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**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

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

**[Docket No. APHIS-2009-0095]**

**RIN 0579-AD10**

**Importation of Sheep, Goats, and Certain Other Ruminants**

**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 sheep, goats, and certain other non-bovine ruminants, and products derived from sheep and goats, with regard to transmissible spongiform encephalopathies such as bovine spongiform encephalopathy (BSE) and scrapie. We are proposing to remove BSE-related import restrictions on sheep and goats and most of their products, and to add import restrictions related to transmissible spongiform encephalopathies for certain wild, zoological, or other non-bovine ruminant species. The conditions we are proposing for the importation of specified commodities are based on internationally accepted scientific literature and will in general align our regulations with guidelines set out in the World Organization for Animal Health's Terrestrial Animal Health Code.

**DATES:** We will consider all comments that we receive on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0095>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2009-0095, 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-2009-0095> 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) 799-7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** For information concerning live animals, contact Dr. Oriana Beemer, Veterinary Medical Officer, Animal Permitting and Negotiating Services, National Import Export Services, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231; (301) 851-3300.

For information regarding ruminant products and for other information regarding this proposed rule, contact Dr. Christopher Robinson, Director, Animal Products Permitting and Negotiation Services, National Import Export Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 851-3300.

## **SUPPLEMENTARY INFORMATION:**

### I. Executive Summary

#### Need for the Regulatory Action

The current bovine spongiform encephalopathy (BSE)-related import regulations prohibit the importation of most live sheep and goats and most sheep and goat products from countries that are considered a risk for BSE. The current regulations allow the importation of non-pregnant slaughter or feeder sheep that are under 12 months old from Canada, certain products from sheep and goats, and sheep and goat semen. The conditions we are proposing for the importation of sheep and goats and their products are based on internationally accepted scientific literature and are consistent with World Organization for Animal Health (OIE) guidelines. We are proposing 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 will continue to guard against the introduction of transmissible spongiform encephalopathies (TSEs) such as BSE and scrapie into the United States, while allowing the importation of additional animals and animal products into this country.

#### Legal Authority for the Regulatory Action

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

## Summary of the Major Provisions of the Regulatory Action

We are proposing to remove BSE-related import restrictions on sheep and goats and the products derived from them. We are also proposing to add import restrictions related to TSEs for certain wild, zoological, or other non-bovine ruminant species. The existing BSE-related import restrictions also function as protection against the introduction of other TSEs, such as scrapie. While the BSE-related restrictions are no longer warranted for non-bovine ruminant products, it is necessary for us to add appropriate safeguards against the introduction of other TSEs for non-bovine ruminants.

### Costs and Benefits

This proposed rule's impact would stem from its effect on U.S. imports of the affected commodities. Assuming an increase in imports of 1,966 metric tons (MT) in a net trade welfare model, we project a decrease in wholesale prices of a little more than 1 percent and a fall in domestic production of 615 MT. We estimate consumption would increase by 1,351 MT. As a result, producer welfare would decline by about \$6.3 million and consumer welfare would increase by about \$14.4 million, yielding an annual net welfare benefit of about \$8.1 million. USDA does not have an estimate of the costs or benefits of the change in import restrictions for certain wild, zoological, or other non-bovine ruminant species, and we request comment on such an estimate.

## II. Background

In order to guard against the introduction and spread of livestock pests and diseases, APHIS regulates the importation of animals and animal products into the United States. The regulations in 9 CFR parts 92, 93, 94, 95, 96, and 98 (referred to below as the regulations) govern the importation of certain animals, meat, other animal products and byproducts, hay and

straw, embryos, and semen into the United States in order to prevent the introduction of various livestock pests and diseases.

Two of the diseases addressed by the current regulations regarding sheep and goats are scrapie and BSE. Scrapie and BSE belong to the family of diseases known as TSEs. In addition to scrapie and BSE, TSEs include, among other diseases, chronic wasting disease in deer and elk, and variant Creutzfeldt-Jakob disease in humans.

The current BSE-related import regulations restrict the importation of most live ruminants and ruminant-derived products and by-products. The regulations in § 94.18 provide for the importation of meat, meat products, and other edible products derived from bovines (Bos indicus, Bos taurus and Bison bison). The current regulations in § 93.419 allow only the importation of sheep and goats for immediate slaughter or restricted feeding for slaughter from Canada, provided that the sheep and goats are under 12 months of age and are not pregnant.

In a final rule published on December 4, 2013 (78 FR 72979-73008, Docket No. APHIS-2008-0010), we amended the BSE-related import requirements for B. indicus, B. taurus, B. bison, and removed the BSE-related import restrictions on camelids and cervids from any region.<sup>1</sup> However, that rule did not address BSE-related restrictions on domesticated sheep and goats or other non-bovine ruminant species. We believe that further refinement of the regulations is in order given the latest scientific information regarding BSE and scrapie. In this proposed rule, therefore, we are proposing to amend the regulations regarding BSE and scrapie as they apply to the importation of sheep and goats and products derived from sheep and goats, as well as to other ruminant species that are not bovines, cervids, and camelids. We first discuss the changes we are proposing regarding BSE and sheep and goats, then the changes we are

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<sup>1</sup> To view the rule, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0010>.

proposing regarding scrapie. Lastly, we address the changes we are proposing for other non-bovine ruminants with respect to TSEs generally.

In addition to these changes, we are also proposing to establish provisions that would allow the importation, in specific cases, of other ruminants that would not otherwise be eligible for importation due to TSEs, if the Administrator determines that the disease risk posed by the animals can be adequately mitigated through pre-entry and post-entry mitigation measures. Conversely, we are proposing that certain ruminants whose importation is not currently restricted due to TSEs would, in specific cases, be subject to specified pre-entry and post-entry requirements, if the Administrator determines that the measures are necessary to guard against the transmission of TSEs to livestock in the United States. These provisions are discussed in more detail in this document under the heading “Zoological Ruminants.”

#### Nature of BSE

As noted, BSE belongs to the family of diseases known as TSEs. All TSEs affect the central nervous systems of the 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.

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 the primary route of transmission is through ingestion of feed that has been contaminated with a sufficient amount of tissue from an infected animal. This route of transmission can be prevented by excluding potentially contaminated materials from ruminant feed.

#### Current Regulations Regarding BSE

The protective measures APHIS has taken against BSE 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 was known to exist, and those regions that presented an undue risk of introducing BSE into the United States because their import requirements were less restrictive than those that would be acceptable for import into the United States and/or because the regions had inadequate surveillance. In a January 2005 final rule (70 FR 460-553, Docket No. 03-080-3), 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. The December 4, 2013, final rule amended the BSE regulations to change the categories of regions in which BSE is known to exist. Formerly, we had used the following classifications: Regions of undue risk for BSE and BSE minimal-risk regions. In the final rule, we adopted the system used by the OIE of classifying areas as being either of negligible risk, controlled risk, or undetermined risk for BSE. Whether live bovines and bovine-derived products are eligible for importation into the United States, and under what conditions, is in many cases determined by the BSE category of the region from which the animal or product originates.

The prohibitions on the importation of animals, meat, and other animal products into the United States are set forth in 9 CFR parts 93, 94, 95, and 96. Section 93.401 prohibits the importation of any non-bovine ruminant that has been in a region listed in § 94.24(a). Section 94.24 restricts the importation of meat and edible products from ovines and caprines due to BSE. Section 94.25 restricts the importation from Canada of meat and edible products other than gelatin from sheep and goats, and § 94.26 provides for the importation of gelatin derived from horses or swine, or from sheep and goats that have not been in a region restricted because of BSE. Section 94.27 provides for the transit shipment of 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. Section 96.2 prohibits the importation of casings, except stomach casings, from ovines or caprines that originated in or were processed in any region listed in § 95.4(a)(4), unless certain conditions are met.

When the BSE regulations were codified in 1991 (56 FR 19794-19796, Docket No. 90-252), they applied to all ruminants. Over the past two decades, however, extensive research has been conducted regarding BSE. Based on the information now available, it does not appear to be necessary to continue to prohibit or restrict the importation of sheep and goats and their products with regard to BSE, except in certain limited situations. Therefore, we are proposing to amend the BSE regulations to remove the current prohibitions and restrictions regarding such commodities, except as noted. We discuss below the scientific literature regarding BSE and sheep and goats and the rationale for our proposed changes to the regulations.

Experiments dating back to the 1990s have demonstrated the ability of BSE to be transmitted to domestic sheep and goats via oral challenge and other routes of inoculation, and, in one study, for inoculated sheep to transmit BSE laterally (Foster, Hope et al. 1993; Foster,

Parnham et al. 2001; Foster, Parnham et al. 2001; Jeffrey, Ryder et al. 2001; Bellworthy, Hawkins et al. 2005; Andreoletti, Morel et al. 2006; Bellworthy, Dexter et al. 2008; Konold, Bone et al. 2008). However, information on BSE transmission in sheep and goats that were not experimentally inoculated or exposed to experimentally inoculated sheep or goats is extremely limited. There have been only two retroactively diagnosed cases of naturally occurring BSE in goats. In these two cases there was no evidence of lateral spread.

In 2005, BSE in a goat was confirmed at the Community Reference Laboratory in Weybridge, United Kingdom. The goat was slaughtered in 2002 in France and was tested as part of a slaughter surveillance program. An epidemiologic investigation conducted at the time of the initial TSE diagnosis did not detect any additional cases in the herd. The goat and its entire herd were destroyed at the time the initial test results were received, and no additional TSE cases were detected. It is not known how the goat acquired BSE; however, because the goat was born prior to the enactment of a ruminant-to-ruminant feed ban, it is possible that consumption of infected ruminant protein was the route of inoculation (Eloit, Adjou et al. 2005; ProMED 2005).

A second naturally occurring case of BSE in a goat was confirmed in 2011 in the United Kingdom (U.K.) in a goat born in 1990 and evaluated as part of a retrospective study. This goat was also born prior to the enactment of strict BSE control measures in feed (Spiropoulos, Lockey, et al. 2011). There have been no other naturally occurring cases of BSE reported in sheep or goats. Based on the absence of detection of BSE in sheep and goats born after the effective implementation of feed bans, APHIS believes it is unlikely that BSE is being laterally transmitted within domestic sheep or goat populations.

Because of concerns that BSE may be present in sheep and goats, some countries have embarked on testing programs to detect BSE in these animals. Due to the clinical similarities

between BSE and scrapie, surveillance programs for BSE in sheep and goats often target animals that have tested positive to TSE screening tests (sometimes using archived samples of animals that were presumed to have had scrapie) in order to increase the likelihood of finding a BSE-positive animal. Because the United Kingdom was the epicenter of the bovine BSE epizootic in the 1990s, most experts believe that if BSE were to exist within domestic sheep or goat populations, it would most likely occur and be detectable in the United Kingdom. To date, studies conducted in the United Kingdom have not detected any cases of BSE in domestic sheep (Gravenor, Ryder et al. 2003; Stack, Jeffrey et al. 2006) and only one case in a goat (Spiropoulos, Lockey, et al. 2011), despite the testing of thousands of animals, and have concluded that BSE does not appear to be amplifying through lateral transmission in these populations.

Additional estimates show that if BSE were present in U.K. domestic sheep populations, it would exist at an extremely low level. Two recent studies evaluated the potential prevalence of BSE in the domestic sheep population of the United Kingdom. In order to maximize efficiency, both studies used historical samples in which a TSE, presumably scrapie, had been detected. Additional testing was performed on these samples to determine if BSE, rather than scrapie, was responsible for the initial positive results. Neither study identified any cases of BSE, but both were able to determine that the highest likely prevalence of BSE in the U.K. sheep population was extremely low (Gravenor, Ryder et al. 2003; Stack, Jeffrey et al. 2006).

Since 2005, the European Commission has required that each index case of a TSE in a flock receive additional testing to determine if BSE is the diagnosis. Estimates of the likely prevalence of BSE in sheep have been made based on data collected during 2005 and 2006. With over 1.5 million sheep tested, it was calculated with 95 percent confidence that there were

at most 0.3-0.5 cases (depending on the model used) of BSE per 10,000 healthy slaughter sheep in the European Union (EU) countries at highest risk for BSE (United Kingdom, Ireland, France, and Portugal) (EFSA 2007). No cases of BSE in sheep have been reported since this study was published, so we would expect the risk to be lower if the calculation was repeated to include data from subsequent years.

Based on the evidence discussed above, we believe it is not warranted to continue to prohibit or restrict trade of live sheep and goats and the products of sheep and goats due to BSE, other than processed animal protein. We continue to consider processed animal protein containing materials derived from sheep and goats to be a BSE risk due to the possibility that such material has been commingled with bovine materials, and because one significant use of these materials is in animal feed. For these reasons, we would continue to restrict the importation of these commodities.

