for BSE: Clinical presentation and age. For the purpose of disease detection, it is most efficient to collect as many samples as possible from the surveillance stream that has the greatest likelihood of finding the disease—cattle displaying clinical signs consistent with BSE. This is referred to as targeted surveillance.

The OIE Code provides guidelines for surveillance programs based on a weighted point system (Article 11.5.22). This system reflects international scientific consensus that the best BSE surveillance programs focus on obtaining quality samples from targeted subpopulations, rather than looking at the entire adult cattle population.

OIE has identified the following four subpopulations of cattle for surveillance purposes:

1. *Clinical suspects:* Cattle over 30 months of age that display behavioral or clinical signs consistent with BSE.
2. *Casualty slaughter:* Cattle over 30 months of age that are nonambulatory, recumbent, unable to rise or to walk without assistance, sent for emergency slaughter, or condemned at ante-mortem inspection.
3. *Fallen stock:* Cattle over 30 months that are found dead on-farm or during transport to or at an abattoir.
4. *Healthy slaughter:* Cattle over 36 months that exhibit no clinical signs consistent with BSE or other diseases.

The number of points a sample receives correlates directly to an animal's clinical presentation at the time of sampling. The highest point values are assigned to those samples from the subpopulation of animals with classic clinical signs of the disease. The lowest point values correspond to animals from the subpopulation of clinically normal animals tested at routine slaughter. This weighted approach allows countries the flexibility to sample readily available surveillance streams, while taking into account the differences in the statistical value of samples from different streams. As a result, countries have the option of using varying approaches that can provide equal levels of assurance in defining the level of disease.

Type A Surveillance

Type A surveillance is recommended for countries that would like to meet the controlled-risk status. The OIE BSE surveillance guidelines recommend a target number of surveillance points for Type A surveillance based on the size of a country's cattle population. For instance, a country with an adult cattle population of 800,000 to 1 million should collect samples whose total point value equals 240,000 points. These points are accrued over 7 consecutive years, and are weighted according to the surveillance stream and age of the animal sampled.

Type B Surveillance

Type B surveillance may be carried out by countries of negligible BSE risk status to confirm the conclusions of the risk assessment (e.g., by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximize the likelihood of identifying failures of such measures).

Type B surveillance may also be carried out by countries of controlled BSE risk status (OIE Code, Article 11.5.4) following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance. As with Type A surveillance, the recommended number of points for Type B surveillance is based on the size of a country's cattle population. For instance, a country with a cattle population of 800,000 to 1 million should collect samples whose total point value equals 120,000.

Presence of a BSE Awareness Program

The OIE will evaluate information about the existence of any awareness programs; the target audience; the curriculum; how long the program has been in place; and any contingency and/or preparedness plans that address BSE.

Compulsory Notification and Investigation

Proper management of the disease requires that there be incentives and/or obligations to report and investigate suspect BSE cases. Therefore, the OIE will evaluate information about any guidance given to veterinarians, producers, workers at auctions, slaughterhouses, etc., with regard to the criteria that would initiate the investigation of an animal as a BSE suspect; whether these criteria have changed over time; the date and content of the legal act making notification of BSE suspects compulsory; and any measures in place to stimulate notification, such as compensation payments or penalties for not reporting a suspect.

Sample Testing

For a country's BSE surveillance system to be recognized by the OIE, samples must be tested in accordance with the OIE's Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. The OIE evaluates whether countries seeking BSE classification uses diagnostic procedures and methods that are consistent with those described in OIE's disease diagnostic manual and whether these diagnostic procedures and methods have been applied throughout the entire surveillance period.

BSE History of the Country

It is important to note that in order to retain classification by OIE as a country of negligible risk or controlled risk for BSE, a country must continue to observe OIE's guidelines and report any significant events that might change that status. The OIE reserves the right to revoke the given disease status of any country that fails to comply with this process. In order to retain classification, Member countries are obligated to notify the OIE in writing that the epidemiological situation with respect to each of the diseases for which the OIE has classified the country has remained unchanged in order to retain classification. APHIS also believes that it is essential to have periodically updated information from a country that APHIS recognizes as either negligible risk or controlled risk for BSE, and are including a requirement for such updated information in this proposed rule, as discussed below under the heading ''Requirement for Updated Information.''

The Process for APHIS Recognition of the BSE Risk Classification of a Region

Under this proposed rule, each country of the world will be considered by APHIS to be in the BSE undetermined risk category, unless APHIS has recognized that country as either a region of negligible risk for BSE or a region of controlled risk for BSE.

APHIS recognition of a region as a region of negligible risk or controlled risk for BSE could be achieved in one of two ways.

- If the OIE has classified a country as either BSE negligible risk or BSE controlled risk, APHIS would 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 would announce in the **Federal Register**, subject to public comment, our intent to concur with an OIE classification. APHIS would also post the summary of the BSE OIE ad hoc group conclusions for review during the comment period. The summaries would be available for review on the APHIS Web site. Following review of any comments received, the Administrator would 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 would include that country in a list of regions of negligible risk or controlled risk for BSE, as applicable, that APHIS would make available to the public on the Agency's Web site.

• A region that has not received categorization by OIE as either negligible risk or controlled risk for BSE and that wishes to be recognized by USDA as negligible risk or controlled risk could submit to the Administrator a request for such classification, along with documentation sufficient to allow the USDA to conduct an evaluation of whether the region meets the criteria for such classification. If, following such evaluation, the Administrator determines that the region meets the criteria for negligible or controlled risk, APHIS would announce that determination in the **Federal Register** and would make available to the public the evaluation conducted by APHIS, as well as the information provided by the requesting region. APHIS would accept public comment on its intent. Following review of any comments received, the Administrator would 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.

Requirement for Updated Information

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:

• Relevant changes in BSE legislation, compared to the previous year;

• The importation into the region during the year of cattle, processed animal protein and products containing such material;

• 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 of MBM or greaves to ruminants;

• Audit findings in rendering plants and feed mills that process nonruminant material, related to the prohibition of the feeding to ruminants of ruminant-derived MBM and greaves;

• Infractions at the types of facilities listed above;

• If and why, in light of the audit findings, there has been no significant exposure of cattle to the BSE agent through consumption of ruminant-derived MBM and greaves;

• Surveillance efforts;

• All clinical BSE suspects;

• Any new cases of BSE.

If APHIS at any time determines that a region no longer meets the criteria for the risk classification it had previously received, APHIS would remove it 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.

Conditions for Importation of Commodities

The BSE-related importation conditions we are proposing for live bovines and products derived from bovines are based on internationally accepted data and research. These same data and research are used by the OIE in formulating its recommendations regarding trade in cattle and products derived from cattle with regard to BSE, and include experimental data, epidemiological data, information about risk mitigation strategies regarding processing, and data from risk assessment studies.

In the following section, we discuss the pertinent scientific information regarding each type of commodity considered for importation and explain APHIS' conclusions regarding mitigation measures, if any, that we consider necessary to safely allow for the importation of that type of commodity, taking into account the BSE risk classification of the region of export. In most cases, the conclusions we have reached are consistent with those reached by the OIE. In those few cases where our conclusions regarding mitigation measures differ from that of the OIE, we note the differences and explain our rationale for differing with the OIE Code. If the information we considered is based on research or other data concerning cattle and products from cattle, we discuss the information as it applies to cattle. However, for the reason we stated above in footnote 3 of this document, where we propose to modify our regulations based on that information, we propose to apply the amendments to bovines, rather than just to cattle. In the sections that follow, we discuss the OIE recommendations regarding trade of specific types of bovine commodities.

Live Bovines

The OIE Code recommends that trade in live cattle be allowed from regions of negligible, controlled, and undetermined risk for BSE under the following conditions.

From regions of negligible risk and regions of controlled risk for BSE: The bovines are accompanied by an international veterinary certificate attesting to the BSE risk classification of the region of export. Additionally, for exports of live cattle from regions of negligible risk for BSE that have had an indigenous case of BSE and from regions of controlled risk for BSE, the following conditions must be met and attested to on the certificate: The cattle intended for export were born after the date a ban on the feeding of MBM and greaves of ruminant origin to ruminants was effectively enforced, and are identified with a permanent identification system that enables them to be identified if they are birth or feed cohorts of an infected animal.

From regions of undetermined risk for BSE: The bovines were born at least 2 years after a ban on the feeding of MBM and greaves of ruminant origin to ruminants was effectively enforced, and are identified by a permanent identification system in such a way that enables them to be identified if they are birth or feed cohorts of an infected animal. In addition, the region must demonstrate that, if alive in the region, bovines that are included in either of the following two categories are officially identified with unique individual identification that is traceable to the premises of origin of the animal, their movements are controlled, and, when slaughtered or at death, they are completely destroyed:

1. 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 feed that potentially contained SRM material as the infected animal during that period;

2. 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.

APHIS' Proposed Provisions Regarding the Importation of Live Bovines With Regard to BSE Risk

In this proposed rule, we concur with the conclusions reached by the OIE regarding import conditions for cattle from regions of negligible risk and controlled risk with regard to BSE, but differ from the OIE Code regarding the importation of bovines from regions of undetermined BSE risk. We discuss our proposed provisions regarding importations from undetermined risk regions, below. With regard to importations of live bovines from regions of negligible or controlled risk for BSE, we are proposing in § 93.436(a) and (b) that bovines may be imported under the following conditions:

• The bovines are accompanied by an original certificate that indicates the APHIS BSE risk classification of the region of export and states that the following conditions, where applicable, have been met.

• From regions of negligible risk for BSE that have had an indigenous case of BSE and from regions of controlled risk for BSE, before the animals' arrival at the port of entry into the United States, each bovine imported into the United States is officially identified with unique individual identification that is traceable to the premises of origin of the animal. We consider this requirement necessary for us to determine the likelihood of exposure to potentially contaminated materials. We would provide that 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.

• From regions of negligible risk for BSE that have had an indigenous case of BSE and from regions of controlled risk for BSE, 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:

1. 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);

2. A tattoo with letters identifying the exporting country must be applied to the inside of one ear of the animal;

3. 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 the BSE minimal-risk exporting region.

• From regions of negligible risk for BSE that have had an indigenous case of BSE and from regions of controlled risk for BSE, the bovines were born after the date from which the ban on the feeding of ruminants with processed ruminant proteins has been effectively enforced.

Additionally, if there has been an indigenous case of BSE in the region, the following restrictions would apply:

• 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 feed that potentially contained SRM material as the infected animal during that period would not be eligible for importation to the United States; and

• 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, no bovine 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 would be eligible for importation into the United States.

Date of Effective Enforcement of a Feed Ban

As noted, for the importation of cattle from certain risk classifications of countries, one of the OIE-recommended mitigations is that the animals were born after the date a feed ban was effectively enforced. The primary source of BSE infection, and the only documented route of field transmission of the disease, is commercial feed contaminated with ruminant protein derived from infected animals (Wilesmith, *et al.,* 1988; 1991; 1992; Prince, *et al.,* 2003). Bans that prohibit incorporation of mammalian or ruminant protein into ruminant feed have been shown to be effective in mitigating the risk of BSE transmission and are an integral factor in evaluating the BSE risk of a region. The experience regarding BSE in the United Kingdom, which was discussed in detail in the risk assessment we conducted for our September 2007 final rule, demonstrated the effectiveness of a ruminant-to-ruminant feed ban in reducing the prevalence of BSE (APHIS, 2007).

Although, in evaluating a country for BSE risk classification, the OIE examines whether the country has an effectively enforced ban on the feeding of ruminant-derived processed animal protein to other ruminants, and although some of the trade conditions recommended by the OIE with regard to BSE are dependent on when a country achieved effective enforcement of such a feed ban, the OIE does not provide specific recommendations for determining the date of effective enforcement of a feed ban. For a country that wishes to export live bovines to the United States and that is classified by APHIS as controlled risk for BSE or as negligible risk for BSE and the country has reported an indigenous case of BSE, APHIS would need to determine the date a feed ban was effectively enforced in the country.