The changes we are proposing with regard to sheep and goats and BSE are consistent with the approach taken by the OIE. 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 are published in the OIE Terrestrial Animal Health Code (Code). 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 to amend the OIE guidelines for BSE based on increased scientific evidence regarding the disease. Current OIE recommendations regarding BSE in ruminants do not include any BSE-related measures for sheep and goats other than the general requirements applied to all ruminant meat and bone meal (processed animal proteins).

## Importation of Live Ruminants

In this proposed rule, we would amend the regulations to remove most of the current BSE provisions regarding sheep and goats. Below, we identify specific sections and paragraphs in the regulations from which regulatory text relating to BSE and sheep and goats would be removed or revised.

§ 93.400 Definitions: We would remove the definition of suspect for a transmissible spongiform encephalopathy because this term would no longer appear in the regulations. We would also revise the definitions for designated feedlot and flock. The definition of designated feedlot is being changed to reference scrapie-related restrictions rather than BSE-related restrictions. The current definition of flock is being expanded to include goats as well as sheep. We would add definitions for certified status, classical scrapie, country mark, flock of birth, flock of residence, goat, killed and completely destroyed, non-classical scrapie, sheep, transmissible spongiform encephalopathies (TSEs), and TSE-affected sheep or goat, since these terms are currently not defined.

Specifically, we propose to define certified status as “a flock that has met the requirements equivalent to the Export Certified status of the U.S. Scrapie Flock Certification Program while participating in a program under the supervision of the national veterinary authority of the region of origin, as determined by an evaluation conducted by APHIS of the program.” In the U.S. Scrapie Flock Certification Program, Export Certified flocks receive a high level of monitoring, including annual inspections and inspection of all cull animals, and are subject to official identification and recordkeeping requirements, among other things. Export Certified flocks in the United States are considered scrapie free. These requirements are consistent with OIE recommendations in Article 14.8.5 of the OIE Terrestrial Health Code.

We would define classical scrapie as “any form of scrapie that the Administrator has determined poses a significant risk of natural transmission” and non-classical scrapie as “any form of scrapie that the Administrator has determined poses a low risk of natural transmission.” We are proposing these definitions to distinguish between strains of the disease that pose a significant risk of natural transmission and thus present a significant livestock disease risk, and those strains that pose a low risk of natural transmission and do not present a significant livestock disease risk.

We would define country mark as “a permanent mark approved by the Administrator for identifying a sheep or goat to its country of origin.” We are proposing this definition to distinguish this mark from other forms of identification, such as eartags or backtags, that might be used on an animal. We are proposing to require the use of country marks for sheep and goats because this permanent identification allows APHIS to trace an animal back to the country of origin in the event that the animal shows symptoms of a TSE.

We would define flock of birth as “the flock into which a sheep or goat is born” and flock of residence as “the flock (1) within which an individual sheep or goat was born, raised, and resided until exported to the United States; or (2) in which the sheep or goat resided for breeding purposes for 60 days or more until exported to the United States; or (3) in which sheep and goats for export were assembled for export to the United States and maintained for at least 60 days immediately prior to export, without any addition of animals or contact with animals other than through birth, on a single premises, or on more than one premises under the same ownership and between which unrestricted movement occurred.” We are proposing to add these two definitions to clarify to which flocks certain requirements pertain.

We would define goat as “any animal of the genus Capra” and sheep as “any animal of the genus Ovis” to clarify that the requirements for sheep and goats apply not only to domesticated sheep and goats, but also to wild animals of those genera which are also susceptible to scrapie.

We are proposing to define killed and completely destroyed as “killed, or maintained under quarantine in a manner that will prevent disease spread until the animal is no longer living; and the remains have been disposed of in a way that prevents disease spread” to clarify that sheep and goats known to be affected by TSEs are not to enter slaughter channels.

We are proposing to define transmissible spongiform encephalopathies (TSEs) as “A family of progressive and generally fatal neurodegenerative disorders thought to be caused by abnormal proteins, called prions, that typically produce characteristic microscopic changes, including but not limited to non-inflammatory neuronal loss, giving a spongiform appearance to tissues in the brains and central nervous systems of affected animals.” The Administrator may make a determination that a disease meeting these general criteria is not a TSE of whose introduction or dissemination would cause adverse animal health or disease concerns and that animals affected by it would not be subject to the regulations if the disease presents a low risk of transmission.

We are proposing to define TSE-affected sheep or goat as “A sheep or goat suspected or known by the national veterinary authority of the region of origin to be infected with a transmissible spongiform encephalopathy prior to the disposal of the animal” in order to clarify to which animals the provisions would apply.

§ 93.404 Import Permits for Ruminants: We are proposing to add a new paragraph (a)(2) to this section to specify additional information that an importer would have to submit with the

application for an import permit for sheep and goats. Specifically, we would require that, for sheep and goats imported for immediate slaughter or restricted feeding for slaughter, the slaughter establishment to which the animals will be imported, or the designated feedlot in which the animals will be maintained until moved to slaughter be specified. We need this information to validate that the animals are slaughtered and to rapidly locate the animals should the country of origin report a disease outbreak. It will also clarify that these animals are in, and are not to be removed from, slaughter channels.

For sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter, we would require that the importer provide the flock identification number if imported to a flock, and the premises or location identification number of the flock or other premises to which the animals are imported, as listed in the Scrapie National Database. If the sheep and goats originate in regions not free of classical scrapie, the importer would have to provide documentation showing that the animals have reached and maintained certified status in a scrapie flock certification program that has been evaluated and approved by the Administrator. The documentation would have to specify the address, or other means of identification, of the premises and flock of birth, and any other flocks in which the animal has resided. We need this information to ensure that a continuous previous health history is available for animals that may be considered for importation into the United States.

We are also proposing to add a new paragraph (a)(5) to this section to address mitigation measures to allow the importation of zoological ruminants. This change is discussed below under the heading “Zoological Ruminants.”

Last, we would add a new paragraph (a)(6) which would provide for permits to be issued by the Administrator for sheep of certain classical scrapie-resistant genotypes, as determined by

testing at the National Veterinary Services Laboratories (NVSL) or another laboratory approved by the Administrator. This would reduce import restrictions on animals found to be genetically resistant to scrapie.

Current paragraphs (a)(2), (a)(3), and (a)(4) would be redesignated as paragraphs (a)(3), (a)(4) and (a)(7), respectively.

§ 93.405 Health Certificate for Ruminants: Paragraph (a)(4) describes the information that must be included on a health certificate accompanying sheep or goats from Canada. We are proposing to remove this paragraph because paragraph (b), which contains additional requirements for health certificates for goats, would be revised to incorporate requirements for health certificates for sheep. These additional requirements would include some of the information currently required under paragraph (a)(4), because that information is relevant to animal diseases other than BSE. Paragraph (c), which currently contains additional requirements for health certificates for sheep, would be removed, and paragraph (d) would be redesignated as paragraph (c).

§ 93.419 Sheep and goats from Canada: This section would be removed and reserved. Provisions for the importation of sheep and goats from Canada would be moved to § 93.435.

§ 93.420 Ruminants from Canada for immediate slaughter other than sheep and goats: The reference in paragraph (a) to the provisions regarding sheep and goats for immediate slaughter in § 93.419 would be replaced by a reference to the provisions in § 93.435.

§ 93.424 Import permits and applications for inspection of ruminants (from Mexico): Paragraphs (a)(1) and (2) would be removed, and paragraph (a) would be revised to state that sheep and goats for immediate slaughter do not need to be accompanied by an import permit if entering the United States through a port on the U.S./Mexico border. Currently the regulations

provide that wethers (castrated male sheep or goats) do not need to be accompanied by an import permit if they enter the United States from Mexico through land border ports, even if they are not being imported for immediate slaughter. We are proposing to remove this exemption because we need the information from the import permit to conduct a traceback investigation in the event of a disease outbreak.

§ 93.428 Sheep and goats and wild ruminants from Mexico: This section would be revised to refer to the scrapie provisions in § 93.435 which would also apply to sheep and goats from Mexico.

§ 93.435 Sheep and goats: This section would be revised to contain provisions for importing sheep and goats from anywhere in the world. The provisions for sheep and goats imported for immediate slaughter and restricted feeding for slaughter would be similar to the existing requirements for sheep and goats imported for those purposes from Canada, currently contained in § 93.419. The requirements for importing sheep and goats for other purposes, currently contained in § 93.435, would be updated to make them in general consistent with international standards, by limiting imports for these purposes to animals from classical scrapie-free countries or flocks, except as permitted by the Administrator under paragraph (a)(5) of § 93.404. This would allow for the importation of animals that are very low risk due to their genotype or other factors. We would also revise this section to establish a notice-based approach for recognizing regions as free of classical scrapie. The regulations would provide the Web address and a contact for requesting copies of the list of classical scrapie-free regions by mail, fax, or email. The regulations also would explain APHIS' process for adding or removing a region to or from the list.

This proposed action would allow more timely changes to the list than if we had to do it through rulemaking, as we do now. APHIS considers a disease to exist in a region when we receive reports of an outbreak of the disease in the region from veterinary officials of the national government of the region and/or the OIE, or from another source that the Administrator determines to be reliable, e.g., APHIS inspectors based in foreign countries.

As it is now, when APHIS determines that a disease is present in a region and presents a potential threat to animal health in the United States, we would take immediate action to restrict imports from that region. We would no longer need to follow that action with an interim rule in the Federal Register to change text in the regulations. Instead, we would immediately list the region on the APHIS Web site and announce the listing through a notice, rather than a rule, in the Federal Register. The notice would provide an opportunity for public comment.

We would add a region to a list of regions we recognize as free of classical scrapie only after completing an evaluation and making it available for public comment. We would do this through a notice in the Federal Register. Following the close of the comment period, we would publish another notice responding to comments and announcing APHIS' decision. The criteria we are proposing for evaluating a region's classical scrapie disease status would be consistent with current scientific understanding, international standards, and 9 CFR part 92, "Importation of Animals and Animal Products: Procedures for Requesting Recognition of Regions." Additional details about the factors APHIS reviews to determine a region's status may be found on the APHIS Web site at [http://www.aphis.usda.gov/import\\_export/animals/reg\\_request.shtml](http://www.aphis.usda.gov/import_export/animals/reg_request.shtml).

#### Zoological Ruminants

Section 93.404 of the regulations contains provisions regarding permits for the importation of ruminants into the United States. With several exceptions, ruminants are not

eligible for importation if the importer has not first applied for and obtained an import permit from APHIS. Part 93 subpart D contains a number of provisions that specifically prohibit or restrict the importation of ruminants into the United States with regard to specified diseases, or that set forth risk mitigation measures that must be taken or agreed to before an import permit will be issued. Among the specific prohibitions and restrictions in current part 93 subpart D are those, discussed above, that prohibit the importation of live non-bovine ruminants from regions listed in § 94.24(a).

Currently, non-bovine ruminants other than sheep and goats from regions not listed in § 94.24(a) are not subject to any import restrictions with regard to BSE. We believe, however, that there is a certain category of ruminants that present enough of a potential risk of spreading TSEs that their importation should be prohibited unless certain risk mitigation measures are in place. This category of ruminants includes certain ruminants held in zoological facilities and certain wild ruminants. For the purposes of discussion, we will refer to such animals as zoological ruminants to distinguish them from domesticated sheep, goats, and bovines.

Scientific literature indicates that at least certain zoological ruminants are susceptible to TSEs caused by the BSE agent. In association with the BSE epidemic in domestic cattle in Europe, TSEs have been diagnosed in several species of zoo animals, all from the families Bovidae and Felidae. Sixteen cases of TSEs have been recorded from antelope in U.K. zoos including one nyala (Tragelaphus angasi), six eland (Taurotragus oryx), six greater kudu (Tragelaphus strepsiceros), one gemsbok (Oryx gazelle), one Arabian oryx (Oryx leucoryx), and one scimitar-horned oryx (Oryx dammah) (Travis and Miller 2003). The first recorded case was a nyala euthanized at a wildlife park in England in 1986, the same year that the first BSE cases in cattle were recognized (Wells, Scott et al. 1987; Jeffrey and Wells 1988). Reported cases of

TSEs in zoo bovids peaked around 1991, and no additional cases in zoo antelope have been reported since 1996 (Kirkwood 2000).