It is important to note that the existence of an effectively enforced feed ban does not mean there will be no instances of contravention of the feed ban, either accidentally or intentionally, just as isolated transgressions of U.S. laws do not necessarily constitute ineffective enforcement of those laws. Nor does it mean that BSE will never be detected in a bovine born after the date from which a feed ban is considered to have been effectively enforced. Human error is expected, and no regulatory effort can ensure 100 percent compliance, which is why a feed ban is comprised of a number of interrelated measures that have a cumulative effect.

In our September 2007 final rule to allow additional live bovines and certain bovine products from BSE minimal-risk regions (72 FR 53314–53379, Docket No. APHIS–2006–0041), we explained the considerations and process used by APHIS to determine the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada. In this proposal, we are proposing to base our determination of the date of effective enforcement of a ruminant-to-ruminant feed on similar considerations. The information would include, but not necessarily be limited to:

• Policies and infrastructure for feed ban enforcement, including an awareness program for producers and farmers;

• Livestock and husbandry practices;

• Disposition of processed animal protein produced from domestic bovines, including the feeding of any animal species;

• Measures taken to control cross-contamination and mislabeling of feed intended for bovines with processed animal protein;

• Monitoring and enforcement of the ruminant feed ban, including audit findings in rendering plants and feed mills that process ruminant material.

Additionally, in determining the date of effective enforcement of a country's feed ban, APHIS may conduct a site visit to the requesting country to complement and verify the information provided by the country.

After receiving and evaluating the necessary information, APHIS would publish 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 would make available to the public the evaluation conducted by APHIS, as well as the supporting documentation. Following review of any comments received, the Administrator would announce his or her final determination in the **Federal Register**, along with a discussion of and response to pertinent issues raised by commenters.

Live Bovines From Regions of Undetermined Risk for BSE

With regard to the importation of live bovines, we propose allowing the importation of live bovines from regions of undetermined risk for BSE only in very limited situations.

We believe that the nature of a region that is classified as undetermined with regard to BSE risk is such that making a general determination in this regulation that the conditions recommended by the OIE have been met could not be made with a sufficient degree of confidence. When it comes to the overall BSE risk of an exporting region, factors in addition to a feed ban—such as veterinary infrastructure, surveillance, and import controls—play a role. Such factors are taken into consideration when determining whether to classify a region as negligible or controlled risk for BSE. If enough evidence has been evaluated to conclude that a region of undetermined risk for BSE has in place an effectively enforced feed ban—upon which importation of live bovines would be dependent—and that the region can demonstrate that the other conditions have been met, APHIS believes the region would qualify as at least controlled risk. We believe that the fact that a region is in the BSE undetermined-risk category argues against a generalized determination by way of this proposed rule that the OIE-recommended conditions have been met.

For the reasons discussed above, we are proposing to allow the importation of live bovines from regions of undetermined risk for BSE only in very limited situations. In § 93.436(c) of this proposed rule, we provide that, with regard to BSE, live bovines may be imported from regions of undetermined risk for BSE for specific limited uses, such as movement to exhibitions and zoos, under specified conditions on a case-by-case basis, if the Administrator determines that the bovines can be imported under conditions that will prevent the introduction of BSE into the United States. Instructions for applying for a permit for the importation of live ruminants are included in current § 93.404.

Provisions Regarding the Importation of Live Bovines From Canada

Canada is classified by the OIE as a region of controlled risk for BSE and, under our proposal, live bovines from Canada would be subject to all of the import requirements we are proposing for regions of controlled risk for BSE. However, Canada is currently singular in the APHIS BSE regulations in that it is the only region recognized by APHIS as a BSE minimal-risk region. As a BSE minimal-risk region, Canada is eligible to import live bovines into the United States that are prohibited importation from other regions listed in § 94.18(a). Under the current regulations, live bovines are eligible for importation from Canada if the conditions in § 93.436 and related sections are met.

Some of the requirements that are included in current § 93.436 would continue to apply to imports from Canada, in some cases for reasons other than BSE risk, but would not apply as a general rule to every region of controlled risk for BSE. These include the requirement in current § 93.436(a)(4) that bovines from Canada intended for immediate slaughter be moved from the port of entry to a slaughtering establishment in a sealed means of conveyance, which we are proposing to include in § 93.420 of this proposal for the importation of all ruminants imported from Canada for immediate slaughter. This provision exists as a safeguard against diseases other than BSE.

Certain of the requirements in current § 93.436 for the importation of live bovines from Canada are substantively the same as the requirements we are proposing for the importation of live bovines from any region of controlled risk for BSE—such as the requirement that live bovines intended for importation be permanently identified—by branding, tattooing, or some other method—as to country of export, and the requirement that the bovines were born on or after the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of origin. However, the provisions in current § 93.436 include specifics as to how those general requirements apply to Canada. For instance, the regulations in current § 93.436 specify the lettering that must be used for a brand or tattoo to identify the bovines as being of Canadian origin and specify that APHIS recognizes March 1, 1999, as the date of effective enforcement of a ruminant-to-ruminant feed ban in Canada.

Because this proposed rule would retain these specifics, we are proposing to set forth the importation requirements for live bovines from Canada in sections of the CFR that would be dedicated to imports from Canada, specifically §§ 93.418 and 93.420.

Commodities Recommended for Unrestricted Trade With Regard to BSE

A review of scientific literature (discussed in the ''Supporting document for Chapter 2.3.13 of the Terrestrial Animal Health Code on Bovine Spongiform Encephalopathy'' (OIE TAHSC, 2006)) (the contents of Chapter 2.3.13 have been updated and currently appear in Chapter 11.5) has led the OIE to recognize certain products as safe for trade with regard to BSE, regardless of the BSE status of the exporting region.

Bovine-derived commodities that the OIE recommends be allowed to be traded without any restrictions for BSE include:

• Milk and milk products;

• Semen and *in vivo* derived embryos;

• Hides and skins;

• Gelatin and collagen from hides and skins;

• Tallow with a maximum level of insoluble impurities of 0.15 percent in weight; and

• Dicalcium phosphate with no trace of protein or fat.

APHIS has reached the same conclusions. Some of the commodities listed above are already eligible for importation without BSE-related restrictions from regions listed in § 94.18(a) of the regulations. These are milk and milk products, semen, and hides and skins. For these commodities, we are proposing no changes to their importation status with regard to BSE. The rationale for allowing their importation has been discussed in previous rulemaking and is not addressed in this document.

The remaining commodities listed above—those that are not currently eligible for unrestricted importation into the United States with regard to BSE—would become so under the provisions of this proposed rule.

Commodities Recommended for Trade Under the Same Conditions, Regardless of the Risk Classification of the Exporting Region

The OIE recommends that several other types of bovine commodities be eligible for trade without ''any BSE-related conditions, regardless of the BSE risk status of the cattle population of the exporting country, zone, or compartment'' (OIE Code Article 11.5.1). Although the OIE Code refers to an absence of ''BSE-related conditions'' for these commodities, the OIE recommendations do include qualifying conditions regarding the processing of such commodities, in order to guard against the contamination of the commodities by other materials that might contain BSE infectivity. These commodities are:

- Boneless skeletal muscle meat (excluding mechanically separated meat [14]) from cattle, provided (1) the cattle were not subjected to air injected stunning before slaughter or to pithing, (2) the cattle passed ante-mortem and post-mortem inspections, and (3) the product has been prepared in a manner that avoids contamination with SRMs;
- Blood and blood byproducts from cattle that were not subjected, prior to slaughter, to air-injected stunning or to pithing.

We are proposing to allow the importation of these commodities [15] from any region under the same conditions recommended by the OIE, with one exception. With regard to blood and blood products, we are proposing some additional requirements regarding the collection of blood and blood products to guard against contamination. We reference the scientific rationale for allowing such importation in a discussion of each type of commodity, below, and explain as well our rationale for proposing several risk mitigation measures slightly different from those recommended by the OIE.

Specified Risk Materials

For some commodities, a condition for importation under this proposed rule is that the commodity not contain or be potentially contaminated with SRMs. Under this proposed rule, tissues from bovines from regions of negligible risk for BSE are not considered SRMs and what is considered an SRM in a region of controlled risk differs somewhat from what is considered an SRM in a region of undetermined risk.

Regions of Negligible Risk for BSE

By definition, in a region that has been evaluated and has been determined to be a region of negligible animal health risk, there is a negligible risk of circulating BSE infectivity. Consequently, we do not believe it is necessary to consider any tissues from bovines from a region of negligible risk for BSE to be SRMs. This conclusion is consistent with internationally accepted BSE-related standards. It is also consistent with the approach taken by FSIS in an affirmation of interim final rules with amendments published on July 13, 2007 (72 FR 38199–38730, Docket No. 03–025F).

In that document, FSIS amended its September 7, 2005 interim final rule to exclude from the FSIS definition of SRMs materials from cattle from foreign countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as does prohibiting SRMs for use as human food in the United States. In its document, FSIS stated that an ''evaluation of a country's BSE risk status would consider whether appropriate measures are in place to manage identified risks. This would include consideration of import policies and import history to determine the likelihood of the introduction of BSE into the country. It could also include (among other things) consideration of any of the following: Effective surveillance efforts; measures to identify and effectively control pathways for the amplification of BSE; appropriate awareness programs; effective epidemiological investigations as necessary, with appropriate tracing, control and destruction of risk animals; continuing risk considerations with corresponding revisions of existing mitigations; appropriate public health control measures commensurate with risk; and the infrastructure sufficient to define and implement any of the above.'' (72 FR 38718) FSIS stated further that evaluation of a country's measures would be conducted by FSIS officials with technical program expertise along with, where appropriate, technical experts from other agencies, such as APHIS and FDA, with FSIS making the final determination.

Regions of Controlled Risk and Negligible Risk

As noted above, in January 2004, FSIS regulations established as SRMs the skull, brain, spinal cord, trigeminal ganglia, eyes, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age or older, as well as the tonsils and distal ileum of the small intestine of cattle of all ages.[16] FSIS designates potentially infective materials, as well as certain materials that are closely associated with potentially infective materials, from cattle 30 months of age or older as SRMs. Although the skull and vertebral column of cattle infected with BSE have not demonstrated infectivity, the skull contains the eyes, trigeminal ganglia, and brain, and the vertebral column contains DRG and spinal cord. Thus, because they contain high-risk tissues, skulls and vertebral column are included in FSIS' definition of SRMs. Unlike other parts of the vertebral column, the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum do not contain spinal cord or DRG. Therefore, FSIS excludes these parts of the vertebral column from the materials designated as SRMs. Under FSIS regulations, head meat, cheek meat, and tongue may be used for human food, provided they are not contaminated with SRMs.

In §§ 92.1, 94.0, and 95.1 of this proposed rule, APHIS defines SRMs from regions of controlled risk for BSE and undetermined-risk regions as the same tissues considered by FSIS to be SRMs, with one exception. For regions of undetermined risk for BSE, APHIS is consistent with OIE in considering the tissues that FSIS considers to be SRMs in animals 30 months of age or older to be SRMs if the tissues come from animals over 12 months of age. Research demonstrates that the incubation period

[14] Mechanically separated meat is 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. A definition of mechanically separated meat is included in § 94.0 of this proposed rule.

[15] Additionally, 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.

[16] On July 13, 2007, FSIS published an affirmation with amendments (72 FR 38700, Docket No. 03–025F) of its January 2004 interim final rule. Among the amendments included in July 2007 was a provision that excludes from the definition of SRMs materials from cattle from countries that can demonstrate that their BSE risk status can reasonably be 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.

for BSE is apparently linked to the infectious dose received, i.e., the larger an infectious dose received, the shorter the incubation period (EC SSC, 2002). While some cases have been found in animals less than 30 months of age, these have been relatively few and have occurred primarily in countries with significant levels of circulating infectivity. Specifically, BSE was found in animals less than 30 months of age in the United Kingdom in the late 1980s to early 1990s, when the incidence of BSE was extremely high (the youngest case, detected in 1989, was 21 months). The exceptional detection of BSE in young animals during the peak of the BSE epidemic in the United Kingdom supports a cautious approach in defining SRMs for regions of undetermined risk for BSE. Theoretically, in such regions, high levels of circulating infectivity could exist if the region is not implementing BSE risk management measures.

Because BSE infectivity is detectable in central nervous system tissue at three-quarters of the incubation period, the 12-month provision would ensure the removal of tissues potentially containing infectivity from even the single youngest animal observed since the start of BSE surveillance in the United Kingdom.

Other Bovine Commodities

According to the OIE recommendations, certain bovine commodities may or may not be eligible for importation, depending on the BSE risk classification of the country that would be exporting the commodity and on whether specified conditions have been met to mitigate BSE risk based on the country's risk classification.

These commodities include:

- Meat that does not meet the conditions, described above, for boneless skeletal muscle meat;
- Gelatin and collagen prepared from bones;
- Tallow, tallow derivatives, and dicalcium phosphate (other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight and dicalcium phosphate with no trace of protein or fat); and
- MBM and greaves.

Although APHIS' proposed provisions regarding these commodities are broadly based on OIE recommendations, we are also proposing some modifications to those guidelines, where necessary, to reflect APHIS' interpretation of the scientific literature and current USDA regulations and policies.

In the sections that follow, we discuss the science that supports the OIE recommendations and the import conditions we are proposing, and present the rationale for the few instances where our proposed provisions differ from OIE recommendations.

Meat, Meat Byproducts, and Meat Food Products

In our discussion, where we refer to meat, meat byproducts, and meat food products, we consider those commodities to be as defined in the FSIS regulations in 9 CFR 301.2.

As noted earlier in this document, BSE infectivity has not been demonstrated in the muscle tissue of BSE-infected cattle examined in either mouse bioassay studies (in which different bovine tissues are inoculated into mice to determine which tissues carried infectivity) or in cattle assays in the United Kingdom pathogenesis study (Wells, *et al.,* 1996; 2005; Wells, personal communications, 2008). Some reports have identified the presence of prions in muscle tissue from rodents, humans, and small ruminants infected with TSEs other than BSE (Bosque *et al.,* 2002). Those findings are consistent with differences in the transmission, host range, genetic susceptibility, infectivity distribution, and epidemiology found in different TSEs that affect animals and humans. In the transgenic mice over-expressing the bovine PrP gene (Tg bov XV), infectivity was detected in one muscle (semitendinosus) from a single clinical case of BSE in Germany (Buschmann and Groschup, 2005). The sensitivity of these mice to infection is significantly greater than that of the mice used for the United Kingdom pathogenesis study (10,000-fold) and even greater than that of cattle (approximately tenfold).

From studies of the pathogenesis of experimental BSE in cattle, no infectivity has been found in assays of skeletal muscle pools (triceps, masseter, sternocephalicus and longissimus dorsi) completed in wild-type mice bioassay and in cattle bioassay (*masseter, semitendinosus* and *longissimus dorsi*) from selected kill time points of the oral exposure study (Wells *et al.,* 1996 and 2005). All assays of the skeletal muscle pools were completed in March 2007 (Wells, personal communication, 2008).

Recent studies using tissues from asymptomatic cattle challenged orally with BSE and culled at 20, 24, 27, 30, and 33 months, and inoculated intracerebrally into BoPrP–Tg110 mice, have failed to detect infectivity in muscle (Espinosa *et al.,* 2007).

The United Kingdom's Spongiform Encephalopathy Advisory Committee (SEAC, 2001) and the European Commission's (EC) Scientific Steering Committee (SSC) evaluated the implications of the findings of the presence of infectivity in muscle for other TSEs in different species in relation to human food safety. EC SSC concluded that there was no reason to revise its opinions regarding the safety of meat, given the consistent negative results in BSE infectivity experiments (EC SSC, 2002a). SEAC concluded that the findings could not be directly applied to BSE in cattle and did not change the assessment of the risk to humans of consumption of beef. Updated opinions from the EC SSC are consistent with its original reports.

Skeletal muscle meat in and of itself is regarded as safe with regard to BSE, regardless of the BSE risk category of the region of export and origin. Any blood that might be associated with the meat is also, in and of itself, regarded as safe with regard to BSE, as discussed below under the heading ''Blood and Blood Products.''

However, it is possible that, in regions in which there is some circulating BSE infectivity, such meat could become contaminated with the BSE agent unless certain measures are taken to preclude such contamination. In this proposed rule, although we are proposing to allow the importation of boneless skeletal muscle meat from any BSE category of region, such importation would be contingent on the necessary safeguards against contamination having been met in the region of export.

One of these safeguards is that the bovines from which the meat was derived 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 (EFSA Journal, 2004; TAFS, 2004). Several studies have shown that penetrative captive bolt stunners that incorporate air-injection can force visible pieces of brain and other central nervous system tissue into the circulatory system of stunned cattle (Anil, *et al.,* 1999; Schmidt, *et al.,* 1999). In addition, the pithing process could cause dissemination of central nervous tissue throughout the body.

Another safeguard is the removal of SRMs. Handling of SRMs in ways that prevent contamination of the carcass is an important mitigation in preventing contamination of edible meat with BSE infectivity (EFSA Journal, 2005).

Therefore, with regard to BSE, we are proposing in § 94.18(b)(2) to allow the importation of boneless skeletal muscle meat from bovines, regardless of the BSE risk status of the region of export, provided that (1) the cattle were not subjected to air injected stunning before slaughter or to pithing, (2) the cattle

passed ante-mortem and post-mortem inspections, and (3) the meat has been prepared in a manner that avoids contamination with SRM tissues.

Additionally, the shipment of such meat to the United States would have to be accompanied by an original certificate stating that the above conditions have been met. The certificate must be issued by a full-time salaried veterinary officer of the national government of the region of export, or be issued by a veterinarian designated by the national government of the region of export and endorsed by a full-time salaried veterinary officer of the region of export, representing that the veterinarian issuing the certificate was authorized to do so. Our listing of who would be eligible to issue a certificate differs slightly from the list in § 94.19 of the current regulations regarding the importation of meat and other edible products from BSE minimal-risk regions, in that we would not include veterinarians accredited by the national government of the region of origin. We are not including such individuals to avoid any situations where a veterinarian employed by an exporter might issue a certificate for that exporter's shipment.

Meat Other Than Boneless Skeletal Muscle Meat, Meat Food Products, and Meat Byproducts Derived From Bovines

For meat other than the boneless skeletal meat described above, meat food products, and meat byproducts, the conditions for importation would depend on the BSE risk classification of the region of export. These conditions are discussed in the following paragraphs.

Regions of Negligible Risk for BSE

With regard to regions of negligible risk for BSE, we are proposing in § 94.19 the conditions under which bovine meat that is not boneless skeletal meat, meat food products, and meat byproducts would be eligible for importation. These conditions are as follows; either:

1. The commodity is accompanied by certification that the region of export is a region of negligible risk for BSE in which there has not been an indigenous case of BSE, and that the commodity is derived from bovines that passed ante-mortem and post-mortem inspection; or

2. If there has been an indigenous case of BSE in the region of negligible risk, the commodity is accompanied by certification that the region of export is a region of negligible risk for BSE and that the commodity was derived from bovines that passed ante-mortem and post-mortem inspection and were subject to a ban on the feeding to ruminants of processed animal protein derived from ruminants.

Our proposed conditions for the importation of such commodities from negligible risk regions that have had an indigenous case of BSE are modified somewhat from those recommended by the OIE. The OIE recommends that such commodities be sourced from animals born after the date a ban on feeding ruminant MBM and greaves to ruminants had been effectively enforced. The OIE also recommends this condition for the importation of MBM and greaves derived from ruminants from such regions. There is a wide range of bovine products that could fall under these categories, including products that may have gone through multiple processing steps after slaughter. APHIS recognizes the difficulty in providing specific certification about the age of the animal from which the products were derived, given these steps. This difficulty, in combination with the overall low risk of such products from a negligible risk region, is why we propose to modify the OIE guidelines somewhat. We feel that because the criteria for this particular risk categorization calls for any indigenous case to be born more than 11 years ago and requires demonstration through an appropriate level of control and audit that for at least 8 years processed animal protein from ruminants has not been used in the feeding of ruminants (these criteria are discussed above under the heading ''*Regions of Negligible Risk for BSE*''), it is highly unlikely that such products could contain or be contaminated with the BSE agent. Taking these factors into consideration, APHIS concludes that the commodities under consideration pose an extremely low risk for BSE, as low as to be considered insignificant.

As noted above, in July 2007 FSIS amended its regulations to exclude from the FSIS definition of SRMs materials from cattle from foreign countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as does prohibiting SRMs for use as human food in the United States. Our proposed provisions regarding the importation of meat, meat byproducts, and meat food products from regions of negligible risk for BSE are consistent with the FSIS provisions. In this proposed rule we would add a note to § 94.19 to indicate that, to be eligible to export bovine meat, meat byproducts, and meat food products to the United States under the provisions of that section, a region recognized by APHIS as a one of negligible risk for BSE would also need to be one that has demonstrated to FSIS 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.

Regions of Controlled Risk for BSE

We are proposing in § 94.20 that, in addition to boneless skeletal muscle meat that meets the requirements listed above, bovine meat, meat byproducts, and meat food products would be eligible for importation from regions of controlled risk for BSE if the following requirements are met:

- The bovines from which the commodities were derived passed ante-mortem and post-mortem inspections;
- The bovines from which the commodities were derived were not subjected to a stunning process with a device injecting compressed air into the cranial cavity or to a pithing process;
- The commodity does not contain mechanically separated meat from the skull and vertebral column of bovines 30 months of age or older;
- The commodity was produced in a manner that ensures that it does not contain and is not contaminated with SRMs, as defined in § 94.0 of this proposed rule for regions of controlled risk for BSE;
- The shipment is accompanied by an original certificate stating that the above conditions have been met. The certificate must be issued by a full-time salaried veterinary officer of the national government of the region of export, or be issued by a veterinarian designated by the national government of the region of export and endorsed by a full-time salaried veterinary officer of the region of export, representing that the veterinarian issuing the certificate was authorized to do so.

Regions of Undetermined Risk for BSE

We are proposing in § 94.21 that, in addition to boneless skeletal muscle meat that meets the requirements listed above, bovine meat, meat byproducts, and meat food products would be eligible for importation from regions of undetermined risk for BSE if the following requirements are met:

- The bovines from which the commodities were derived have never been fed processed animal protein derived from ruminants;
- The bovines from which the commodities were derived passed ante-mortem and post-mortem inspections;
- The bovines from which the commodities were derived were not subjected to a stunning process with a

device injecting compressed air into the cranial cavity or to a pithing process; and

• The commodities were produced in a manner that ensures that such products do not contain and are not contaminated with: (1) Mechanically separated meat from the skull and vertebral column of bovines over 12 months of age; or (2) SRMs as defined for regions of undetermined risk for BSE.

• The shipment is accompanied by an original certificate stating that the above conditions have been met. The certificate must be issued by a full-time salaried veterinary officer of the national government of the region of export, or be issued by a veterinarian designated by the national government of the region of export and endorsed by a full-time salaried veterinary officer of the region of export, representing that the veterinarian issuing the certificate was authorized to do so.