Several lines of evidence support the hypothesis that at least some, if not all, of the spongiform encephalopathy cases diagnosed in zoo bovids were caused by the BSE agent. First, the cases in zoos coincide geographically and temporally with the BSE epidemic in Great Britain. Second, epidemiologic investigations indicated that all affected animals, or the herds into which they were born or moved, could have been exposed to feeds containing ruminant-derived protein or other potentially contaminated material (Kirkwood and Cunningham 1994). Finally, comparable patterns of incubation periods and pathologic effects were seen in mice inoculated with brain tissue homogenate from the affected nyala, an affected kudu, and BSE-affected cattle (Jeffrey, Scott et al. 1992).

The greater kudu, a non-domestic African antelope, appears to be particularly susceptible to BSE. Six of eight kudu that died in a small herd at the London Zoo from 1989 through 1992 were diagnosed with spongiform encephalopathy (Kirkwood and Cunningham 1994). The disease is presumed to have been introduced to the kudu herd through feeds containing ruminant-derived protein around the time of the BSE epidemic in U.K. cattle. However, some of the affected kudu were born after the elimination of the potentially contaminated feed from the premises, and one case occurred in a kudu born at another zoo and introduced to the affected herd (Kirkwood, Cunningham et al. 1994). Because most of the affected kudu did not consume feed containing ruminant-derived protein, it was postulated that the disease may have spread naturally in the herd, either by transmission between individuals or through contamination of the environment (Kirkwood, Cunningham et al. 1993).

The epidemiology of the TSE cases in kudu contrasts with BSE in cattle in several respects. The attack rate in the London Zoo kudu herd is notably higher than the attack rate seen in BSE affected cattle herds. The pattern of disease in antelope also differs from cattle affected with BSE, characterized by a younger average age of onset and a shortened clinical course (Kirkwood and Cunningham 1999). Additionally, infectivity in greater kudu with TSE is distributed in a wider range of tissues than in cattle with BSE (Cunningham, Kirkwood et al. 2004).

Information about the infectivity of tissues from TSE-affected zoological ruminants is limited to studies of tissue from four London Zoo kudus with spongiform encephalopathy. Fifteen of 32 kudu tissue homogenates transmitted BSE to mice. Of these, fresh central nervous, lymphoreticular, and distal ileum tissue indicated moderate or high levels of spongiform encephalopathy infectivity. Traces of infectivity were demonstrated in kudu spleen, lung, skin, conjunctiva, and salivary gland (Cunningham, Kirkwood et al. 2004).

A wide range of species in zoological collections were probably exposed to BSE-contaminated feed; new cases in other captive zoological species may emerge, or it is possible that some species may carry and transmit the disease without showing clinical signs. The possibility of transmission of BSE-related encephalopathy between members, or from mother to offspring, within herds of zoological ruminants, as suspected with the London Zoo kudus, cannot be ruled out. Although there is currently no evidence that TSEs exist in free-living zoological ruminants (veterinary authorities in southern African countries conducting passive surveillance in wildlife have not encountered any clinical cases or histopathological lesions compatible with TSEs (Horn, Bobrow et al.), active surveillance has not been implemented in any region of the world for TSEs in antelope or free-living Caprinae.

Many of the non-domestic ruminants are endangered species. The scimitar-horned oryx, for example, is listed as “Extinct in the Wild” on the International Union for Conservation of Nature Red List (<http://www.iucnredlist.org/>), and 13 species of the Caprinae subfamily are listed as threatened on the Red List. In order to maintain genetic diversity in these very small populations, animals must be moved between zoological collections, both domestically and internationally (Shackleton 1997). Movement of animals may also be a goal of conservation programs seeking to reintroduce captive-bred endangered species into the wild. Both types of movement carry the risk of inadvertent introduction of infectious diseases that may have serious consequences for conservation efforts. The management of animal genetic resources must include a consideration of the potential risk of importing undetected prion diseases with rare breeding stock.

Although each of the cases to date of ruminant TSEs possibly connected to BSE in zoo animals was diagnosed in a region known to be affected with BSE, we believe that even zoological ruminants in regions not categorized as BSE-affected or as posing undue risk of BSE could be at risk for BSE-related TSEs, due to possible origin in a BSE-affected region or feeding with BSE-contaminated protein. Even in countries that have enforced a ban on the feeding of ruminant protein to domestic ruminants for an identifiable period of time, it can be difficult in some cases to determine when and if a country ceased feeding ruminant protein to zoo ruminants.

Because of the potential variety of practices in the feeding of zoo ruminants, as well as the potential that certain zoo ruminants may have originated in BSE-affected countries, we believe it is necessary to consider on a case-by-case basis the potential spongiform encephalopathy risk of zoological ruminants. As noted above, a ruminant may not be imported

into the United States unless the importer has first applied for and obtained a permit from APHIS for such importation. In the case of zoological ruminants, the Administrator will consider the disease risk of each animal and the ability of the receiving zoo to manage the risks before deciding whether to issue an import permit.

Paragraph (a)(3) of § 93.404 currently provides that an application for a permit to import ruminants may be denied due to, among other reasons, the lack of satisfactory information necessary to determine that the importation will not be likely to transmit any communicable disease to livestock or poultry of the United States.

Even with zoological ruminants that would otherwise be denied importation into the United States, however, we believe that, in most cases, adequate mitigation measures with respect to potential TSE risks can be taken to allow the animal to be safely imported into the United States. Although the precise measures APHIS considers necessary could vary on a case-by-case basis, such measures could include the following:

- That the animal be held at approved permanent post-entry quarantine facilities;
- That any movement of the animal out of or among such facilities occur only in accordance with a compliance agreement between APHIS and the owners of approved facilities; and
- That, upon the death of the animal, the APHIS Service Center Director be notified, and the carcass be tested for TSEs and be completely destroyed in a manner acceptable to the Administrator.

Any conditions for the importation of a zoological ruminant would be spelled out in the import permit for that animal. Any such conditions could also be applied to any progeny of the animal, as well to as any ruminants housed with either the animal or its progeny. In the event

that the conditions of importation of a zoological ruminant were applied to its progeny or contact animals, the Administrator could require that a zoo enter into a cooperative, compliance, or other agreement that sets out specific requirements for releasing the progeny or contact animals based on postmortem testing of the imported animal with negative results.

#### Ruminants from Regions Where BSE Exists

As noted above, the current regulations contain broad prohibitions and restrictions regarding the importation of non-bovine ruminants other than sheep and goats from regions listed in § 94.24(a). The prohibitions apply to zoological ruminants as well as to domesticated ruminants. However, the regionally based prohibitions do not address individual situations where a ruminant that would otherwise be denied entry from a region listed in § 94.24(a) could be safely entered into the United States, provided certain risk mitigation measures are taken.

Section 93.401 of the regulations contains general prohibitions on the importation of ruminants. We would amend paragraph (a) of this section by revising the second sentence to remove the reference to § 94.24(a). That section contains a list of regions in which BSE is known to exist, but is no longer needed since we have changed the way we recognize regions for BSE risk. We are proposing to amend the second sentence to read “Notwithstanding any other provision of this subpart, the importation of any ruminant that is not a bovine, camelid, cervid, sheep, or goat is prohibited.” This change would remove BSE restrictions on the importation of many non-bovine ruminants, but would continue to protect against the introduction of TSEs into the United States.

Currently § 93.401(a) also provides that the Administrator may, upon request in specific cases, allow ruminants or products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such

action will not endanger the livestock or poultry of the United States. Providing for the importation of specific animals in individual cases has great value for conservation efforts. In order to maintain genetic diversity in species with very small populations, animals must be moved between zoological collections, both domestically and internationally.

In the preceding section of this document, we discussed the type of mitigation measures that could be used to adequately mitigate TSE risk from zoo ruminants from regions other than those listed in § 94.24(a). We believe that the same types of mitigation measures can be employed to safely import zoological ruminants from regions listed in § 94.24(a).

In this document, therefore, we are proposing to add a new paragraph (a)(5) to the import permit provisions in § 93.404 to address such situations. The new paragraph would provide that, in specific cases, a permit may be issued for ruminants that would otherwise be prohibited importation due to TSEs pursuant to part 93 subpart D if the Administrator determines that the disease risk posed by the animals can be adequately mitigated through pre-entry or post-entry mitigation measures, or through combinations of such measures. Such measures would be specified in the permit. If it is determined prior to or after importation that any pre-entry or post-entry requirements were not met, or that the ruminants are affected with or have been exposed to TSEs, the ruminants, their progeny, and any other ruminants that have been housed with or exposed to the ruminants will be disposed of or otherwise handled as directed by the Administrator.

We would also provide that importers seeking a permit pursuant to the paragraph must send their request by postal mail to the Administrator, c/o National Import Export Services, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231, or make their request online via APHIS' electronic permitting system, by email or by fax. Information about using these

methods to request a permit can be found on the APHIS Web site at [http://www.aphis.usda.gov/animal\\_health/permits/](http://www.aphis.usda.gov/animal_health/permits/).

### Sheep and Goat Products

The regulations in 9 CFR parts 94, 95, and 96 prohibit or restrict the importation of certain animals and animal products, byproducts, and foreign animal casings into the United States to prevent the introduction of communicable diseases of livestock and poultry. We are also proposing to amend part 94, part 95, and part 96 of the regulations to remove the current BSE provisions regarding sheep and goats. In the following sections, we identify those CFR sections and paragraphs from which regulatory text relating to BSE and sheep and goats would be removed.

### Transit Shipment of Articles

The regulations in §§ 94.15, 94.27, and 95.15 currently provide requirements for the transit shipment of animal products and materials. Section 94.15 provides general requirements for the movement and handling of animal products and materials through the United States for immediate export. Section 94.27 provides requirements for transit shipment of meat, meat products, and other edible products derived from bovines, ovines, or caprines through air or ocean ports or by overland transport. Section 95.15 provides requirements for transit shipment of animal byproducts through air or ocean ports or by overland transport.

We are proposing to revise § 94.15 to consolidate the requirements for transit shipment of all these products into one section and to eliminate some BSE-related restrictions that are no longer warranted. The new requirements would be similar to those that already exist in § 94.15. Paragraphs (b) and (c) of § 94.15 would be redesignated as (c) and (d), respectively. The specific requirements for meat, meat products, and other edible products derived from bovines,

ovines, or caprines in § 94.27 would be removed because they are no longer warranted. Section 95.15 would also be removed.

#### Restrictions on the Importation of Meat and Edible Products Due to BSE

The regulations in § 94.24 restrict the importation of meat and edible products, including gelatin, from ovines and caprines due to BSE, those in § 94.25 restrict the importation from Canada of meat and edible products from ovines and caprines other than gelatin, and those in § 94.26 apply to gelatin derived from horses or swine or from ovines or caprines that have not been in a region restricted because of BSE. While there is no BSE risk associated with gelatin or meat and other edible products derived from sheep and goats, these restrictions also function as protection against the introduction of other TSEs, such as scrapie.

We are proposing to remove §§ 94.24 and 94.25. This will remove both the prohibition on the importation of meat and other edible products ovines and caprines from regions in which BSE is known to exist, and the requirement that meat and edible products from sheep and goats from Canada, other than gelatin, be derived only from animals less than 12 months of age. These restrictions were related to concerns about BSE risk and are no longer warranted since there is no scientific evidence that BSE is circulating in sheep or goats.

We are proposing to amend § 94.26 by removing the references to ovines and caprines that have not been in a region restricted because of BSE from the section heading and the regulatory text. In place of those references we would add a reference to non-bovine ruminants. Gelatin derived from non-bovine ruminants, like gelatin derived from horses and swine, does not present a risk for BSE since there is no scientific evidence that BSE is circulating in sheep or goats.

## Restrictions on Importation of Byproducts Derived from Ruminants Due to BSE

Part 95 of the regulations prohibits or restricts the importation of products other than meat and other edible products to prevent the introduction of certain animal diseases. We are proposing to amend § 95.1 by removing the definitions for positive for a transmissible spongiform encephalopathy and suspect for a transmissible spongiform encephalopathy because those terms no longer appear in the regulations.

Section 95.4 contains restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy. We are proposing to amend this section first by revising the section heading to remove the exception for certain tallow derivatives. We would also revise paragraph (b)(1) to remove the exception for tallow derivatives from that paragraph. We are making these changes in order to be consistent with our requirements for bovine-derived tallow derivatives, which are subject to restrictions set out in § 95.9.

Paragraph (a) contains a list of regions in which BSE is known to exist. We would revise the paragraph to remove this list, which is no longer needed since we have changed the way we recognize regions for BSE risk.

In paragraph (c), we would remove the reference to paragraph (a)(4) from paragraph (c)(1)(iv), and remove paragraphs (c)(2) and (c)(3). These revisions would remove BSE-related restrictions from these products when derived from sheep and goats. We would also amend paragraphs (c)(1)(ii) and (iv) to add the words “and the material is not ineligible for importation under the conditions of § 95.5” after the words “cervids and camelids” and “ovines and caprines,” respectively. These would not be new requirements; the regulations in § 95.5 have always applied to products derived from all ruminant species, due to concerns about

commingling or cross-contamination. However, this change would clarify that the restrictions in that section continue to apply to products derived from cervids, camelids, ovines, and caprines. Paragraphs (c)(4) through (c)(8) would be redesignated as paragraphs (c)(2) through (c)(6), respectively.

In newly redesignated paragraph (c)(3), we would amend the first sentence to remove the requirement that facilities that process or handle any material derived from mammals be inspected at least annually for compliance with the provisions of this section, either by a representative of the government agency responsible for animal health in the region, or by APHIS. Instead, we would require only facilities that process or handle processed animal protein be inspected at least annually. The rendering process used to make processed animal protein creates a material that cannot be differentiated by species without a polymerase chain reaction test, and much rendering is performed involving multiple species. As a result, there is a risk of cross-contamination with processed animal protein that does not exist with the other products. For this reason we would continue to require inspections for facilities that process or handle processed animal proteins.

Paragraphs (d) and (e) contain restrictions on serum, serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines and caprines due to BSE. We are proposing to remove both of these paragraphs because BSE-related restrictions on these products are no longer warranted. These products present a risk of introducing other diseases, however, and would continue to be 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 animal diseases into the United States.

Paragraph (g) contains restrictions on offal derived from ovines and caprines. These restrictions are no longer warranted and paragraph (g) would be removed.

Section 95.40 contains additional certification requirements for certain materials derived from sheep and goats, including processed animal protein, tankage, offal, glands and unprocessed fat tissue, and derivatives of those products. These additional certification requirements were established due to BSE concerns and are no longer warranted; therefore, we are proposing to remove § 95.40.

#### Restrictions on the Importation of Foreign Animal Casings

Part 96 of the current regulations includes provisions regarding the importation of animal casings into the United States. The regulations in § 96.2 prohibit the importation of ruminant casings into the United States to prevent the introduction of BSE. We would remove the restrictions on casings derived from sheep and goats by removing paragraph (b)(1), which pertains to casings derived from sheep slaughtered in Canada. We would also redesignate paragraph (b)(2) as (b)(1).

#### Sheep and Goat Germ Plasm

The regulations in 9 CFR part 98 govern the importation into the United States of germ plasm (embryos and semen), including germ plasm from sheep and goats. Subpart A sets forth requirements for ruminant and swine embryos from regions free of rinderpest and foot-and-mouth disease (FMD), and for embryos of horses and asses. Subpart B sets forth requirements for ruminant and swine embryos from regions where rinderpest and FMD exist. Subpart C sets forth the requirements for the importation of animal semen from species regulated by APHIS.

Currently, the regulations in § 98.10a provide that embryos from sheep in regions other than Australia, Canada, and New Zealand may be imported only if the embryos are transferred to

females in a flock that participates in the Voluntary Scrapie Flock Certification Program (9 CFR part 54, subpart B) and qualifies as a “Certified” flock, or:

- The embryos are transferred to females in a flock that participates in the Voluntary Scrapie Flock Certification Program and the flock owner has agreed, in writing, to maintain the flock, and all first generation (F1) progeny resulting from the embryos in accordance with all requirements of the Voluntary Scrapie Flock Certification Program; and
- The importer provides the Voluntary Scrapie Flock Certification Program identification number as part of the application for an import permit; and
- The embryos are the progeny of a dam and sire that are part of flocks in the region of origin that participate in a program that has been determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, and those flocks have been determined to be at a level equivalent to “Certified.”

In addition, the flock to which the embryos are transferred must also be monitored for scrapie until the flock, and all first generation progeny resulting from the embryos qualifies as a “Certified” flock.

Because sheep and goat embryos and oocytes present similar disease risks, those risks can be addressed by the same mitigations, and also because we anticipate that use of oocytes will increase as reproductive technology continues to improve, we are proposing to add provisions for goat embryos and both sheep and goat oocytes to the regulations in § 98.10a. Specifically, we would revise the section heading to read “Sheep and goat embryos and oocytes.” We would also add a definition of oocyte to read “the first and second maturation stages of a female

reproductive cell prior to fertilization” to § 98.2 of the regulations. This definition is consistent with international standards.

We are proposing to allow the importation of in vivo-derived sheep and goat embryos and oocytes with the requirement that, if these embryos and oocytes are collected from donors in, or originating from, regions not free of classical scrapie, the health certificate required under § 98.5 must include additional declarations stating that the embryos or oocytes were collected, processed, and stored in accordance with the requirements in § 98.3, and, for in vivo-derived sheep embryos only, that the embryo is of either of the scrapie-resistant genotypes, AARR or AAQR, based on official testing of the parents or the embryo. The testing may be performed at the NVSL or at another laboratory approved by the Administrator.

The certificate that would accompany sheep embryos that are not of either of these genotypes, sheep embryos that are in vitro-derived or processed, and all goat embryos, would also have to include statements that in the region where the embryos originate:

- TSEs of sheep and goats are compulsorily notifiable;
- A classical scrapie awareness, surveillance, monitoring, and control system is in place;
- TSE-affected sheep and goats are killed and completely destroyed; and
- The feeding of meat-and-bone meal of ruminant origin has been banned and effectively enforced in the whole country.

The certificate would also have to state that the donor animals:

- Have been kept since birth in flocks in which no case of classical scrapie had been confirmed during their residency;

- Are permanently identified to enable traceback to their flock of birth or herd of origin, and the identification is recorded on the certificate accompanying the embryos and linked to the embryo container identification;
- Showed no clinical sign of classical scrapie at the time of embryo or oocyte collection; and
- Have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy.

We are adding these certification requirements for embryo genotypes that are not scrapie resistant, but which originate from regions not considered by APHIS as free of classical scrapie, to ensure that mitigations are in place to detect classical scrapie if it is present in sheep or goat populations.

We are also proposing to remove the existing requirement that sheep embryos from regions other than Australia, New Zealand, or Canada be transferred only to flocks in the Voluntary Scrapie Flock Certification program (SFCP). Enrollment in this program requires an annual inspection with inventory reconciliation and submission of tissues from certain animals for scrapie testing. We are making this change because the scientific literature demonstrates that embryos are low risk for scrapie transmission. APHIS has determined that requiring all F1 offspring to be maintained in an SFCP flock is unnecessary as well as overly burdensome on importers.

Instead, we would require that sheep and goat embryos or oocytes from regions that are not free of classical scrapie be imported only for transfer to females in flocks listed in the National Scrapie Database, or to an APHIS-approved storage facility where they may be kept and later transferred to recipient females in a flock that is listed in the National Scrapie Database.

We would also allow imported embryos or oocytes that are not otherwise restricted by the conditions of an import permit to be transferred from a listed flock to any other listed flock with written notification to the responsible APHIS Veterinary Services (VS) National Import Export Services (NIES) Service Center. To be listed in the National Scrapie Database, a flock owner must contact the local VS Surveillance, Preparedness and Response (SPRS) field office or a cooperating State Veterinarian's office and request to be listed; and provide the location of the flock and the owner's contact information. The VS SPRS field office or State Veterinarian's Office will enter the information in the database, and will issue the flock identification and the premises identification number that are required to be submitted on the permit application. To find the nearest VS NIES Service Center or SPRS field office, contact the State or Territory Point of Contact (POC). A list of POCs can be found on the APHIS Web site at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/contact-us>.

Finally, we would require the importer, owner of a recipient flock, or the owner of an APHIS-approved embryo or oocyte storage facility to maintain records of the disposition (including destruction) of imported or stored embryos or oocytes for 5 years after the embryo or oocyte is transferred or destroyed. These records would have to be made available during normal business hours to APHIS representatives on request for review and copying. This recordkeeping requirement is consistent with the recordkeeping requirements for imported semen that already exist, and would allow us to conduct traceback investigations in the event of a disease introduction.

The regulations in § 98.3(h) currently require that ruminant and swine embryos have an intact zona pellucida, which effectively prohibits the importation of in vitro-derived and processed embryos except as provided under § 98.10. We intend to continue to allow such

importations on a case-by-case basis, if the Administrator determines that any disease risk posed by the embryos can be adequately mitigated through pre-entry or post-entry mitigation measures, or through combinations of such measures.

The regulations in 98.13 provide requirements for import permits for ruminant and swine embryos from regions where rinderpest or FMD exist. We are proposing to add a new paragraph (c) to this section specifying that applications for a permit to import sheep and goat embryos and oocytes must include the flock identification number of the receiving flock and the premises or location identification number assigned in the APHIS National Scrapie Database; or, in the case of embryos or oocytes moving to a storage facility, the premises or location identification number must be included. We are proposing this change to ensure that the permit requirements for sheep and goat embryos and oocytes from regions where rinderpest or FMD exist are consistent with the requirements for sheep and goat embryos and oocytes from regions that are free of those diseases.

The regulations in § 98.15 set forth the requirements for ruminant and swine embryos from regions where foot-and-mouth disease or rinderpest exist. Currently, § 98.15(a)(1) and (2) require that, for ruminants, no case of BSE (among other diseases) occurred (1) during the year before collection in the embryo collection unit or in any herd in which the donor dam was present, or (2) in or within 5 kilometers of the embryo collection unit, or in any herd in which the donor dam was present. We are proposing to remove these requirements because we believe the proposed requirements for sheep and goat embryos in § 98.10a will provide adequate protection against a TSE introduction via embryo or oocyte transfer.

Section 98.15(a)(7)(i)(A) currently requires that, for ruminants, not less than 30 days, nor more than 120 days after embryo collection, the donor dam must be examined and found free of

BSE (among other diseases). We are proposing to amend this requirement by removing the requirement that sheep and goats be found free of clinical signs of BSE because sheep and goat embryos do not present a risk for transmitting BSE since BSE is not circulating in the sheep and goat populations.

Currently § 98.15(a)(8)(i)(A) requires that, for ruminants, between the time of embryo collection and all required examinations and tests are completed, no animals in the embryo collection unit with the donor dam, or in the donor dam's herd of origin, exhibited clinical evidence of BSE (among other diseases). We are proposing to remove BSE from the list of diseases in this paragraph because we believe the proposed requirements for sheep and goat embryos in § 98.10a will provide adequate protection against a TSE introduction through embryo or oocyte transfer.

Currently, the regulations in § 98.35(e) require that, for sheep and goat semen from any part of the world to be imported into the United States:

- The donor animals must be permanently identified to enable traceback to their establishment of origin;
- They have been kept since birth in establishments in which no case of scrapie has been confirmed during their residency;
- They neither showed clinical signs of scrapie at the time of semen collection nor developed scrapie between the time of semen collection and the export of semen to the United States; and
- The dam of the semen donor is not, or was not, affected with scrapie.

The regulations also require that in the region where the semen originates, scrapie is a compulsorily notifiable disease, an effective surveillance and monitoring program for scrapie is

in place, affected sheep and goats are slaughtered and completely destroyed, and the feeding of meat and bone meal or greaves derived from ruminants has been banned and the ban effectively enforced for the whole region.

At the time the regulations were established, they were consistent with the then current scientific understanding of scrapie and existing international standards. However, advances in scientific understanding of the disease now allow us to relieve some restrictions on the importation of sheep and goat semen. Epidemiological evidence from natural cases in the field suggests that classical scrapie is unlikely to be transmitted via semen (Wrathall 1997). In addition, studies to date have failed to detect PrPSc in components of semen (Gatti, Meyer et al. 2002).

As part of a study to investigate transmission of classical scrapie through embryo transfer, Wang, et al., used a classical scrapie-positive ram to mate with two donor ewes, one scrapie positive, the other negative (Wang, Foote et al. 2001). None of the lambs resulting from embryos of either ewe developed classical scrapie, nor did the uninfected ewe that was bred to the infected ram. The study did not provide information about the scrapie strain or the genotypes of the rams, donor ewes, and recipient ewes.

A more recent study evaluated the infectivity of semen from infected rams by injecting it via intracerebral inoculation into classical scrapie-susceptible transgenic mice overexpressing the VRQ allele. Semen from three classical scrapie-positive VRQ homozygous sheep was injected into a total of 40 transgenic mice, with none subsequently developing classical scrapie. One of the infected sheep was exhibiting clinical signs of classical scrapie and the other two were asymptomatic at the time of collection. In comparison, the injection of brain homogenate from

4 scrapie-infected sheep intracerebrally into 23 transgenic mice resulted in infection of 100 percent of the mice (Sarradin, Melo et al. 2008).