Offal

In this proposed rule, § 95.6 contains provisions regarding BSE and the importation of offal derived from bovines. In § 95.1 of the current regulations, *offal* is defined as the inedible parts of a butchered animal that are removed in dressing, consisting largely of the viscera and trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, or kidneys. We are proposing to apply the same import requirements to bovine-derived offal as those described above for bovine-derived meat, meat byproducts, and meat food products, with one exception. The proposed provisions for the importation of bovine-derived meat, meat byproducts, and meat food products include the requirement that the bovines from which the commodities were derived passed ante-mortem and post-mortem inspections. That requirement is a safeguard for commodities intended for human consumption. Because offal is, by definition, inedible, there is no need to require that the offal was derived from bovines that passed ante-mortem and post-mortem inspections.

Meat or Dressed Carcasses of Hunter-Harvested Bovines

In the current regulations, § 94.19(e) contains provisions for the importation into the United States of meat or carcasses of hunter-harvested wild sheep, goats, or other ruminants other than cervids from BSE minimal-risk regions (the importation of cervid meat from BSE minimal-risk regions is unrestricted with regard to BSE). For hunter-harvested meat or carcasses to be eligible for importation with regard to BSE, the following conditions must be met:

• The meat or dressed carcass is derived from an animal 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

• 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 FDA at 21 CFR 589.2000.

Consistent with the approach we are taking in this document not to propose any changes at this time to BSE regulations related to ovines or caprines, in § 94.25(c) of this proposed rule, we are retaining the conditions described above as they apply to hunter-harvested wild ovines or caprines from BSE minimal-risk regions. In § 94.22 of this proposed rule, we are including provisions for the importation of hunter-harvested wild bovines from any region. Under those provisions, the meat or carcass of a hunter-harvested wild bovine would be eligible for importation into the United States if it 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 United States Customs and Border Protection official. Additionally, the carcass of a hunter-harvested wild bovine would have to be dressed (eviscerated and the head and spinal cord removed). We are not including a requirement comparable to that described above for ovines and caprines regarding the feeding of the wild bovines. BSE has been detected in wild bovines kept in captivity but not in non-captive wild bovines, and APHIS considers it very unlikely that wild bovines could be exposed to processed animal protein.

Gelatin and Collagen

Gelatin is a highly purified protein manufactured from hides, skin, and/or bones of animals using various refining processes in which each step is able to significantly inactivate BSE infectivity. A similar process, with similar inactivation results, is used in the production of collagen.

Derived From Hides or Skins

Bovine hides have not demonstrated BSE infectivity, even in infected animals. The safety of bovine hides with regard to BSE is recognized internationally. The OIE Code recommends that gelatin derived exclusively from the hides of bovines not be subject to trade restrictions. The European Commission Scientific Steering Committee's *Updated Opinion on the Safety With Regard to TSE Risk of Gelatine Derived From Ruminant Bones or Hides* (adopted by the Scientific Steering Committee at its December 5–6, 2002, meeting) states in section B(c): ''When ruminant hides are used for the production of gelatine, they are usually obtained from bovines. On the basis of current knowledge, it can be considered that the parts of the bovine hides used for the production of gelatine do not present a risk with regard to TSE's [transmissible spongiform encephalopathies, which include BSE], provided contamination with potentially infected materials is avoided.''

Therefore, we believe there is no scientific basis for prohibiting the importation of gelatin derived from the hides of bovines and are proposing in § 94.23(b) to allow the importation of gelatin derived from the hides or skins of bovines, regardless of the BSE risk classification of the region of origin, provided the gelatin has not been commingled with materials ineligible for entry into the United States. In § 95.7(b), we are proposing equivalent provisions for the importation of collagen derived from bovine hides or skins.

Derived From Bones

The different steps of the refining process in producing gelatin from bones, as well as the resulting infectivity reduction, are described below.

1. *Degreasing:* Before bone can be used to manufacture gelatin, fat must be removed. This is done by crushing the bones, washing, and degreasing the chips with hot water to remove fat residues. Studies evaluating the efficiency of the degreasing process in decreasing the amount of nervous tissues present in bones have shown that, during the degreasing step, 98–99 percent of the proteins of nervous origin are eliminated (Mantze, *et al.,* 1996).

2. *Acid treatment:* The treatment consists of immersing the degreased chip bone into hydrochloric acid (approximately 4 percent, < pH 1.5) for a period of at least 2 days. This acid treatment changes the structure of the

collagen protein and reduces the infectivity that might be present (Grobben, *et al.,* 2004).

3. *Alkaline treatment:* The materials are soaked in a saturated lime solution (pH 12.5) for a period of 20 to 50 days. The alkaline treatment changes the internal structure of the BSE protein, if present. The combination of time, temperature, and concentration of the alkaline treatments reduces the levels of BSE infectivity in the event they were present in the raw materials (Grobben, *et al.,* 2004).

4. *Further acid treatments:* In the event gelatin is produced from ossein by an acid process, the ossein is immersed for 12 to 24 hours in acid (pH 2–3.5).

5. *Gelatin extraction:* Once all the procedures are performed, gelatin is extracted by a series of hot water steps. These include purification by filtration and sterilization, both of which further remove suspended materials and thus further reduce the level of any remaining BSE infectivity, if present, which is unlikely at this stage in the production.

Research studies mimicking the manufacturing process described above were unable to show detectable levels of infectivity in the mouse bioassay. The results are consistent with TSE infectivity reduction capacity exceeding a factor of 30.000 (4.5 logs, although results from most recent research indicate clearance factors exceeding 4.8 logs) (EC SSC adopted at the 12–13 September 2002 meeting). These studies have demonstrated that the common process of manufacturing bovine gelatin provides significant assurance of gelatin safety.

Experimental studies have confirmed that the chemical processes used in the manufacture of gelatin derived from bones are sufficient to inactivate BSE infectivity that might have been present in the raw material (EC SSC, 1998). These experimental studies were designed to ensure that they accurately represented the ''lowest common denominator'' of current manufacture practices.

A quantitative risk assessment (EFSA Journal, 2006) of the residual risk in bone-derived gelatin, obtained from bones fit for human consumption calculated different scenarios resulting in different risk levels. The study did not take into consideration the sourcing of bones. Results of the risk assessment indicate that the relevant exposures are very small compared to the historical exposure of the human population in the United Kingdom (1980–2001) due to meat and meat products in its diet. The removal of skull and vertebral column from the source materials results in only a very small risk reduction. However, the input parameters to the supporting risk assessment model sourced animals only from the healthy slaughter subpopulation and did not address the scenario where material was sourced from cattle not subject to ante- and post-mortem inspection.

Although this evidence points to the conclusion that gelatin derived from bones that is produced using common manufacturing processes could be considered safe regardless of the region from which the bones originate, we believe that the limited parameters of the input data in the European Food Safety Authority (EFSA) assessment make it advisable to propose additional risk mitigations based on the BSE risk classification of the region of origin. Therefore, we are proposing in § 94.23 to allow the importation of gelatin derived from the bones of bovines under the following conditions:

Region of negligible risk: We are proposing in § 94.23(c) for gelatin and § 95.7(c) for collagen that gelatin and collagen derived from the bones of bovines would be eligible for importation from a region of negligible risk for BSE, provided that the bovines from which the gelatin was derived passed ante-mortem and post-mortem inspection, and provided the shipment is accompanied by certification as to the BSE risk classification of the region from which the gelatin or collagen originates and that the conditions for import have been met.

Region of controlled risk or undetermined risk: We are proposing in § 94.23(d) for gelatin and § 95.7(d) for collagen that gelatin and collagen derived from the bones of bovines would be eligible for importation from a region of controlled risk or undetermined risk for BSE provided that: (1) The bovines from which the gelatin was derived passed ante-mortem and post-mortem inspection; (2) skulls from bovines of any age have been excluded from the processing (due to the fact that skull might still have pieces of brain attached), as has the vertebral column from bovines 30 months of age or older; (3) and the bones are subjected to a process that includes all of the following steps, or to a process at least as effective in reducing BSE infectivity:

1. Degreasing;
2. Acid demineralization;
3. Acid or alkaline treatment;
4. Filtration; and
5. Sterilization at 138 °C (280.4 °F) or greater for a minimum of 4 seconds.

Shipments of gelatin and collagen imported into the United States under the above conditions would need to 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.

We are proposing, additionally, in § 94.23(f) for gelatin and § 95.7(f) for collagen, to allow the importation of gelatin and collagen under conditions other than those described above 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. A United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors would need to be obtained. Application for a permit would need to 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 for such a permit must state the intended use of the material and the name and address of the consignee in the United States.

Dicalcium Phosphate

Considerable mineral content is recovered from the hydrochloric acid treatment of bone chip used in the production of gelatin. As stated earlier, before bones can be used in the manufacture of gelatin, fat and other impurities must be removed by a process called ''degreasing.'' The bones are crushed to a small size and then washed and degreased in a process that removes any residues of fat, marrow, or other soft tissues. Before degreased bone chip material can be used to produce gelatin, minerals—including calcium and phosphate—must be removed. To remove minerals, the bone chip is soaked in hydrochloric acid (approximately 4 percent, < pH 1.5) for a period of at least 2 days. The recovered minerals are further purified, followed by precipitation and drying. The resultant product is dicalcium phosphate.

In 2003, the EC SSC stated that the residual risk in dicalcium phosphate derived from bovine bones was negligible when the raw material for the production of bovine bone dicalcium phosphate is obtained from a country of any risk categorization if (1) the dicalcium phosphate is derived from appropriate tissues (i.e., from animals fit for human consumption, with SRMs—including skull and vertebrae—excluded, and cross-contamination with these bones avoided) and (2) submitted

to a production process that has a proven TSE infectivity reduction capacity (EC SSC, 2003).

The same processing steps applied for the pretreatment of bones used to produce bone-derived gelatin are followed for pretreatment of bones for the production of dicalcium phosphate. Accordingly, studies that demonstrate the safety of gelatin resulting from the pretreatment of bone during degreasing and acid demineralization (Grobben, *et al.,* 2004; Manzke, *et al.,* 1996) also indicate that a very safe dicalcium phosphate is yielded as a byproduct of the gelatin manufacturing process. Further, a significant reduction of TSE infectivity under experimental conditions has been demonstrated for dicalcium phosphate by a recent validation study in which dicalcium phosphate was prepared from bone artificially contaminated with TSEs and assayed for the presence of infectivity (Grobben, *et al.,* 2006).

In addition, according to the EC SSC (EC SSC, 2003) a 2003 validation study by Groben, *et al.,* shows that the acid process after degreasing and demineralization (as described above under the heading ''Gelatin'') together result in a reduction of infectivity of 2.6 log 10. The production process as a whole reduces the infectivity further up to 3.8 to 3.9 log 10.

Research indicates that dicalcium phosphate is not a risk factor for the transmission of the BSE agent when the dicalcium phosphate contains no traces of protein or fat. However, there is evidence that dicalcium phosphate produced from bones under normal manufacturing processes can contain a small residual proteinaceous fraction. Although the scientific evidence points to a significant reduction in infectivity during processing of dicalcium phosphate, there is a potential that it will present higher risk when it contains traces of protein or fat.

The OIE Code recommends no BSE-related restrictions for dicalcium phosphate that contains no trace of protein or fat. However, the OIE Code does recommend that dicalcium phosphate that is not free of protein or fat should originate only from negligible or controlled risk regions (OIE Code, 2010, Article 11.5.17), and that, if the material originates from a region of controlled risk for BSE, additional risk mitigation measures be applied. These additional measures are that the dicalcium phosphate is derived from cattle that have passed ante-mortem and post-mortem inspections and that the SRMs from cattle 30 months of age or older at the time of slaughter have been excluded (OIE Code, 2010, Article 11.5.17).