Recently, 8 ewes in a historically scrapie-negative sentinel flock of 24 sheep were discovered to be scrapie-positive 4 months after having been bred to scrapie-positive rams from an adjacent highly infected flock. The flock had also been bred in previous years by other rams from the infected flock and had fence line contact with rams from the infected flock. The ewes had been bred to these rams in order to increase the scrapie-susceptibility of the sentinel flock to the 'Caine' strain of scrapie (i.e., to increase the proportion of sheep with at least one valine insertion at codon 136). This strain has a relatively short incubation period, particularly in sheep that are homozygous for valine at codon 136. The discovery of the infected ewes led to an investigation by Rubenstein et al. (2012) to determine whether it was possible that scrapie could have been transmitted to the ewes through exposure to the semen of infected rams (Rubenstein, Bulgin et al. 2012).

Using newly developed detection techniques such as serial protein misfolding cyclic amplification, combined with an optical fiber immunoassay, the investigators detected prion disease-associated-seeding activity, which is assumed to imply the presence of PrPSc in semen samples from the rams in the affected flock described above. In addition, intracerebral inoculation of a newly-generated sheep scrapie-susceptible transgenic mouse line with semen from both infected and uninfected rams from the flock resulted in the detection of PrPSc in all of the mice inoculated with semen from scrapie-positive rams, but in none of the mice inoculated with semen from scrapie-negative rams.

These experiments suggest that semen from scrapie-infected rams could harbor infectious PrPSc; however, additional studies are necessary to determine whether the level of infectivity in

semen is sufficient to transmit scrapie laterally to ewes or to embryos resulting from the use of scrapie-infected semen donors.

To date, there has been no direct evidence to support the transmission of TSE infectivity through semen of sheep and goats to other sheep or goats; however, the studies conducted have been somewhat limited.

Based on the findings of these studies, we have determined that the previous restrictions in our regulations are no longer consistent with APHIS' assessment of the scrapie transmission risks associated with sheep or goat semen, or with international standards. We are therefore proposing to amend § 98.35 to remove paragraph (e)(1)(ii) to eliminate the requirement that donor animals have been kept since birth in establishments in which no case of scrapie has been confirmed during their residency, and redesignate paragraphs (e)(1)(iii) and (e)(1)(iv) as (e)(1)(ii) and (e)(1)(iii), respectively. We would also amend newly redesignated paragraph (e)(1)(iii) to require that the donor animals were not, and are not, restricted in the country of origin or destroyed due to exposure to a TSE, and will add a new paragraph (e)(1)(iv) to allow APHIS to establish testing requirements for semen and/or semen donors.

We are also proposing to revise paragraph (e)(3) to include semen from all countries, and to allow semen to be imported to an APHIS-approved semen storage facility prior to being transferred to females in a flock listed in the National Scrapie Database. This change will provide an additional option for producers and importers. Further, we are proposing to add new paragraphs (e)(4) and (5) to describe recordkeeping requirements for APHIS-approved semen storage facilities, including a requirement that progeny of imported semen be officially identified and records maintained of their disposition in order to allow these animals to be traced if a need arises.

## 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 provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available 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).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

This analysis examines impacts on U.S. entities of a rule that would remove BSE restrictions on the importation of live sheep and goats and most of their products. The rule also would align our scrapie regulations generally with OIE guidelines and establish a notice-based approach for recognizing regions as free of scrapie. We are also proposing to amend the BSE and scrapie regulations as they apply to other ruminant species that are not bovines, cervids, camelids, sheep or goats. The rule is part of a continuing program to allow the importation of agricultural products that APHIS has determined are without significant risk of introducing exotic animal diseases into the United States.

This proposed rule's impact would stem from its effect on U.S. imports of the affected commodities. Consumer welfare gains from the potential increase in imports are expected to exceed producer welfare losses. While the rule could affect U.S. imports of a wide range of commodities, we focus our attention on the production and trade of live sheep and goats and their meat. This rule may affect imports of other ruminants such as animals received by zoos, but APHIS does not have information that would allow us to evaluate such impacts. Estimated net benefits of the rule are demonstrated in terms of increased imports of lamb, mutton, and goat meat.

U.S. imports of sheep and goat meat come almost entirely from Australia and New Zealand, with chilled or frozen lamb the main product. To evaluate potential effects of the rule, we estimate impacts for U.S. production, consumption, and prices of sheep and goat meat imports using a net trade welfare model. The imports are expected to be small in comparison to an already large import base. We model three levels of additional sheep and goat meat imports into the United States: 983 MT, 1,966 MT, and 3,932 MT. These quantities are equal to approximately 5, 10, and 20 percent of the sum of (i) average EU sheep and goat meat exports to

non-EU markets, 2010-2014, excluding Australia and New Zealand and (ii) average sheep and goat meat exports to EU countries by 21 other countries, 2010-2014. The largest assumed quantity is equivalent to less than 3 percent of average annual U.S. sheep and goat meat consumption during this same period.

The medium level of assumed additional imports, 1,966 MT, would cause a decrease in wholesale prices of a little more than 1 percent and a fall in domestic production of 615 MT. Consumption would increase by 1,351,255 MT. Producer welfare would decline by about \$6.3 million and consumer welfare would increase by about \$14.4 million, yielding an annual net welfare benefit of about \$8.1 million. Similarly, the other two assumed import levels yield positive net benefits. To the extent that sheep and goat meat imported as a result of this rule may displace imports from existing sources, the price and welfare effects would be smaller than indicated; we note that over one half of the current U.S. market is imported.

The majority of establishments that may be affected by the proposed rule are small, and the economic impacts are likely to be small as well. If an additional 1,966 MT of sheep and goat meat were to be imported by the United States because of this rule, the annual decrease in producer welfare per small entity would be about \$48, or the equivalent of about 1 percent of average annual sales by small entities. We welcome public comment that would allow us to better understand likely economic effects of the rule.

#### 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 proposed rule will be preempted; (2) no retroactive effect will be given to

this proposed rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this proposed rule.

#### Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The Animal and Plant Health Inspection Service has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Animal and Plant Health Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

#### National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with changes to the import regulations pertaining to sheep, goats, and certain other non-bovine ruminants, and products derived from sheep and goats, 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. (A link to 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 individual listed under FOR FURTHER INFORMATION CONTACT.

#### Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), some of the reporting and recordkeeping requirements included in this proposed rule have been approved under Office of Management and Budget (OMB) control numbers 0579-0040 and 0579-0101. The new reporting and recordkeeping requirements included in this proposed rule have been submitted as a new information collection for approval to OMB. Please send comments on the information collection request (ICR) to OMB's Office of Information and Regulatory Affairs via email to [oir-submissions@omb.eop.gov](mailto:oir-submissions@omb.eop.gov), Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2009-0095. Please send a copy of your comments to USDA using one of the methods described under ADDRESSES at the beginning of this document, preferably the use of the Federal eRulemaking Portal.

APHIS uses a variety of information collection procedures and forms to gather data in its effort to prevent the introduction or spread of disease. Information collected via these

procedures and forms includes, but is not limited to, the names of the exporter and importer of the animal commodities; the origins of the animals or animal products to be imported; the health status of the animals or the processing methods used to produce animal products to be imported; the destination of delivery in the United States; and whether the animals or animal products were temporarily offloaded in another country during transit to the United States.

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 0.531 hours per response.

Respondents: State representatives; Foreign governments/veterinary officials; accredited veterinarians; importers and owners of sheep, goats, and certain other small ruminants; slaughter plant personnel; and feedlot personnel.

Estimated annual number of respondents: 7,423.

Estimated annual number of responses per respondent: 8.73.

Estimated annual number of responses: 64,771.

Estimated total annual burden on respondents: 34,408 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 new information collection are located at <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0095> and can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

USDA will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

#### 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 Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

#### **List of Subjects**

##### *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 93, 94, 95, 96, and 98 as follows:

**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**

1. 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.

2. Section 93.400 is amended as follows:

a. By adding, in alphabetical order, definitions for “Certified status”, “Classical scrapie”, and “Country mark”;

b. By revising the definitions for “Designated feedlot” and “Flock”;

c. By adding, in alphabetical order, definitions for “Flock of birth”, “Flock of residence”, “Goat”, “Killed and completely destroyed”, “Non-classical scrapie”, and “Sheep”;

d. By removing the definition of “Suspect for a transmissible spongiform encephalopathy”; and

e. By adding, in alphabetical order, definitions for “Transmissible spongiform encephalopathies (TSEs)”, and “TSE-affected sheep or goat”.

The additions and revisions read as follows:

**§ 93.400 Definitions.**

\* \* \* \* \*

Certified status. A flock that has met requirements equivalent to the Export Certified status of the U.S. Scrapie Flock Certification Program while participating in a program under the supervision of the national veterinary authority of the region of origin, as determined by an evaluation conducted by APHIS of the program.

\* \* \* \* \*

Classical scrapie. Any form of scrapie that the Administrator has determined poses a significant risk of natural transmission.

\* \* \* \* \*

Country mark. A permanent mark approved by the Administrator for identifying a sheep or goat to its country of origin.

\* \* \* \* \*

Designated feedlot. A feedlot that has been designated by the Administrator as one that is eligible to receive sheep and goats from regions that are not free of classical scrapie, and whose owner or legally responsible representative has signed an agreement as specified in § 93.435(c)(11) and is in full compliance with all the provisions of the agreement.

\* \* \* \* \*

Flock. Any group of one or more sheep or goats maintained on a single premises, or on more than one premises under the same ownership and between which unrestricted movement is allowed; or two or more groups of sheep or goats under common ownership or supervision on two or more premises that are geographically separated, but among which there is an interchange or movement of animals.

Flock of birth. The flock into which a sheep or goat is born.

Flock of residence. The flock:

(1) Within which an individual sheep or goat was born, raised, and resided until exported to the United States; or

(2) In which the sheep or goat resided for breeding purposes for 60 days or more until exported to the United States; or

(3) In which sheep and goats for export were assembled for export to the United States and maintained for at least 60 days immediately prior to export, without any addition of animals or contact with animals other than through birth, on a single premises, or on more than one premises under the same ownership and between which unrestricted movement occurred.

Goat. Any animal of the genus Capra.

\* \* \* \* \*

Killed and completely destroyed. Killed, or maintained under quarantine in a manner that will prevent disease spread until the animal is no longer living; and the remains have been disposed of in a way that prevents disease spread.

\* \* \* \* \*

Non-classical scrapie. Any form of scrapie that the Administrator has determined poses a low risk of natural transmission.

\* \* \* \* \*

Sheep. Any animal of the genus Ovis.

\* \* \* \* \*

Transmissible spongiform encephalopathies (TSEs). A family of progressive and generally fatal neurodegenerative disorders thought to be caused by abnormal proteins, called prions, that typically produce characteristic microscopic changes, including, but not limited to, non-inflammatory neuronal loss, giving a spongiform appearance to tissues in the brains and central nervous systems of affected animals.

TSE-affected sheep or goat. A sheep or goat suspected or known by the national veterinary authority of the region of origin to be infected with a transmissible spongiform encephalopathy prior to the disposal of the animal.

\* \* \* \* \*

3. In § 93.401, paragraph (a) is revised to read as follows:

**§ 93.401 General prohibitions; exceptions.**

(a) No ruminant or product subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and part 94 of this subchapter;<sup>3</sup> nor shall any such ruminant or product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations. Notwithstanding any other provision of this subpart, the importation of any ruminant that is not a bovine, camelid, cervid, sheep, or goat is prohibited. Provided, however, the Administrator may upon request in specific cases permit ruminants or products of such to be brought into or through the United States under such

conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock of the United States.

<sup>3</sup> Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

\* \* \* \* \*

4. Section 93.404 is amended as follows:

a. Paragraphs (a)(2), (a)(3), and (a)(4) are redesignated as paragraphs (a)(3), (a)(4), and (a)(7), respectively;

b. By adding new paragraph (a)(2) and paragraphs (a)(5), and (6);

c. In newly redesignated paragraph (a)(7)(v), the reference to “paragraph (a)(4)(iv)” is removed and a reference to “paragraph (a)(7)(iv)” is added in its place; and

d. In newly redesignated paragraph (a)(7)(vi), the references to “paragraph (a)(4)(iv)(A)” and “paragraph (a)(4)(iv)(B)” are removed and references to “paragraph (a)(7)(iv)(A)” and “paragraph (a)(7)(iv)(B)”, respectively, are added in their place.

The additions read as follows:

**§ 93.404 Import permits for ruminants and for ruminant test specimens for diagnostic purposes; and reservation fees for space at quarantine facilities maintained by APHIS.**

(a) \* \* \*

(2) In addition to the requirements in paragraph (a)(1) of this section, the importer must submit the following information along with the application for an import permit:

(i) For sheep or goats imported for immediate slaughter, or for restricted feeding for slaughter:

(A) The slaughter establishment to which the animals will be imported; or

(B) The designated feedlot in which sheep and goats imported for restricted feeding for slaughter will be maintained until moved to slaughter.

(ii) For sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter:

(A) The flock identification number, if imported to a flock, and the premises or location identification number, of the flock or other premises to which the animals are imported as listed in the Scrapie National Database.

(B) For sheep and goats from regions not free from classical scrapie, the importer must provide documentation that the animal has reached and maintained certified status in a Scrapie Flock Certification program that has been determined by the Administrator to provide equivalent risk reduction as the Export Category of the U.S. Scrapie Flock Certification Program. The documentation must specify the address, or other means of identification, of the premises and flock of birth, and any other flock(s) in which the animals have resided.

\* \* \* \* \*

(5) In specific cases, a permit may be issued for ruminants that would otherwise be prohibited importation due to TSEs pursuant to this subpart, if the Administrator determines that the disease risk posed by the animals can be adequately mitigated through pre-entry or post-entry mitigation measures, or through combinations of such measures. These measures will be specified in the permit. If it is determined prior to or after importation that any pre-entry or post-entry requirements were not met, or that the ruminants are affected with or have been exposed to TSEs, the ruminants, their progeny, and any other ruminants that have been housed with or exposed to the ruminants will be disposed of or otherwise handled as directed by the Administrator. Importers seeking a permit pursuant to this paragraph must send their request to

the Administrator, c/o National Import Export Services, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231, or via the APHIS Web site at [http://www.aphis.usda.gov/import\\_export/animals/live\\_animals.shtml](http://www.aphis.usda.gov/import_export/animals/live_animals.shtml).

(6) The Administrator may issue permits under paragraph (a)(5) of this section for male sheep that are determined to be AA at codon 136 and either RR, HR, KR or QR at codon 171 and for female sheep that are AA at codon 136 and RR at codon 171 by the National Veterinary Services Laboratories or another laboratory approved by the Administrator. Such sheep must meet all requirements for import other than the requirement that they originate in a flock or region that is free of classical scrapie. The permit will provide for post entry confirmation of the animal's scrapie susceptibility genotype and/or genetic testing for identity.

\* \* \* \* \*

5. Section 93.405 is amended as follows:

- a. Paragraph (a)(4) is removed;
- b. Paragraph (b) is revised;
- c. Paragraph (c) is removed; and
- d. Paragraph (d) is redesignated as paragraph (c) and revised.

The revisions read as follows:

**§ 93.405 Health certificate for ruminants.**

\* \* \* \* \*

(b) Sheep and goats. (1) In addition to the statements required by paragraph (a) of this section, the certificate accompanying sheep or goats from any part of the world must also include the name and address of the importer; the number or quantity of sheep or goats to be imported; the purpose of the importation; the official individual sheep or goat identification applied to the

animals; and, when required by § 93.435, the permanent country mark and other identification present on the animal, including registration number, if any; a description of each sheep or goat linked to the official identification number, including age, sex, breed, color, and markings, if any; the flock of residence; the address (including street, city, State, and ZIP Code) of the destination where the sheep or goats are to be physically located after importation, including the premises or location identification number assigned in the APHIS National Scrapie Database and when applicable the flock identification number; the name and address of the exporter; the port of embarkation in the region of export; the mode of transportation, route of travel and port of entry in the United States; and, for sheep or goats imported for purposes other than immediate slaughter or restricted feeding for slaughter, the certificate must specify the region of origin and, for regions not free of scrapie, the address or other identification of the premises and flock of birth, and any other flock in which the animals have resided.

(2) The certificate accompanying sheep or goats from any part of the world, except as provided in paragraph (b)(4) of this section for sheep or goats imported for immediate slaughter, and in paragraph (b)(5) of this section for sheep or goats for restricted feeding for slaughter, must also state:

(i) That the sheep or goats originated from a region recognized as free of classical scrapie by APHIS; or that the animals have reached and maintained certified status in a scrapie flock certification program approved by APHIS;

(ii) That the sheep or goats have not commingled with sheep or goats of a lower health status, or resided on the premises of a flock or herd of lower health status, after leaving the flock of residence and prior to arrival in the United States;

(iii) That any enclosure, container or conveyance in which the sheep or goats had been placed during the export process, and which had previously held sheep or goats, was cleaned and disinfected in accordance with § 54.7(e)(2) of this chapter prior to being used for the sheep or goats;

(iv) That none of the female sheep or goats is carrying an implanted embryo from a lower health status flock; or that any implanted embryo met the requirements for import into the United States when implanted and documentation as required in part 98 of this subchapter is attached;

(v) That the veterinarian issuing the certificate has inspected the sheep or goats, and their flock(s) of residence, within 30 days of consignment for import to the United States, and found the animals and the flock(s) of residence to be free of any evidence of infectious or contagious disease;

(vi) That as far as it is possible for the veterinarian who inspects the animals to determine, none of the sheep or goats in the flock(s) of residence has been exposed to any infectious or contagious disease during the 60 days immediately preceding shipment to the United States; and

(vii) The animals' movement is not restricted within the country of origin due to animal health reasons.

(3) The certificate accompanying sheep or goats from any part of the world, except as provided in paragraph (b)(4) of this section for sheep or goats imported for immediate slaughter, or in paragraph (b)(5) of this section for sheep or goats for restricted feeding for slaughter, must also include:

- (i) The results of any testing required in the import permit; and
- (ii) Any other information required in the import permit.

(4) For sheep or goats imported for immediate slaughter, in addition to the statements required under paragraph (a) of this section, the certificate must include statements that:

(i) The region is recognized as free of classical scrapie by APHIS; or

(ii) The region has not been recognized as free of classical scrapie by APHIS but the following criteria have been met:

(A) TSEs in sheep and goats are compulsorily notifiable;

(B) An effective classical scrapie awareness, surveillance, monitoring, and control system is in place;

(C) TSE-affected sheep and goats are killed and completely destroyed;

(D) The sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment and are fit for travel;

(E) The sheep and goats have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy; and

(F) The animals' movement is not restricted within the country of origin due to animal health reasons.

(5) Sheep or goats for restricted feeding for slaughter. For sheep or goats imported for restricted feeding for slaughter, in addition to the statements required under paragraph (a) of this section, the certificate must include statements that:

(i) The region is recognized as free of classical scrapie by APHIS; or

(ii) The region has not been recognized as free of classical scrapie by APHIS but the following criteria have been met:

(A) TSEs in sheep and goats are compulsorily notifiable;

(B) An effective classical scrapie awareness, surveillance, monitoring and control system is in place;

(C) TSE-affected sheep and goats are killed and completely destroyed;

(D) The sheep or goats showed no clinical sign of scrapie or any other infectious disease on the day of shipment and are fit for travel;

(E) The sheep or goats have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy;

(F) The animals' movement is not restricted within the country of origin due to animal health concerns;

(G) Female sheep and goats are not known to be pregnant, are not visibly pregnant, and female animals have not been exposed:

(1) To a sexually intact male at over 5 months of age; or

(2) To a sexually intact male within 5 months of shipment;

(H) That the veterinarian issuing the certificate has inspected the sheep or goats for export, and their flock(s) of residence, within 30 days of consignment for shipment to the United States, and found the animals and the flock(s) of residence to be free of any evidence of infectious or contagious disease; and

(I) That as far as it is possible for the veterinarian who inspects the animals to determine, none of the sheep or goats has been exposed to any infectious or contagious disease during the 60 days immediately preceding shipment to the United States.

(c) If ruminants are unaccompanied by the certificate as required by paragraphs (a) and (b) of this section, or if such ruminants are found upon inspection at the port of entry to be affected with a communicable disease or to have been exposed thereto, they shall be refused

entry and shall be handled or quarantined, or otherwise disposed of as the Administrator may direct.

\* \* \* \* \*

**§ 93.406 [Amended]**

6. Amend § 93.406(b) by removing the references “§§ 93.419 and 93.428(b)” and adding “§§ 93.428(b) and 93.435” in their place.

**§ 93.419 [Removed and Reserved]**

7. Section 93.419 is removed and reserved.

8. In § 93.420, paragraph (a) introductory text is amended by adding a sentence after the paragraph heading to read as follows:

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

(a) \* \* \*. The requirements for the importation of sheep and goats from Canada for immediate slaughter are contained in § 93.435. \* \* \*

\* \* \* \* \*

9. Section 93.424 is amended by revising paragraph (a) to read as follows:

**§ 93.424 Import permits and applications for inspection of ruminants.**

(a) For ruminants intended for importation from Mexico, the importer shall first apply for and obtain from APHIS an import permit as provided in §93.404: Provided, that: An import permit is not required for sheep or goats imported for immediate slaughter if the animal is offered for entry at a land border port designated in § 93.403(c).

\* \* \* \* \*

10. Section 93.428 is amended by revising paragraph (a) to read as follows:

**§ 93.428 Sheep and goats and wild ruminants from Mexico.**

(a) Sheep and goats intended for import from Mexico must be imported in accordance with § 93.435, and shall be accompanied by a certificate issued in accordance with § 93.405 and stating, if such sheep and goats are shipped by rail or truck, that such animals were loaded into cleaned and disinfected cars or trucks for transportation direct to the port of entry.

Notwithstanding such certificate, such sheep and goats shall be detained as provided in § 93.427(a) and shall be dipped at least once in a permitted scabies dip under supervision of an inspector.

\* \* \* \* \*

11. Section 93.435 is revised to read as follows:

**§ 93.435 Sheep and goats.**

(a) General provisions. (1) Sheep and goats imported from anywhere in the world shall be accompanied by a certificate issued in accordance with § 93.405. If the sheep or goats are not accompanied by the certificate, or if they are found upon inspection at the port of entry to be affected with or exposed to a communicable disease, they shall be refused entry and shall be handled or quarantined, or otherwise disposed of, as the Administrator may direct.

(2) All imported sheep and goats must be officially identified at the time of presentation for entry into the United States with unique identification numbers using official identification devices, or by other means that have been approved by the Administrator, and which will allow the animals that are not imported for immediate slaughter or for feeding for slaughter to be traced at any time to the farm or premises of birth, and for animals imported for immediate slaughter or for feeding for slaughter to the flock of residence. Official identification may not be removed or altered at any time after entry into the United States, except by an authorized USDA

representative at the time of slaughter. A list of the acceptable types of official identification may be found on the APHIS Web site at [ADDRESS TO BE ADDED IN FINAL RULE].

(3) All imported sheep and goats other than for immediate slaughter or as provided in paragraph (c) of this section for restricted feeding for slaughter must be identified at the time of presentation for entry into the United States with a country mark using a means and in a location on the animal that has been approved by the Administrator for this use. A list of the acceptable country marks may be found on the APHIS Web site at [ADDRESS TO BE ADDED IN FINAL RULE]

(4) Except as provided in paragraph (b) of this section for sheep or goats imported for immediate slaughter, and in paragraph (c) of this section for sheep or goats for restricted feeding for slaughter, the importer shall maintain records of the sale, death or other disposition of all imported animals which include the official identification number(s) and country marks on the animals at the time of import; a record of the replacement of any lost identification devices linking the new official identification number to the lost device number; the date and manner of disposition; and the name and address of the new owner. Such records must be maintained for a period of 5 years after the sale or death of the animal. The records must be available for APHIS to view and copy during normal business hours.

(b) Sheep and goats imported for immediate slaughter from anywhere in the world. (1) Sheep and goats imported for immediate slaughter must be imported only through a port of entry allowed in § 93.403, in a means of conveyance sealed in the country of origin with seals of the national government, and must be moved directly as a group from the port of entry to a recognized slaughtering establishment for slaughter as a group; and

(2) The sheep and goats shall be inspected by the port veterinarian or other designated APHIS representative at the port of entry to determine that the animals are free from evidence of communicable disease and are considered fit for further travel; and

(3) The seals on the means of conveyance must be broken only at the port of entry by the APHIS port veterinarian or at the recognized slaughtering establishment by an authorized USDA representative. If the seals are broken by the APHIS port veterinarian at the port of entry, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the recognized slaughtering establishment; and

(4) The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17-33.