Based on our review of the science regarding dicalcium phosphate, we concur with the OIE's recommendations regarding trade of dicalcium phosphate. Therefore, we are proposing in § 95.10 to allow the importation of bovine-derived dicalcium phosphate that contains no trace of protein or fat from any region, regardless of the region's BSE risk classification. We are proposing to provide in § 95.10(b) to allow the importation from a region of negligible risk for BSE of bovine-derived dicalcium phosphate other than that with no trace of protein or fat if the dicalcium phosphate is accompanied by certification of the BSE classification of the exporting region. We are proposing to provide in § 95.10(c) to allow the importation from a region of controlled risk for BSE of bovine-derived dicalcium phosphate other than that with no trace of protein or fat if the dicalcium phosphate is accompanied by certification that it is derived from bovines that have passed ante-mortem and post-mortem inspection and was produced in a manner that ensures that it does not contain and is not contaminated with SRMs.

Bovine-derived dicalcium phosphate other than that with no trace of protein or fat would not be eligible for importation from a region of undetermined risk for BSE, except on a case-by-case basis as provided in the next paragraph.

We are proposing in § 95.10(e) to allow the importation of dicalcium phosphate that is not protein free under conditions other than those described above if the Administrator determines that the derivatives 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. A United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors must be obtained. 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 material and the name and address of the consignee in the United States.

Tallow

Several studies have evaluated TSE infectivity in tallow that was spiked with infected brain material and then subjected to rendering. In two rendering studies, one with BSE (Taylor *et al.,* 1995) and the other with scrapie (Taylor, *et al.,* 1997), no detectable infectivity from either agent was demonstrated from any of the tallow samples when assayed in mice. The BSE rendering study did not demonstrate any infectivity in crude unfiltered tallow, although the same rendering procedure produced MBM with almost the same infectivity levels as the untreated raw material. These studies suggest that during the manufacturing process of tallow, both BSE and scrapie agents do not preferentially separate with tallow during rendering but tend to remain with the MBM fraction.

A review of inactivation of TSE agents during rendering (Taylor and Woodgate 2003) suggests that tallow is generally not considered to be related to risk of BSE infection for two main reasons: (1) That the BSE-spiked rendering studies confirmed the lack of detectable infectivity of tallow through mice bioassay; and (2) because epidemiological studies were not able to link the distribution and use of tallow in cattle feed to the incidence of BSE in the United Kingdom.

Some countries (e.g., Denmark and Japan) have implicated tallow in milk replacers as a potential source of BSE infection. A 2003 epidemiological report on BSE in Japan hypothesized tallow in calf milk replacer as one possible source and route of infection. However, statistical analysis of the data did not support the conclusion of any correlation between the use of milk replacer and BSE incidence (BSE Epidemiological Study Group report, 2003).

A quantitative risk assessment of BSE transmission through tallow-based milk replacer (Paisley and Hostrup-Pedersen, 2004) modeled the effects of level of impurities (0.02, 0.15, and 0.5 percent), inclusion of SRMs, and other inputs on the probability of occurrence of BSE cases. Although the results were associated with a high level of uncertainty, the study found that, under certain scenarios, tallow-based milk replacer could be associated with transmission of BSE to calves. The simulations demonstrated the importance of SRM exclusion in limiting the probability of BSE infection, particularly from tallow with high impurity levels (0.5 percent). Uncertainty in the results stemmed from infectivity in central nervous system tissue and from the level of impurities in tallow.

A quantitative risk assessment on the residual BSE risk posed by tallow (EFSA

Journal, 2005a) concluded that tallow was not a risk factor in transmitting the BSE agent, if the tallow was derived from cattle that have passed ante-mortem and post-mortem inspection. Likewise, while the level of soluble impurities did not significantly affect the risk of exposure, the assessment concluded that the source of raw material warranted further consideration. In addition, removal of SRMs corresponded to a 2 log reduction in potential BSE infectivity. The EFSA Scientific Panel concluded that, for the scenarios evaluated in the quantitative risk assessment, the exposure levels for tallow were minimal, thereby posing no risk of transmission.

The OIE guidelines regarding tallow derived from bovines, and the current APHIS regulations regarding the importation of tallow from BSE minimal-risk regions are based on the conclusion that tallow with a maximum level of insoluble impurities of 0.15 percent in weight and derivatives made from this are not a risk factor in the transmission of the BSE agent. APHIS concludes that such tallow and derivatives made from this tallow can be imported without BSE restrictions, regardless of the BSE risk classification of the region of origin. We are proposing in § 95.8(b) to allow such importation of tallow with a maximum level of insoluble impurities of 0.15 percent in weight.

In addition, the evidence suggests that tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight is not a risk factor provided it is sourced from cattle that have passed ante-mortem and post-mortem inspections and SRMs are excluded. Therefore, we are proposing in § 95.8 that tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight would be eligible for importation under the following conditions. Either:

- It is sourced from a region of negligible risk for BSE; or
- If it is sourced from a region of controlled risk for BSE, it was derived from bovines that have passed ante-mortem and post-mortem inspections and has not been prepared using SRMs.

Additionally, to be eligible for importation, bovine-derived tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight would need to be accompanied by certification of the BSE risk classification of the exporting region and that the applicable conditions, above, have been met.

Tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight would not be eligible for importation from a region of undetermined risk for BSE, except on a case-by-case basis as provided in the next paragraph.

We are proposing in § 95.8(f) to allow the importation of tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight under conditions other than those described above if the Administrator determines that the tallow 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. A United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors must be obtained. 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 material and the name and address of the consignee in the United States.

Tallow Derivatives Other Than Those Made From Tallow With a Maximum Level of Insoluble Impurities of 0.15 Percent in Weight

In addition to tallow itself, derivatives of tallow are a commercially traded commodity. Several studies have evaluated the effects of various time, temperature, and pressure processes on prion inactivation. The BSE-spiked tallow study (Taylor, *et al.,* 1995) showed that, while infectivity does not persist in tallow during rendering, the level of infectivity of BSE subjected to a poorly inactivated rendering process remained at almost the same level as the untreated material.

The current APHIS regulations in § 95.4 allow the importation of derivatives from bovine-derived tallow without restriction with regard to BSE. Under § 95.9(b) of this proposal, derivatives from bovine-derived tallow with a maximum level of insoluble impurities of 0.15 percent in weight would continue to be eligible for importation into the United States without restriction due to BSE.

With regard to derivatives from bovine-derived tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight, the OIE Code recommends that trade be allowed in such a commodity under any of the following conditions:

- It originates from a country of negligible risk for BSE;
- It originates from a country of controlled risk for BSE, is derived from bovines that have passed ante-mortem and post-mortem inspections, and does not contain SRMs; or
- It originates from either a country of controlled risk for BSE or a country of undetermined risk for BSE and was produced by hydrolysis, saponification, or transesterification. Those processes create conditions of high enough temperature and pressure to inactivate the BSE agent.

The OIE Code does not define *tallow derivative.* However, in 21 CFR 589.2001, the FDA defines *tallow derivative* as follows: ''* * * [A]ny 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.'' According to the FDA definition, all bovine-derived tallow derivatives would meet the guideline in the OIE Code under which tallow derivatives from any country could be traded. In this document, we are proposing in § 95.1 to define *tallow derivative* as FDA does. In § 95.9, we are proposing to allow the importation from any region of tallow derivatives that meet our definition in § 95.1. In § 95.9 of this proposal, we are also providing that if an importer wishes to import a commodity the importer considers to be a tallow derivative, but that does not meet our proposed definition of *tallow derivative,* and the commodity was not derived from tallow with a maximum level of insoluble impurities of 0.15 percent in weight, it must meet one of the following conditions to be eligible for importation:

- It originates from a country of negligible risk for BSE;
- It originates from a country of controlled risk for BSE, is derived from bovines that have passed ante-mortem and post-mortem inspections, and does not contain SRMs.

Additionally, to be eligible for importation, derivatives from bovine-derived tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight would need to be accompanied by certification that the applicable conditions, above, have been met.

We are proposing in § 95.9(g) to allow the importation of derivatives of tallow other than tallow with a maximum level of insoluble impurities of 0.15 percent in weight under conditions other than those described above if the Administrator determines that the derivatives 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. A United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors must be obtained. 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 material and the name and address of the consignee in the United States.

In-Vivo-Derived Embryos

The current regulations in part 98 include BSE-related restrictions on the importation of embryos from ruminants. The regulations in § 98.15(a) provide that ruminant embryos may be imported into the United States from regions in which foot-and-mouth disease or rinderpest exists only if certain conditions apply with regard to BSE and other diseases. Among the conditions related to BSE are the following:

- During the year before embryo collection, no case of BSE occurred in or within 5 kilometers of the embryo collection unit;
- During the year before embryo collection, no case of BSE occurred in any herd in which the donor dam was present;
- Not less than 30 days nor more than 120 days after embryo collection, the donor dam was examined by an official veterinarian and was found free of clinical evidence of BSE;
- Between the time the embryos were collected and all required examinations and tests were conducted, no animals in the embryo collection unit with the donor dam, or in the donor dam's herd of origin, exhibited any clinical evidence of BSE.

We are proposing to remove the BSE-related restrictions in § 98.15(a) on the importation of embryos derived from bovines, cervids, or camelids. This change would be consistent with the OIE Code regarding trade in in-vivo-derived embryos derived from bovines, and would be consistent with our proposal, discussed above under the heading ''Cervids and Camelids,'' to remove BSE-related import restrictions on cervids and camelids.

No detectable infectivity has been found in susceptible mice fed placenta from confirmed cases of BSE (Middleton and Barlow, 1993; Barlow and Middleton, 1990; Bradley, 1990), nor in placenta, placental fluids, or ovary or uterine caruncle following mouse inoculation (Fraser and Foster, 1994; MAFF, 1997; EC SSC, 2000). Male reproductive tissues (e.g., testis, epididymis, prostate, semen, seminal vesicle) inoculated into mice showed no infectivity (Fraser and Foster, 1994; MAFF, 1999). In addition, infectivity was not detected in the fetal membranes and placenta of cattle with clinical BSE after cattle were dosed oro-nasally with a pooled tissue homogenate from BSE cattle. Animals were killed at 24 and 84 months post infection with no evidence of disease (Bradley, 1996; EC SSC, 2000).

A different study examined the potential for washed embryos to transmit BSE (Wrathall *et al.,* 2002). In this study, semen from 13 bulls, 8 with clinical BSE, was used for artificial insemination (AI) of 167 clinically affected cows in the terminal stages of BSE. The resulting embryos were treated according to the recommendation of the International Embryo Transfer Society. The embryos were always transferred singly, but repeat transfers were done if returns to estrus occurred within the particular transfer session. Five hundred eighty-seven viable embryos were transferred into 347 recipient heifers imported from New Zealand. A total of 266 live offspring were born, of which 54.1 percent had a BSE-positive sire as well as a BSE-positive dam. The recipient heifers were monitored for clinical signs of BSE for 7 years after transfer, and the offspring were also monitored for 7 years after birth. Twenty-seven heifers and 20 offspring died during monitoring, but none showed signs of BSE. The brains of these animals, in addition to the brains of animals killed, as scheduled, after 7 years were examined for BSE by histopathology, PrP immunohistochemistry, and by electron microscopy for scrapie-associated fibrils. All results were negative. In addition to the embryos transferred into recipient heifers, 1,020 nonviable embryos were sonicated and inoculated intracerebrally into susceptible mice (20 embryos per mouse) that were monitored for up to 700 days post inoculation; their brains were then examined for spongiform lesions. All results were negative. Additionally, uterine flush fluid samples from 41 cows were tested for BSE infectivity by intracerebral and intraperitoneal inoculation of 946 mice. One of these mice had some vacuolar pathology, but its relevance proved difficult to determine, since the putative incubation period was inconsistent with the survival of remaining mice in the group. All other mice with injections of flush fluids from the same cow were negative when finally killed and examined. Results of the study indicate that embryos are unlikely to carry BSE, and do not transmit the disease to recipients and their embryo transfer offspring, even when they are collected from donor cows at the end-stage, when the risk of maternal transmission (if it were to exist) would potentially be the highest.

In a cohort study, 316 offspring of BSE confirmed cows (cases) and 316 offspring from cows over 6 years old and without BSE from the same farm and age cohort (controls) have been observed under controlled conditions over a 7-year period. The purpose of the study was to determine whether maternal transmission occurs, and, if so, at what level of incidence. There was a statistically significant risk difference between the two cohorts examined (i.e., calves born to dams with BSE and calves born to healthy dams more than 6 years old). This difference was 9.7 percent, with a relative risk of 3.2 for offspring of cows that developed clinical BSE. This enhanced risk for the offspring of BSE dams appeared to decline the later the offspring were born after the 1988 feed ban was in place, but increased the closer that parturition was to the onset of clinical disease in the dam. The results cannot distinguish between a genetic component and true maternal transmission for which there is no other evidence. Instead, a combination of a genetic cause (i.e., increased susceptibility to feed exposure that could have occurred in any cattle in the study) and genuine transmission fits the computer model of the epidemic best (Donnelly, *et al.,* 1997). Later studies by Donnelly, *et al.* (2002) significantly reduced the estimated risk to offspring, although they recognized that the introduction of culling of offspring of confirmed cases made estimation of the risk impossible other than by back-calculation methods. The route for the hypothetical maternal transmission of BSE has not been established. Based on the modeling study, given that less than 1 percent of the offspring of affected cattle in the United Kingdom epidemic may succumb to this means of exposure, it is likely to be difficult to determine the route. More recent work on cases born after the 1996 feed ban fails to demonstrate evidence of maternal transmission (Hill, 2005). Thus, although maternal transmission may be possible, more recent epidemiologic

evidence suggests that maternal transmission of BSE is unlikely to occur at any appreciable level, if at all.

For the reasons discussed above, we do not believe it is necessary to retain the BSE-related restrictions in § 98.15(a) on the importation of embryos derived from bovines, cervids, or camelids.

Blood and Blood Products

Blood and blood products can be divided into two main groups: (1) Whole blood and cellular derivatives such as red cell concentrate, platelets, and other cellular elements; and (2) plasma-derived products including serum (including fetal bovine serum (FBS), clotting factors, immunoglobulins, and albumin (Farshid, *et al.,* 2005)). Plasma is the cell-free portion of the blood. Serum is plasma with fibrinogen and clotting factors removed.

Transmission Studies

BSE infectivity has not been demonstrated in cattle blood or any tested derivatives (EC SSC, 2002). This conclusion derives from studies in which tissues from infected cattle were injected intracerebrally and intraperitoneally into mice (the ''mouse bioassay''), or intracerebrally into cattle (the ''cattle bioassay''). Mouse bioassays were performed using buffy coat (the white cell fraction of centrifuged whole blood), clotted blood, fetal calf blood, and serum from confirmed clinical cases (Kimberlin, 1996 cited in EC SSC, 2002). Wild-type mouse and cattle bioassays were performed on buffy coat from cattle experimentally exposed orally to the BSE agent. In all cases, no evidence of infectivity was detected. However, brain damage caused by certain stunning techniques can produce central nervous system tissue emboli in venous blood draining the head (EFSA Journal, 2004). A recent study (Espinosa, *et al.,* 2007), utilizing material derived from the second United Kingdom Veterinary Laboratories Agency pathogenesis study (cattle challenged orally with BSE and culled 20, 24, 27, and 30 months post exposure), revealed no detectable blood infectivity by assay in transgenic BoPrP–Tg110 mice.

Investigators have demonstrated that BSE can be transmitted to sheep by transfusion of whole blood from sheep experimentally infected with BSE (Houston, *et al.,* 2000; Hunter, *et al.,* 2002). In these studies, a transfusion of 400 ml of whole blood, taken from clinically normal infected sheep, caused disease in 2 of 24 recipients. Blood or buffy coat taken from clinically ill animals, however, did not cause disease in the four recipients. These same investigators also examined scrapie in sheep. A total of 4 sheep out of 21 transfused with blood from sheep naturally infected with scrapie developed disease. The transfusion of buffy coat derived from a clinically ill animal caused disease in the recipient. The EC SSC examined these studies and their implications. They concluded that the finding of infectivity in the blood of sheep could not be extrapolated to BSE in cattle (EC SSC, 2002b).

Brown, *et al.* (1999), using a human strain of TSE (Gerstmann-Straussler-Scheinker) in mice inoculated intracerebrally, concluded that infectivity was present in the buffy coat (platelets, white cells) during the preclinical phase of TSE, but absent or in only trace amounts in the plasma or plasma fractions. Following the onset of clinical signs, increased infectivity of both buffy coat and plasma was found, but still at very low levels compared to levels in the central nervous system. As cited in a review of the relevant literature (Comer, 2004, p. II.18), most studies using a rodent model and adapted strains of scrapie or CJD demonstrated that the fractions containing white blood cells have the highest levels of infectivity.

In contrast to investigations of the natural distribution of infectivity in rodent blood fractions, one ''spiking'' study added high levels of hamster-adapted scrapie infectivity from brain homogenate to normal human blood. Following fractionation by centrifugation into red cells, white cells/platelets, and plasma components, titrations indicated that the majority of infectivity was in the red cell component (Brown, *et al.,* 1998). These results, although not as relevant to understanding the natural distribution of TSEs in blood, may potentially apply to the distribution following cross-contamination at blood collection. Therefore, if contrary to current research, or if the proposed mitigations are not properly implemented, BSE infectivity is present in bovine blood, either naturally or via cross-contamination, it would likely be highest in the cellular components. These fractions, both red and white cells, are excluded when harvesting FBS and bovine serum albumin used in the preparation of vaccines and drugs.

Further decrease in TSE infectivity occurs with fractionation of plasma proteins. Fractionation is the process whereby specific proteins, such as albumin, are separated out from other components of the plasma. Infectivity in various fractions has been examined. For example, using data from several cited studies, Comer (2004) estimated that human albumin contains 3.1x10–5 vCJD ID_{50}/gram. Compared to Comer's estimates of infectivity in whole blood (2 iv vCJD ID_{50}/gram), this figure represents a dramatic decrease.

Although BSE has never been detected in any bovine blood, blood product, or fetal blood, APHIS recognizes the possibility of cross-contamination with SRMs at the time of collection, particularly in a slaughter environment. Certain slaughterhouse stunning practices–specifically the use of devices that inject compressed air or gas into the cranial cavity or pithing processes—may introduce macro-emboli of tissue from the central nervous system into the circulatory system (Anil *et al.,* 1999; Schmidt, *et al.,* 1999). In addition, collection of blood in an open manner may allow other tissues to contaminate the blood.

In order to prevent contamination due to such potential sources of infectivity, we are proposing in § 95.12 to require mitigations to decrease the risk of cross-contamination. For all blood and for products derived from blood, a condition of importation eligibility would be that the blood was collected in a hygienic manner, as determined by the Administrator, that prevents contamination of the blood with SRMs. For blood collected at slaughter and for products derived from such blood, we would require that the slaughtered animal: (1) Pass ante-mortem inspection; and (2) not be subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process. For blood collected from live donor bovines and for products derived from such blood, we would require that the donor animal be free of clinical signs of disease. Although this requirement regarding the disease status of live donor animals, which is set forth in the § 95.4(e) of the current regulations, is not included in the OIE Code, we are including it here as an additional precaution against BSE contamination of the blood collected.

Additionally, we would require that each shipment of blood and blood products to the United States must be accompanied by certification that the applicable requirements have been met.

Restrictions on Processed Animal Protein Derived From Nonruminants

Although materials derived from nonruminants do not pose a BSE risk in and of themselves, the importation of such materials into the United States could pose a BSE risk if the nonruminant materials are commingled with materials from BSE-infected

ruminants. To guard against such a possibility, the current regulations in § 95.4 restrict the importation of certain animal materials, regardless of the species from which it is derived, unless it can be demonstrated that the nonruminant material (or ruminant material if the ruminants are from a country not listed in § 94.18(a)) has not been commingled with ruminant materials that are prohibited entry into the United States. The regulations in § 95.4(c)(4) also contain provisions under which a facility that wishes to export such material to the United States from a region listed in § 94.18(a), and that process or handle any material derived from mammals, must allow for periodic APHIS inspection of its facilities, records, and operations to ensure there is no commingling. Facilities in regions listed in § 94.18(a)(1) or (a)(2) that wish to export such material to the United States are required to enter into a cooperative service agreement with APHIS to provide for the payment of the costs of APHIS inspections.

This proposed rule would continue to include safeguards against the commingling of nonruminant materials with materials that could contain BSE infectivity. The non-commingling provisions in proposed § 95.4(c) regarding materials derived from ovines and caprines would continue to apply to a variety of materials—e.g., processed animal protein, tankage, offal, tallow other than tallow derivatives, processed fats and oils, and derivatives of processed animal protein, tankage, and offal, pending any future rulemaking regarding ovines and caprines. However, in proposed §§ 95.13 and 95.14, which address potential BSE contamination of nonruminant-derived materials due to commingling with materials derived from bovines, the provisions would apply only to processed animal protein, based on the scientific evidence discussed above regarding the role of such material in BSE transmission.

We are proposing in § 95.13 that processed animal protein from a region of negligible risk for BSE that is derived from animals other than ruminants may not be imported into the United States unless the following conditions are met:

- The material is not otherwise prohibited under the provisions in § 95.4 regarding materials derived from ovines or caprines;
- The shipment of materials into 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 indicate the BSE risk classification of the region of export;
- 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/*.)

We are proposing in § 95.14 that processed animal protein from a region of controlled risk or undetermined risk for BSE that is derived from animals other than ruminants may not be imported into the United States unless, in addition to the requirements for importation listed above for importation from a region of negligible risk for BSE, the following conditions are met:

- Except as provided in the next bulleted condition for blood and blood products, the processed animal protein does not contain and was not commingled with material derived from ruminants originating in a region of controlled risk or undetermined risk for BSE.
- 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. Because, as noted above, BSE infectivity has not been demonstrated in cattle blood or any tested derivatives (EC SSC, 2002), we do not believe it is necessary to require that processed animal protein derived from nonruminants not contain or be commingled with blood and blood products derived from any ruminant from a BSE controlled- or undetermined-risk region. However, because of the possibility that blood derived from bovines could be contaminated with the BSE agent if collected in a manner that does not ensure that it is not contaminated with tissues containing the BSE agent, we consider it necessary to prohibit the contamination or commingling of nonruminant processed animal protein from controlled- or undetermined-risk regions with blood or blood product that does not meet all the conditions (e.g., collection in a hygienic manner) necessary to make it eligible for importation into the United States.
- 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.

- If APHIS conducts the required inspection, 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.

Processed Animal Protein Derived From Ruminants

Epidemiological evidence indicates the consumption by a susceptible animal of processed animal protein of ruminant origin contaminated by the BSE agent is the route by which BSE is transmitted. A region recognized by APHIS as a region of negligible risk for BSE and in which there has never been an indigenous case of BSE would have a negligible likelihood of circulating BSE infectivity and, therefore, pose a negligible risk that a BSE-infected animal would be incorporated into rendered protein. Therefore, we are proposing in § 95.5 to allow the

importation of processed animal protein derived from ruminants from such a region.

In the case of a region of negligible risk for BSE that has had an indigenous case of the disease, we would require in § 95.5 that the product be derived from ruminants that were subject to a ruminant-to-ruminant feed ban.

Under this proposal, processed animal protein derived from ruminants would not be eligible for importation into the United States from a region of controlled risk for BSE or a region of undetermined risk. Because the primary source of BSE exposure has been shown to be processed animal protein derived from ruminants contaminated with the BSE agent, and because processed animal protein could potentially carry or be contaminated with the BSE agent, we are proposing to prohibit the importation of processed animal protein from regions of controlled risk for BSE unless it can be demonstrated that such product has not been commingled or contaminated with ruminant MBM or greaves. We would prohibit the importation of processed animal protein derived from ruminants from regions of undetermined risk for BSE because of the possibility that such a region may not have adequate infrastructure and the capability to implement BSE-related risk mitigations, including an effectively enforced feed ban.