(c) Sheep and goats imported for restricted feeding for slaughter. (1) Sheep and goats for restricted feeding for slaughter purposes may only be imported into the United States from countries or regions that are have been determined to be free of classical scrapie by APHIS, or that have scrapie awareness, surveillance, and control programs that have been evaluated and determined by APHIS to be effective.

(2) The sheep and goats must be imported only through a port of entry allowed in § 93.403 in a means of conveyance sealed in the region of origin with seals of the national government of the region of origin. The seals may be broken either by an APHIS representative at the port of entry, or at the designated feedlot by an authorized APHIS representative. If the seals are broken by an APHIS representative, the means of conveyance must be resealed with seals of the U.S. Government before being moved to the designated feedlot; and

(3) The sheep and goats shall be inspected by the port veterinarian or other designated representative at the port of entry to determine that the animals are free from evidence of communicable disease and are considered fit for further travel; and

(4) The sheep and goats must be moved directly as a group from the port of entry to a designated feedlot; and

(5) The sheep and goats may not be commingled with any sheep or goats that are not being moved directly to slaughter from the designated feedlot; and

(6) The sheep and goats may be moved from the port of entry only to a feedlot designated in accordance with paragraph (c)(11) of this section and must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 17-130 or other movement documentation stipulated in the import permit; and

(7) Upon arrival at the designated feedlot, the official identification for each animal must be reconciled by an APHIS veterinarian, or other official designated by APHIS, with the accompanying documentation; and

(8) The sheep and goats must remain at the designated feedlot until transported to a recognized slaughtering establishment. The sheep and goats must be moved directly to the recognized slaughtering establishment in a means of conveyance sealed by an accredited veterinarian, a State representative, or an APHIS representative with seals of the U.S. Government. The seals must be broken at the recognized slaughtering establishment only by an authorized USDA representative; and

(9) The sheep and goats must be accompanied to the recognized slaughtering establishments by APHIS Form VS 1-27 or other documentation stipulated in the import permits; and

(10) The sheep and goats must be slaughtered within 12 months of importation.

(11) To be eligible as a designated feedlot to receive sheep and goats imported for feeding, a feedlot must be approved by APHIS. To be approved by APHIS, the feedlot operator or his or her agent must enter into a compliance agreement with the Administrator. The compliance agreement must provide that the operator:

(i) Will monitor all imported feeder animals to ensure that they have the required official identification at the time of arrival to the feedlot; and will not remove official identification from animals unless medically necessary, in which case new official identification will be applied and cross referenced in the records. Any lost official identification will be replaced with eartags provided by APHIS for the purpose and will be linked the new official identification with the lost identification. If more than one animal loses their official identification at the same time, the new official identification will be linked with all possible original identification numbers;

(ii) Will monitor all incoming imported feeder animals to ensure that they have the required country mark, or will maintain all imported animals in separate pens from U.S. origin animals, and that all sheep and goats that enter the feedlot are moved only for slaughter;

(iii) Will maintain records of the acquisition and disposition of all imported sheep and goats entering the feed lot, including the official identification number and all other identifying information, the age of each animal, the date each animal was acquired and the date each animal was shipped to slaughter, and the name and location of the plant where each animal was slaughtered. For imported animals that die in the feedlot, the feedlot will remove the official identification device if affixed to the animal, or will record any other official identification on the animal and place the official identification device or record of official identification in a file with a record of the disposition of the carcass;

(iv) Will maintain copies of the APHIS Forms VS 17-130 and VS 1-27 or other movement documentation deemed acceptable by the Administrator that have been issued for incoming animals and for animals moved to slaughter and that list the official identification of each animal;

(v) Will allow State and Federal animal health officials access to inspect its premises and animals and to review inventory records and other required files upon request;

(vi) Will keep required records for at least 5 years;

(vii) Will designate either the entire feedlot or pens within the feedlot as terminal for sheep and goats to be moved only directly to slaughter;

(viii) Agrees that if inventory cannot be reconciled or if animals are not moved to slaughter as required, the approval of the feedlot to receive additional animals will be immediately withdrawn and any imported animals remaining in the feedlot will be disposed of as directed by the Administrator;

(ix) Agrees that if an imported animal gives birth in the feedlot, the offspring will be humanely euthanized and the birth tissues and soiled bedding disposed of in a sanitary landfill or by another means approved by the Administrator; and

(x) Agrees to maintain sexually intact animals of different genders over 5 months of age in separate enclosures.

(xi) For a feedlot to be approved to receive sheep or goats imported for feeding under this section, but which do not have a country mark, the compliance agreement must also provide that the feedlot will maintain all imported animals in separate pens from U.S. origin animals and that all sheep and goats that enter the feedlot are moved only for slaughter.

(d) Sheep or goats imported other than as provided in paragraph (b) of this section for immediate slaughter or as provided in paragraph (c) of this section for sheep and goats imported for restricted feeding for slaughter must originate from a region recognized as free of classical scrapie by APHIS or from a flock that has certified status in a scrapie flock certification program recognized by APHIS as acceptable for this purpose, or as provided in § 93.404(a)(5) or (6).

(e) Sheep and goats transiting the United States. Sheep or goats that meet the entry requirements for immediate slaughter in § 93.405 may transit the United States in accordance with § 93.401 regardless of their intended use in the receiving country.

(f) Classical scrapie status of foreign regions. APHIS considers classical scrapie to exist in all regions of the world except those declared free of this disease by APHIS.

(1) A list of regions that APHIS has declared free of classical scrapie is maintained on the APHIS Web site at

[http://www.aphis.usda.gov/import\\_export/animals/animal\\_disease\\_status.shtml](http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml). Copies of the list are also available via postal mail, fax, or email upon request to Regionalization Evaluation Services, National Import Export Services, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 38, Riverdale, Maryland 20737.

(2) APHIS will add a region to this list only after it conducts an evaluation of the region in accordance with § 92.2 of this subchapter and finds that classical scrapie is not likely to be present in its sheep or goat populations. In the case of a region formerly on this list that is removed due to an outbreak, the region may be returned to the list in accordance with the procedures for reestablishment of a region's disease-free status in § 92.4 of this subchapter.

APHIS will remove a region from the list of those it has declared free of classical scrapie upon determining that classical scrapie exists there based on reports APHIS receives of outbreaks of

the disease in sheep or goats from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), from other sources the Administrator determines to be reliable, or upon determining that the region's animal health infrastructure, regulations, or policy no longer qualifies the region for such status.

(Approved by the Office of Management and Budget under control numbers 0579-0040 and 0579-0101)

**§ 93.505 [Amended]**

12. Amend § 93.505(a), by removing the citation “§ 94.24(b)(6)” and replacing it with the citation “§ 94.31(b)(6)”.

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

13. 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.

14. Section § 94.15 is revised to read as follows:

**§ 94.15 Transit shipment of articles.**

(a) Any meat or other animal product or material (excluding materials that are required to be consigned to USDA-approved establishments for further processing) that is eligible for entry into the United States, as provided in this part or in part 95 of this subchapter, may transit the

United States by air and ocean ports and overland transportation if the articles are accompanied by the required documentation specified in this part and in part 95.

(b) Any meat or other animal product or material that is not eligible for entry into the United States, as provided in this part or in part 95 of this subchapter, may transit air and ocean ports only, with no overland movement outside the airport terminal area or dock area of the maritime port, in the United States for immediate export if the conditions of paragraphs (b)(1) through (4) of this section are met.

(1) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain under either Customs seal or Foreign Government seal during the entire time that it is in the United States.

(2) Before transit, the person moving the articles must notify, in writing, the authorized Customs 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) Times and dates of arrival in the United States;
- (ii) Times and dates of exportation from the United States;
- (iii) Mode of transportation; and
- (iv) Serial numbers of the sealed containers.

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

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

(c) Pork and pork products from Baja California, Baja California Sur, Campeche, Chihuahua, Coahuila, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, and Yucatan, Mexico, that are not eligible for entry into the United States in accordance with this part may transit the

United States via land border ports for immediate export if the following conditions of paragraphs (c)(1) through (4) of this section are met:

(1) The person moving the pork and pork products 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 Import Export Services, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at [http://www.aphis.usda.gov/animal\\_health/permits/](http://www.aphis.usda.gov/animal_health/permits/)).

(2) The pork or pork products are packaged at a Tipo Inspección Federal plant in Baja California, Baja California Sur, Campeche, Chihuahua, Coahuila, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, or Yucatan, Mexico, in leakproof containers and sealed with serially numbered seals of the Government of Mexico, and the containers remain sealed during the entire time they are in transit across Mexico and the United States.

(3) The person moving the pork and pork products through the United States notifies, in writing, the authorized Customs inspector at the United States port of arrival prior to such transiting. The notification must include the following information regarding the pork and pork products:

- (i) Permit number;
- (ii) Times and dates of arrival in the United States;
- (iii) Time schedule and route to be followed through the United States; and
- (iv) Serial numbers of the seals on the containers.

(4) The pork and pork products must transit the United States under Customs bond and must be exported from the United States within the time limit specified on the permit. Any pork or pork products that have not been exported within the time limit specified on the permit or that

have not been transited in accordance with the permit or applicable requirements of this part will be destroyed or otherwise disposed of as the Administrator may direct pursuant to the Animal Health Protection Act (7 U.S.C. 8301 et seq.).

(d) Poultry carcasses, parts, or products (except eggs and egg products) from Baja California, Baja California Sur, Campeche, Chihuahua, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, Tamaulipas, or Yucatan, Mexico, that are not eligible for entry into the United States in accordance with the regulations in this part may transit the United States via land ports for immediate export if the following conditions of paragraphs (d)(1) through (4) of this section are met:

(1) The person moving the poultry carcasses, parts, or products through the United States 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 Import Export Services, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at [http://www.aphis.usda.gov/animal\\_health/permits/](http://www.aphis.usda.gov/animal_health/permits/)).

(2) The poultry carcasses, parts, or products are packaged at a Tipo Inspección Federal plant in Baja California, Baja California Sur, Campeche, Chihuahua, Nuevo Leon, Quintana Roo, Sinaloa, Sonora, Tamaulipas, or Yucatan, Mexico, in leakproof containers with serially numbered seals of the Government of Mexico, and the containers remain sealed during the entire time they are in transit through Mexico and the United States.

(3) The person moving the poultry carcasses, parts, or products through the United States must notify, in writing, the authorized CBP inspector at the United States port of arrival prior to

such transiting. The notification must include the following information regarding the poultry to transit the United States:

- (i) Permit number;
- (ii) Times and dates of arrival in the United States;
- (iii) Time schedule and route to be followed through the United States; and
- (iv) Serial numbers of the seals on the containers.

(4) The poultry carcasses, parts, or products must transit the United States under U.S. Customs bond and must be exported from the United States within the time limit specified on the permit. Any poultry carcasses, parts, or products that have not been exported within the time limit specified on the permit or that have not transited in accordance with the permit or applicable requirements of this part will be destroyed or otherwise disposed of as the Administrator may direct pursuant to the Animal Health Protection Act (7 U.S.C. 8301 et seq. ).

(e) Meat and other products of ruminants or swine from regions listed in § 94.11(a) and pork and pork products from regions listed in § 94.13 that do not meet the requirements of § 94.11(b) or § 94.13(a) may transit through the United States for immediate export, provided the provisions of paragraph (b) of this section are met, and provided all other applicable provisions of this part are met.

(Approved by the Office of Management and Budget under control numbers 0579-0040 and 0579-0145)

#### **§ 94.18 [Amended]**

15. In paragraph (a), by adding the word “and” before the citation “94.23” and removing the words “, and § 94.27”.

#### **§ 94.24 [Removed and Reserved]**

16. Section 94.24 is removed and reserved.

**§ 94.25 [Removed and reserved]**

17. Section 94.25 is removed and reserved.

18. Section 94.26 is revised to read as follows:

**§ 94.26 Gelatin derived from horses, swine, or non-bovine ruminants.**

Gelatin derived from horses, swine, or non-bovine ruminants 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.

**§ 94.27 [Removed and reserved]**

19. Section 94.27 is removed and reserved.

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

20. 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.

**§ 95.1 [Amended]**

21. Section 95.1 is amended by removing the definitions of “Positive for a transmissible spongiform encephalopathy” and “Suspect for a transmissible spongiform encephalopathy”.