Transiting Provisions

In the current regulations, §§ 94.18(d) and 95.4(h) provide that articles that are otherwise prohibited importation into the United States under the BSE regulations may transit air and ocean ports in the United States for immediate export, provided certain conditions are met. The requirements are that:

- The person moving the articles has obtained an import permit from APHIS;
- The articles are sealed in leakproof containers bearing serial numbers during transit, and each container remains sealed during the entire time that it is in the United States;
- The person moving the articles notifies, in writing, the inspector at both the place in the United States where the articles will arrive and the port of export before such transit. The notification must include the import permit number; the times and dates of arrival in the United States; the times and dates of exportation from the United States; the mode of transportation; and the serial numbers of the sealed containers; and
- The articles transit the United States in Customs bond.

We are proposing in § 94.27 and § 95.15 to continue to allow such transiting of articles otherwise prohibited importation by the BSE regulations.

Sections 94.18(d) and 95.4(h) of the current regulations also allow the overland transit through the United States of articles from BSE minimal-risk regions, provided the requirements listed above are met, and the following additional requirements are met:

- The articles are eligible to enter the United States in accordance with the BSE provisions in part 94 or part 95, as applicable;
- The shipment is exported from the United States within 7 days of its entry;
- The commodities are not transloaded while in the United States, except for direct transloading under the supervision of an inspector, who must break the seals of the national government of the 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
- A copy of the required import permit is presented to the inspector at the port of arrival and the port of export in the United States.

In this document, we are proposing in § 94.27 and § 95.15 to allow the overland transit of products governed by the BSE regulations, provided the same conditions for overland transit as those listed above are met.

Certification of Certain Materials

Section 95.29 of the current regulations requires certification regarding the source, processing, and storage of certain specified animal materials imported from regions other than those listed in § 94.18(a), which lists regions from which the importation of ruminants and ruminant products are restricted because of BSE. The materials for which certification is required are the following:

- Processed animal protein, tankage, offal, and tallow other than tallow derivatives, unless, in the opinion of the Administrator, the tallow cannot be used in feed, regardless of the animal species from which the material is derived;
- Glands and unprocessed fat tissue from ruminants;
- Processed fats and oils, and derivatives of processed animal protein, tankage, and offal, regardless of the animal species from which the material is derived;
- Derivatives of glands from ruminants; and
- Any product containing any of the listed materials.

We are proposing to amend the provisions of § 95.29 (redesignated as § 95.40 in this proposed rule) to make them apply only to materials derived from ovines or caprines. As discussed above, we are not at this time proposing to make any substantive changes to the BSE regulations governing ovines or caprines or products from such animals. The purpose of the provisions in current § 95.29 as they apply to materials from nonruminant animals and to ruminants other than ovines and caprines—to ensure that materials eligible for entry into the United States have not been commingled with materials ineligible for entry because of their BSE risk—would be met by the provisions we are proposing to set forth in new § 95.13, which we discuss above under the heading ''Restrictions on Processed Animal Protein Derived from Nonruminants.''

Importation of Casings

Part 96 of the current regulations includes provisions regarding the importation of animal casings into the United States. Current § 96.2(b) prohibits the importation of casings, except stomachs, from ruminants that originated in or were processed in any region listed in § 94.18(a) for BSE, unless specified conditions in § 96.2(b)(1) or (b)(2) are met. These provisions are as follows:

- The casings are derived from sheep that were slaughtered in a BSE minimal-risk region listed in § 94.18(a)(3) (currently only 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 FDA at 21 CFR 589.2000; or
- The casings are derived from bovines that were slaughtered in a BSE minimal-risk region, provided, 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 FSIS at 9 CFR 310.22 and the FDA at 21 CFR 189.5.

Casings that are imported in accordance under either of the above scenarios must also be accompanied by certification that the applicable conditions have been met.

In this document, we are proposing to amend § 96.2(b) to specify that the prohibitions in that paragraph that currently apply to casings from all ruminants would apply only to casings derived from ovines or caprines. We are proposing no changes to the current provisions governing the importation of

casings derived from sheep from Canada.

We are proposing to amend the current § 96.2 provisions regarding casings derived from bovines to allow for the importation of casing derived from bovines provided the following conditions are met:

- If the casings are derived from bovines from a region of negligible risk for BSE, the certification required under § 96.3 indicates the APHIS BSE risk classification of the region in which the bovines were slaughtered and the casing processed.
- If the casings are derived from bovines from a region of controlled risk for BSE or a region of undetermined risk for BSE, 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 FSIS at 9 CFR 310.22 and FDA at 21 CFR 189.5.
- The casings are accompanied by a certification that the required conditions have been met.

Provisions Regarding Ovines and Caprines

In this proposal, we retain the current import prohibitions and restrictions regarding ovines and caprines (e.g., sheep and goats) and their products. However, we are proposing to make formatting and wording changes to the regulations regarding such animals, for several reasons.

In many cases, the current import regulations regarding BSE apply to all ruminants or to several types of ruminants. For instance, the regulations in current § 94.18 prohibit or restrict the importation of most products derived from ruminants from regions in which BSE exists (listed in current § 94.18(a)(1)) or that pose an undue risk of BSE (listed in current § 94.18(a)(2)), whether the ruminant from which the product is derived is a bovine, ovine, caprine, cervid, or camelid. Similar blanket prohibitions or restrictions are set forth in current part 93 with regard to live ruminants, in current part 95 with regard to products derived from ruminants other than meat and other edible products, and in current part 96, with regard to casings.

The current regulations apply no BSE prohibitions or restrictions to live cervids and camelids from BSE minimal-risk regions (listed in current § 94.18(a)(3)) or to products derived from such animals. The importation from BSE minimal-risk regions of live bovines, sheep, and goats—and products derived from such animals—is allowed under specified conditions.

Because, in this proposed rule, we would retain the current importation provisions with regard to BSE as they apply to ovines and caprines—but not as they apply to bovines, cervids, and camelids—it is necessary to revise the current regulations to make them particular to ovines and caprines, pending any future rulemaking regarding such animals. Among the revisions we are proposing to the regulations regarding ovines and caprines is the removal of the terminology currently used in § 94.18(a) to refer to the BSE risk status of a region (i.e., regions in which BSE exists, regions of undue risk for BSE, and regions of minimal-risk for BSE). In order to avoid confusion as to our intent regarding our proposed BSE risk classification system with regard to bovines (i.e., BSE negligible-, controlled-, and undetermined-risk regions), when we refer to regions that are listed in current § 94.18(a) with regard to ovines and caprines, we simply list the names of those regions.

In this proposed rule, the provisions in part 94 that are particular to ovines and caprines are set forth in §§ 94.24 through 94.27. The provisions in part 95 that are particular to ovines and caprines are set forth in §§ 95.4, 95.15, and 95.40. In parts 93 and 96, the BSE import provisions related to ovines and caprines and their products are set forth in the same regulatory sections as in the current regulations.

Definitions

In addition to the definitions we are proposing to add to the regulations that we discuss elsewhere in this document, we are proposing to add to § 92.1 definitions of *approved laboratory, OIE, OIE Code,* and *OIE Terrestrial Manual*. Additionally, we are proposing to amend the definition of *recognized slaughtering establishment* in § 93.400 to mean a 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. This proposed definition is the same as that currently contained in 9 CFR 78.1.

Miscellaneous Nonsubstantive Changes

We are also proposing to make nonsubstantive editorial and formatting changes to parts 92, 93, 94, 95, and 96, in order to make the text in those parts consistent with the changes that we discuss above in this document. These nonsubstantive changes include redesignation and reformatting of regulatory sections and amendment of cross-references where necessary.

We are also proposing nonsubstantive editorial changes to § 96.3 to reflect the changes we are proposing to make in § 96.2.

APHIS Classification of BSE Risk Status of Countries That Have Received Classification by the OIE

As we discussed above in this document under the heading ''The Process for APHIS Recognition of the BSE Risk Classification of a Region,'' if the OIE has classified a country as either BSE negligible risk or BSE controlled risk, APHIS would give notice to the public that the Agency considers such classification by the OIE to be a basis for APHIS' recognition of the country as having the BSE risk classification determined by the OIE, subject to public comment regarding that intent.

In accordance with that proposed process we are giving notice in this document that APHIS gives preliminary concurrence to the OIE risk classifications of the following countries:

- *Regions of negligible risk for BSE:* Argentina, Australia, Chile, Denmark, Finland, Iceland, New Zealand, Norway, Panama, Paraguay, Peru, Sweden, and Uruguay.
- *Regions of controlled risk for BSE:* Austria, Belgium, Brazil, Canada, Colombia, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Mexico, the Netherlands, Poland, Portugal, Republic of Korea, Slovak Republic, Slovenia, Spain, Switzerland, and the United Kingdom.[17]

The OIE recommendations regarding each of the above countries can be viewed at *http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/*.

Date of Effective Enforcement of Feed Ban in Mexico

As noted above, we are proposing to recognize Mexico as a country of controlled risk for BSE. Also as discussed above, for a country classified by APHIS as negligible-risk or controlled-risk for BSE that wishes to export live bovines to the United States, APHIS would need to determine the date a feed ban was effectively enforced in the country. Consequently, we have conducted an evaluation to determine the date of effective enforcement of a feed ban in Mexico. Based on that evaluation, we consider the date of

[17] The United States is also classified by the OIE as a region of controlled risk for BSE.

effective enforcement of a feed ban in Mexico to be November 30, 2007. Copies of our evaluation, as well as the supporting documentation, are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

Public Comment Regarding BSE Classification of Countries and Date of Effective Enforcement of Feed Ban in Mexico

We will accept public comment on our preliminary BSE risk classification of the countries listed above, as well as on our preliminary determination of the date of effective enforcement of a feed ban in Mexico, for the length of the comment period for this proposed rule document. Any final classification of countries regarding BSE risk would depend both on whether the classification system and procedures we are proposing in this document are made final and on comments received from the public regarding such classifications. Following review of any comments received, we will inform the public in the **Federal Register** of the Administrator's final determination regarding classification of the countries listed above and the date of effective enforcement of a feed ban in Mexico, along with a discussion of and response to pertinent issues raised by commenters.

Provisions Regarding the Importation of Live Bovines From Mexico

As we discuss earlier in this document with regard to the importation of live bovines from Canada, the provisions we are proposing in § 93.436 for the importation of live bovines from a region of controlled risk are generic to any such region. For instance, the provisions in § 93.436 require that live bovines imported from a controlled risk region for BSE must have been born after the date from which the ban on the feeding of ruminants with MBM and greaves derived from ruminants has been effectively enforced. Also, the provisions in § 93.436 require that live bovines intended for importation be permanently identified—by branding, tattooing, or some other method—as to the country of export. As noted above, in this document we are proposing to recognize November 30, 2007, as the date of effective enforcement of a feed ban in Mexico. Further, in this document, we are proposing to specify that the letters ''MX'' be used to identify sexually intact bovines as being of Mexican origin. (The regulations already require that cattle from Mexico that are other than sexually intact be identified as to country of origin, for diseases other than BSE.) To make this specific information more easily accessible in the regulations, we are proposing to set forth the provisions regarding the importation of live bovines from Mexico with regard to BSE in a new paragraph (f) in § 93.427. Current § 93.427 contains requirements governing the importation of cattle from Mexico with regard to fever ticks, brucellosis, and tuberculosis.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed 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 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 by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

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

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

Live Bovines (Cattle and Bison)

Canada and Mexico are the sources of nearly all U.S. bovine imports. In the past 15 years, they have accounted for 99.9 percent of all cattle and bison imported into the United States. APHIS is proposing to classify Canada and Mexico as countries of controlled risk for BSE (their classification by the OIE).

Imports from Canada are likely to be unaffected by this proposed rule because the proposed requirements would 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. Imports from Mexico also are likely to be largely unaffected, since nearly all cattle imported from Mexico (98 to 99 percent) are estimated to be less than 24 months of age and APHIS is proposing in this rule to establish 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 93 percent of all U.S. bovine product import volume (and 92 percent of the import value) over the five-year period, 2006–2010. Imports from each of the six countries should continue essentially unchanged and without interruption under the proposed rule, because the protocols in place in these countries are already in full compliance with the proposed criteria. Argentina, Australia, New Zealand, and Uruguay are APHIS-proposed negligible risk regions for BSE that have never reported a case of BSE. Canada and Brazil, as proposed controlled risk regions for BSE, already satisfy FSIS inspection requirements and prohibitions on certain animal stunning or pithing and mechanically separated meat.

Imports from the 36 (primarily European) countries listed in 9 CFR 94.18 as prohibited from shipping bovine products to the United States likely would be insignificant under the proposed rule. 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 the current trade climate suggest a significant volume of imports from the 36 countries in the future, at least in the near term. U.S. imports of beef and other bovine products have been in decline, a situation that makes it increasingly difficult for foreign exporters to compete in the U.S. market. Second, while bovine product exports by the European Union (EU–27) more than doubled in nominal value in five years, from $0.43 billion in 2006 to $1.01 billion in 2010, the value of bovine product imports by EU–27 member countries in 2010 ($2.1 billion) was twice the value of their bovine product exports. 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 five years, 2006–2010, annual imports from such countries as a group averaged 6 to 7 percent of all U.S. bovine product imports by volume (7 to 8 percent by value), with virtually all of the products coming from Mexico, Nicaragua, and Costa Rica. Imports from Mexico already meet the proposed 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 proposing to recognize 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 proposed 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 would likely have little or no impact. 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. Moreover, U.S. imports of meat and edible offal of deer have declined since 2005, a situation that makes it increasingly difficult for foreign exporters to compete in the U.S. market. The volume of U.S. imports of camelid products is very small. Their annual value averaged less than $50,000 over the five-year period, 2006–2010, 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 proposed rule would have little impact on consumer choice or import volumes. Likewise, we anticipate little or no impact for U.S. businesses because of changes in import volumes.

Although the impact of this proposed rule on U.S. consumers and producers is expected to be minimal, the benefits of the rule are expected to outweigh 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 fully supported by scientific evidence. Additionally, maintaining the status quo would not provide an opportunity to recognize 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 without allowing for modification deemed necessary by APHIS, 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.

Small entities are prevalent in industries potentially affected by the proposed rule, but as described, we expect at most a minimal economic impact for U.S. businesses. We invite public comment on the rule's potential economic impact, including comment on the potential impact on small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

National Environmental Policy Act

Our affirmation of the position we took in removing the delay of applicability of certain provisions of our January 2005 final rule leaves those regulations unchanged. Therefore, we are also affirming the overall conclusions we reached in the environmental assessments we conducted for our January 2005 and September 2007 final rules.

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the proposed revision of the conditions for the importation of live bovines and products derived from bovines with regard to BSE set forth in this proposed rule, we have prepared an environmental assessment. The environmental assessment was 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 may be viewed on the Regulations.gov Web site or in our reading room. Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule. In addition, copies may be obtained by calling or writing to the individuals 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 requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2008–0010. Please send a copy of your comments to: (1) Docket No. APHIS–2008–0010, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer,

OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

APHIS is proposing to revise the conditions for the importation of live bovines and products derived from bovines with regard to BSE, and is proposing to establish a system and process for classifying regions as to BSE risk that is consistent with the system and process employed by the OIE. For the most part, the changes made by this rule would expand the number and types of commodities eligible for entry into the United States with regard to BSE. However, in many cases, the commodities would be eligible for entry into the United States only if specified conditions have been met, and the commodities are accompanied by certification that the required conditions have been met. In some cases, the person seeking to import a commodity would need to apply for an import permit from APHIS.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

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

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

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

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

Estimate of burden: Public reporting burden for this collection of information is estimated to average .3960737 hours per response.

Respondents: U.S. importers of regulated animal products; full-time salaried veterinary officials of exporting regions; and foreign exporters of edible and inedible products derived from bovines.

Estimated annual number of respondents: 784.

Estimated annual number of responses per respondent: 41.4528.

Estimated annual number of responses: 32,499.

Estimated total annual burden on respondents: 12,872 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

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 proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

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List of Subjects

9 CFR Part 92

Animal diseases, Imports, 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 proposing to amend 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 feed that potentially contained SRM material 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 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 (2) 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-

[1] A list of regions classified by APHIS as regions of controlled risk for BSE is available at [ADDRESS TO BE ADDED IN FINAL RULE]

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 feed that potentially contained SRM material 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. A subpart heading is added after § 92.1 to read as follows:

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

4. A new Subpart B—Procedures for Requesting BSE Risk Status Classification With Regard to Bovines, §§ 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.
92.5 Determination of the BSE risk classification of a region.
92.6 Determination of the date of effective enforcement of a ruminant-to-ruminant feed ban.
92.7 OIE Code standards for surveillance for BSE.

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 of this part. 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 [ADDRESS TO BE ADDED IN FINAL RULE]. The listing can also be obtained by writing to APHIS at [ADDRESS TO BE ADDED IN FINAL RULE]. 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. The summaries would be available for review on the APHIS Web site at [ADDRESS TO BE ADDED IN FINAL RULE]. 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

[2] A list of regions classified by APHIS as regions of negligible risk for BSE is available at [ADDRESS TO BE ADDED IN FINAL RULE].

BSE, as applicable, that APHIS will make available to the public on the Agency's Web site at [ADDRESS TO BE ADDED IN FINAL RULE].

(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 such classification, along with documentation sufficient to allow APHIS to conduct an evaluation of whether the region meets the criteria for the classification. A list of the documentation required can be accessed on the APHIS Web site at [ADDRESS TO BE ADDED IN FINAL RULE]. 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.

(d) *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 derived from ruminants;

(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;

(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.

§ 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 OIE Code standards for surveillance for BSE.

Article 11.6.22 of the OIE Code, effective 2009, are incorporated by reference. This incorporation by reference was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The OIE maintains a copy of these standards on its Internet homepage at *http://www.oie.int/eng/normes/Mcode/en_sommaire.htm*. Copies are 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*.

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 revising the definition of *recognized slaughtering establishment* and adding definitions of *exporting region* and *processed animal protein,* in alphabetical order, 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]

* * * * *

§ 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. In § 93.405, paragraph (a)(4) is amended 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)''.

9. In § 93.418, the section heading is revised and a new paragraph (d) is added to 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 ''CAN'' 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.

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;

(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.

11. In § 93.423, a new 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. In § 93.427, the section heading is revised and a new paragraph (e) is added to 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

[2] See footnote 1.

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 paragraph (e)(1) through (e)(3) of this section have been met.

13. In § 93.432, the section heading is revised and a new 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 chapter, 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 cocygeal vertebrae);

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

(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 the BSE minimal-risk exporting region.

(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 feed that potentially contained SRM material 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.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, EXOTIC NEWCASTLE DISEASE, 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 ''§ 94.28'' in their place.

§ 94.9 [Amended]

18. In § 94.9, paragraph (c) is amended by removing the citation ''§ 94.24'' and adding the citation ''§ 94.30'' in its place.

§ 94.10 [Amended]

19. In § 94.10, paragraph (c) is amended by removing the citation ''§ 94.24'' and adding the citation ''§ 94.30'' 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 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.

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 derived from bovines that were born and raised in 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 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.

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.

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 derived from bovines that were born and raised in either a region of negligible risk for BSE that complies with § 94.19(a) through (c), as applicable, or 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 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.

23. A new § 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 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.

§ 94.27 [Removed]

24. Section 94.27 is removed.

§§ 94.22 through 94.26 [Redesignated]

25. Sections 94.22 through 94.26 are redesignated as §§ 94.28 through 94.32, respectively.

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

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

(1) 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 United States Customs and Border Protection official.

§ 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 that indicates the BSE risk classification of the exporting region and 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.

(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) 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:

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

(3) 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;

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

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

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

(b) The commodities listed in paragraph (a) of this section 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.

(c) *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.

(d) *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 (d) 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 (e) of this section are met:

(a) The person moving the articles 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/*).

(b) 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.

(c) 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:

(i) United States Veterinary Permit for Importation and Transportation of

Controlled Materials and Organisms and Vectors permit number;

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

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

(iv) Mode of transportation; and

(v) Serial numbers of the sealed containers.

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

(e) The commodities must be eligible to enter the United States in accordance with §§ 94.18 through 94.26 and must be accompanied by the certification required by that section. Additionally, the following conditions must be met:

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

(ii) 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;

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

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

27. 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.

28. Section 95.1 is amended by removing the definition of *specified risk materials (SRMs),* and 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.

* * * * *

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.

* * * * *

29. Section 95.4 is revised to read as follows:

§ 95.4 Restrictions due to bovine spongiform encephalopathy 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 (d)(1) through (d)(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(d) of this subchapter.

§§ 95.5 through 95.30 [Redesignated]

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

31. Sections 95.5 through 95.15 are added to read as follows:

§ 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 paragraph (a) and (b) of this section are met:

(a) The exporting region is a region of negligible risk for BSE, or the product is derived from ruminants born and raised in a region of negligible risk for BSE, or it has been demonstrated that the product has not been commingled or contaminated with ruminant meat-and-bone meal or greaves. Additionally, if either paragraph (a)(1) or (a)(2) of this section applies, 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:

(1) The product is exported to the United States from a region of negligible risk for BSE in which there has been at least one indigenous case of BSE; or

(2) The product is derived from ruminants that were born or raised in a region of negligible risk for BSE in

which there has been at least one indigenous case of BSE.

(b) 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 that the exporting region is a region of negligible risk for BSE and that the requirements of paragraph (a) of this section, as applicable, have been met.

§ 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.

§ 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 (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 that indicates the BSE risk classification of the exporting region and 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.

(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.

§ 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 part.

(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.

§ 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.

§ 95.10 Dicalcium phosphate derived from bovines.

(a) The importation of dicalcium phosphate derived from bovines (other than dicalcium phosphate with no trace of protein or fat) is prohibited unless:

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

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

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

(c) 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.

(d) 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) or (c) of this section, as applicable, have been met.

(e) 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.

§ 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.

§ 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 originates from a region classified by APHIS as a region of negligible risk for BSE.

(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/*).

§ 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 indicates the APHIS BSE risk classification of the exporting region and states that the 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/*).

§ 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 (d) 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 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/*).

(b) 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.

(c) 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:

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

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

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

(iv) Mode of transportation; and

(v) Serial numbers of the sealed containers.

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

(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:

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

(ii) 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

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

§ 95.17 [Amended]

32. 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]

33. 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 1 to paragraph (c) is amended by removing the citation ''§ 95.5'' and adding the citation ''§ 95.16'' in its place.

§ 95.19 [Amended]

34. 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]

35. 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 1 to paragraph (c) is amended by removing the citation ''§ 95.5'' and adding the citation ''§ 95.16'' in its place.

§ 95.21 [Amended]

36. 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]

37. 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]

38. 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]

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

§ 95.27 [Amended]

40. 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.

§ 95.29 [Amended]

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

§ 95.32 [Amended]

42. 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]

43. 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]

44. 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.

45. 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.

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

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

46. 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.

47. 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 of this part 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.

* * * * *

48. 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

49. 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.

50. 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.

* * * * *

51. 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 8th day of March 2012.

Edward Avalos,

Under Secretary for Marketing and Regulatory Programs.

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