22. Section 95.4 is amended as follows:

- a. The section heading is revised;
- b. Paragraph (a) is revised;
- c. Paragraph (b)(1) is revised;

- d. Paragraphs (c)(1)(ii) and (iv) are revised;
- e. Paragraphs (c)(2) and (c)(3) are removed, and paragraphs (c)(4) through (c)(8) are redesignated as paragraphs (c)(2) through (c)(6), respectively;
- f. In newly redesignated paragraph (c)(3), the first sentence is revised;
- g. In newly redesignated paragraph (c)(5), the reference “(c)(5)” is removed and the reference “(c)(3)” is added in its place;
- h. In newly redesignated paragraph (c)(6), the words “National Center for Import and Export” are removed and the words “National Import Export Services” are added in their place;
- i. Paragraphs (d) and (e) are removed;
- j. Paragraph (f) and the Note to paragraph (f) are redesignated as paragraph (d) and the Note to paragraph (d), respectively; and
- k. Paragraph (g) is removed.

The revisions read as follows:

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

(a) Except as provided in this section, or in § 94.15, any of the materials listed in paragraph (b) in this section derived from animals, or products containing such materials, are prohibited importation into the United States.

(b) \* \* \* (1) Processed animal protein, tankage, offal, tallow, and tallow derivatives, unless in the opinion of the Administrator, the tallow cannot be used in feed;

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(ii) Cervids and camelids, and the material is not ineligible for importation under the conditions of § 95.5.

\* \* \* \* \*

(iv) Ovines and caprines, and the material is not ineligible for importation under the conditions of § 95.5.

\* \* \* \* \*

(3) If the facility processes or handles any processed animal protein, 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.\* \* \*

\* \* \* \* \*

**§ 95.15 [Removed and reserved]**

23. Section 95.15 is removed and reserved.

**§ 95.40 [Removed and reserved]**

24. Section 95.40 is removed and reserved.

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

25. 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.

**§ 96.2 [Amended]**

26. Section 96.2 is amended as follows:

a. Paragraph (b)(1) is removed.

b. Paragraph (b)(2) is redesignated as paragraph (b)(1).

c. A new paragraph (b)(2) is added and reserved.

d. In paragraph (c)(3), by removing the words “paragraphs (b)(2)(i) through (b)(3)(iv)” and replacing them with the words “paragraph (b)(1).”

**PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN**

27. 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.

28. Section 98.2 is amended by adding, in alphabetical order, definitions for “Oocyte” and “Transmissible spongiform encephalopathies (TSEs)” to read as follows.

**§ 98.2 Definitions.**

\* \* \* \* \*

Oocyte. The first and second maturation stages of a female reproductive cell prior to fertilization.

\* \* \* \* \*

Transmissible spongiform encephalopathies (TSEs). A family of progressive and generally fatal neurodegenerative disorders thought to be caused by abnormal proteins, called prions, that typically produce characteristic microscopic changes, including, but not limited to, non-inflammatory neuronal loss, giving a spongiform appearance to tissues in the brains and nervous systems of affected animals.

\* \* \* \* \*

**§ 98.3 [Amended]**

29. Section 98.3 is amended as follows:

a. In paragraph (d), by adding the words “except that, for sheep and goats only, the donor sire must meet the scrapie requirements in § 98.35 instead of the requirements in § 93.435 of this chapter;” after the words “United States;”;

b. In paragraph (e), by removing the citation “part 92” and adding the citation “part 93” in its place, and by adding the words “except that, for sheep and goats only, the donor dam must meet the requirements for embryo donors in § 98.10(a) instead of the requirements in § 93.435 of this chapter;” after the words “United States;” and

c. In paragraph (f), by removing the words “§ 93.404(a)(2) or (3)” and adding the words “§ 93.404(a)(3) or (4)” in their place.

30. Section 98.4 is amended by adding paragraph (e) to read as follows:

**§ 98.4 Import permit.**

\* \* \* \* \*

(e) Applications for a permit to import sheep and goat embryos and oocytes must include the flock identification number of the receiving flock and the premises or location identification number assigned in the APHIS National Scrapie Database; or, in the case of embryos or oocytes moving to a storage facility, the premises or location identification number must be included.

**§ 98.5 [Amended]**

31. In § 98.5, paragraph (b) is removed and reserved.

32. Section 98.10a is revised to read as follows:

**§ 98.10a Sheep and goat embryos and oocytes.**

(a) Sheep and goat embryos or oocytes collected from donors located in, or originating from, regions recognized by APHIS as free of classical scrapie, or which are from a flock or herd that has certified status in a scrapie flock certification program recognized by APHIS as

acceptable, may be imported in accordance with §§ 98.3 through 98.8. In addition to the requirements of § 98.5, the health certificate must indicate that the embryos or oocytes were collected, processed, and stored in conformity with the requirements in § 98.3(g).

(b) In vivo-derived sheep and goat embryos or oocytes collected from donors located in, or originating from, regions or flocks not recognized by APHIS as free of classical scrapie, may be imported in accordance with §§ 98.3 through 98.8 and the following conditions:

(1) The embryos or oocytes must be accompanied by a health certificate meeting the requirements listed in § 98.5, and with the following additional certifications:

(i) The embryos or oocytes were collected, processed and stored in conformity with the requirements in § 98.3(g).

(ii) For in vivo-derived sheep embryos only: The embryo is of the genotype AAQR or AARR based on official testing of the parents or the embryo.

(iii) Certificates for sheep embryos that are not of the genotype AAQR or AARR, and for all goat embryos, must contain these additional certifications:

(A) In the country or zone:

(1) TSEs of sheep and goats are compulsorily notifiable;

(2) A scrapie awareness, surveillance, monitoring, and control system is in place;

(3) TSE-affected sheep and goats are killed and completely destroyed;

(4) The feeding to sheep and goats of meat-and-bone meal of ruminant origin has been banned and the ban is effectively enforced in the whole country

(B) The donor animals:

(1) Have been kept since birth in flocks or herds in which no case of scrapie had been confirmed during their residency; and

(2) Are permanently identified to enable a traceback to their flock or herd of origin, and this identification is recorded on the certificate accompanying the embryo(s) and linked to the embryo container identification; and

(3) Showed no clinical sign of scrapie at the time of embryo/oocyte collection; and

(4) Have not tested positive for, and are not suspect for, a transmissible spongiform encephalopathy; and

(5) Are not under movement restrictions within the country or region of origin as a result of exposure to a transmissible spongiform encephalopathy.

(c) Any additional certifications or testing requirements established by APHIS, based on genetic susceptibility of the embryo or embryo parents, and/or on scrapie testing of the embryo donor, will be listed in the APHIS import permit. Such certifications or required test results must also be recorded on the health certificate accompanying the embryo(s).

(d) Sheep and goat embryos or oocytes may only be imported for transfer to recipient females in the United States if the flock or herd in which the recipients reside is listed in the National Scrapie Database; except that APHIS may permit importation of sheep and goat embryos or oocytes to an APHIS-approved storage facility where they may be kept until later transferred to recipient females in a flock or herd in the United States that is listed in the APHIS National Scrapie Database, and under such conditions as the Administrator deems necessary to trace the movement of the imported embryos or oocytes. Imported sheep or goat embryos or oocytes that are not otherwise restricted by the conditions of an import permit may be transferred from a listed flock or herd to any other listed flock or herd or from an embryo storage facility to a listed flock or herd with written notification to the responsible APHIS Veterinary Services Service Center.

(e) The importer, the owner of a recipient flock or herd to which delivery of the embryos or oocytes is made, or the owner of an APHIS-approved embryo or oocyte storage facility must maintain records of the disposition (including destruction) of imported or stored embryos or oocytes for 5 years after the embryo or oocyte is transferred or destroyed. These records must be made available during normal business hours to APHIS representatives on request for review and copying.

(f) In vitro-derived or manipulated sheep or goat embryos and oocytes. As provided in § 98.10, APHIS will make a case-by-case determination or establish conditions in an import permit that includes any additional mitigations deemed necessary to prevent the introduction of disease.

(g) The owner of all sheep or goats resulting from embryos or oocytes imported under this section shall:

(1) Identify them at birth with a permanent official identification number consistent with the provisions of § 79.2 of this chapter; such identification may not be removed except at slaughter and must be replaced if lost;

(2) Maintain a record linking the official identification number to the imported embryo or oocyte including a record of the replacement of lost tags;

(3) Maintain records of any sale or disposition of such animals, including the date of sale or disposition, the name and address of the buyer, and the animal's official identification number; and

(4) Keep the required records for a period of 5 years after the sale or death of the animal. APHIS may view and copy these records during normal business hours.

(Approved by the Office of Management and Budget under control numbers 0579-0040 and 0579-0101)

33. Section 98.13 is amended by adding paragraph (c) to read as follows:

**§ 98.13 Import permit.**

\* \* \* \* \*

(c) Applications for a permit to import sheep and goat embryos and oocytes must include the flock identification number of the receiving flock and the premises or location identification number assigned in the APHIS National Scrapie Database; or, in the case of embryos or oocytes moving to a storage facility, the premises or location identification number must be included.

\* \* \* \* \*

**§ 98.15 [Amended]**

34. Section 98.15 is amended as follows:

a. In paragraph (a), introductory text, by removing the words “follows, except that, with regard to bovine spongiform encephalopathy, the following does not apply to bovines, cervids, or camelids” and adding the word “follows:” in their place.

b. In paragraph (a)(1)(i), by removing the words “Bovine spongiform encephalopathy, contagious” and adding the word “Contagious” in their place.

c. In paragraph (a)(2)(i), by removing the words “Bovine spongiform encephalopathy, contagious” and adding the word “Contagious” in their place.

d. In paragraph (a)(7)(i)(A), by removing the words “Bovine spongiform encephalopathy, brucellosis” and adding the word “Brucellosis” in their place.

e. In paragraph (a)(8)(i)(A), by removing the words “Bovine spongiform encephalopathy, brucellosis” and adding the word “Brucellosis” in their place.

35. Section 98.30 is amended by adding, in alphabetical order, a definition for “Establishment” to read as follows.

**§ 98.30 Definitions.**

\* \* \* \* \*

Establishment. The premises in which animals are kept.

\* \* \* \* \*

36. Section 98.35 is amended as follows:

- a. Paragraph (e)(1)(ii) is removed and paragraphs (e)(1)(iii) and (e)(1)(iv) are redesignated as paragraphs (e)(1)(ii) and (e)(1)(iii), respectively;
- b. Newly redesignated (e)(1)(iii) is revised;
- c. New paragraph (e)(1)(iv) is added;
- d. Paragraph (e)(3) is revised; and
- e. Paragraphs (e)(4) and (5) are added.

The revisions and additions read as follows:

**§ 98.35 Declaration, health certificate, and other documents for animal semen.**

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

(iii) The donor animal is not, nor was not, restricted in the country of origin, or destroyed, due to exposure to a TSE.

(iv) Any additional certifications or testing requirements established by APHIS, based on genetic susceptibility of the semen donor, and/or on scrapie testing of the donor or semen, will be

listed in the APHIS import permit. Such certifications or required test results must also be recorded on the health certificate accompanying the semen.

\* \* \* \* \*

(3) Sheep and goat semen may only be imported for transfer to recipient females in the United States if the flock or herd in which recipients reside is listed in the National Scrapie Database; except that APHIS may permit importation of sheep and goat semen to an APHIS-approved storage facility where they may be kept until later transferred to recipient females in a flock or herd in the United States that is listed in the APHIS National Scrapie Database, and under such conditions as the Administrator deems necessary to trace the movement of the imported semen. Imported sheep or goat semen that is not otherwise restricted by the conditions of an import permit may be transferred from a listed flock or herd to any other listed flock or herd or from an approved semen storage facility to a listed flock or herd or another approved semen storage facility with written notification to the responsible APHIS Veterinary Services Service Center.

(4) The importer, the owner of a recipient flock or herd to which delivery of the semen is made, or the owner of an APHIS-approved semen storage facility must maintain records of the disposition (including destruction) of imported or stored semen for 5 years after the semen is transferred or destroyed. These records must be made available during normal business hours to APHIS representatives on request for review and copying.

(5) The owner of all sheep or goats resulting from semen imported under this section shall:

(i) Identify them at birth with a permanent official identification number consistent with the provisions of § 79.2 of this chapter; such identification may not be removed except at slaughter and must be replaced if lost;

(ii) Maintain a record linking the official identification number to the imported semen, including a record of the replacement of lost tags;

(iii) Maintain records of any sale or disposition of such animals, including the date of sale or disposition, the name and address of the buyer, and the animal's official identification number; and

(iv) Keep the required records for a period of 5 years after the sale or death of the animal.

APHIS may view and copy these records during normal business hours.

\* \* \* \* \*

Done in Washington, DC, this 12<sup>th</sup> day of July 2016.

Edward Avalos,

Under Secretary for Marketing and Regulatory Programs.

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