DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 92, 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, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of animals and animal products to revise 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 removing BSE-related import restrictions on sheep and goats and most of their products, and adding import restrictions related to transmissible spongiform encephalopathies for certain wild, zoological, or other non-bovine ruminant species. The conditions we are adopting for the importation of specified commodities are based on internationally accepted scientific literature and will generally align our regulations with guidelines established in the World Organization for Animal Health's Terrestrial Animal Health Code.

DATES: Effective January 3, 2022.

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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 considered a risk for BSE. The current regulations allow only the importation of non-pregnant slaughter or feeder sheep under 12 months old from Canada, certain products from sheep and goats, and sheep and goat semen. We are amending the regulations to remove BSE-related import restrictions on sheep and goats and most of their products because they are no longer warranted, and to add import restrictions related to transmissible spongiform encephalopathies (TSEs) for certain wild, zoological, or other non-bovine ruminant species because those animals pose a risk of introducing or spreading BSE or other TSEs.

The conditions we are adopting for the importation of sheep and goats and their products are based on internationally accepted scientific literature and are generally consistent with World Organization for Animal Health (OIE) guidelines. We are taking this action after conducting a thorough review of relevant scientific literature and a comprehensive evaluation of the issues [1] and concluding that the changes to the regulations will continue to guard against the introduction of transmissible spongiform encephalopathies 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 title 9, chapter I, 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 removing BSE-related import restrictions on sheep and goats and the products derived from them. We are also adding 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 final rule's impact would stem from its effect on U.S. imports of the affected commodities. Assuming an increase in imports of 3,165 metric tons (MT) in a net trade welfare model, we project 1.5 percent decrease in wholesale prices and a fall in domestic production of 878 MT. We estimate consumption would increase by 2,287 MT. As a result, producer welfare decline by about $8.7 million and U.S. consumer welfare would increase by about $23.7 million, yielding an annual net welfare benefit of about $15.1 million.

The rule has the potential to expand the U.S. export market, to the extent that it influences changes in our trading partners' import policies. Because predicting if and when other countries will make changes to their trade policies is highly speculative, our analysis assumes no trade policy changes by foreign countries as a result of the rule and therefore no impact on U.S. exports.

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 byproducts. The exceptions are cervids and camelids, and their products, which are not subject to BSE-related restrictions. 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

[1] To view the supporting scientific documentation, other supporting documents, the proposed rule, and the comments we received, go to *https://www.regulations.gov* and enter APHIS–2009–0095 in the Search field. In the supporting scientific documentation, the list of scientific literature referenced begins on page 17.

Canada, provided that the sheep and goats are under 12 months of age and are not pregnant.

APHIS has had import restrictions related to BSE since 1991 for live ruminants and most ruminant products. In a final rule published in the **Federal Register** on December 4, 2013 (78 FR 72980–73008, 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. However, that rule did not address BSE-related restrictions on domesticated sheep and goats. We therefore believe that further refinement of the regulations is in order given the latest scientific information regarding BSE transmission in sheep and goats.

Scientific Basis

The protective measures APHIS has taken against BSE have evolved over the years, as scientific understanding of the disease has changed. When the BSE regulations were codified on April 30, 1991 (56 FR 19794–19796, Docket No. 90–252), they applied to all ruminants.

Over the past three decades, however, extensive research has been conducted regarding BSE transmissibility for various ruminant species. Based on the information 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.

This scientific information is as follows: Experiments dating back to shortly after the issuance of the regulations 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, naturally occurring BSE has not been identified in sheep, and has only been documented in two goats, as a result of retrospective surveillance studies. Both goats were born prior to our initiation of extended ruminant feed bans, and ongoing surveillance has not shown evidence that BSE is circulating within domestic sheep and goat populations. Therefore, the science suggests that import restrictions for sheep and goats based on BSE, other than general prohibition on processed ruminant proteins and products containing them for use as ruminant feed, are not warranted to address BSE risk.[2] (We discuss the scientific background for removing or revising particular restrictions below in the context of specific changes to the regulations.) APHIS has continued to monitor the scientific literature regarding BSE transmissibility in sheep and goats under conditions other than experimental inoculation and no contravening literature has been published. Additionally, no evidence has emerged to indicate that BSE is circulating in domesticated sheep and goats.

Based on the evidence cited above, which was described at greater length in the proposed rule and the supporting scientific documentation that accompanied it, 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.[3] Conversely, small ruminants can transmit another TSE, scrapie, and scrapie-specific restrictions are warranted.[4]

Therefore, on July 18, 2016, we published in the **Federal Register** (81 FR 46619–46639, Docket No. APHIS–2009–0095) a proposal [5] 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 proposed to remove BSE-specific prohibitions and restrictions, and, in their place, establish a framework for evaluating foreign regions and, as warranted, foreign flocks for scrapie status.

We solicited comments concerning our proposal for 60 days ending September 16, 2016. We received 53 comments by that date. They were from sheep and goat producers, importers, private citizens, and representatives of State and foreign governments. Most of the commenters were generally supportive of the proposed rule, but some asked questions or expressed concerns about some of the provisions.

We describe the changes we proposed below, and whether we received any comments regarding them. We then discuss the comments that we did receive, by topic.

Before going through the changes that we proposed, however, we believe that it is important to note that the primary regulations that we proposed revisions to were those governing the importation of animals, meat, and other animal products into the United States, which 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 93.405 contains BSE-specific requirements for health certificates for sheep and goats intended for importation. 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 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. 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) as having BSE, unless certain conditions are met.

While these regulatory provisions, which contain BSE-specific restrictions and prohibitions on the importation of small ruminants and their products, were those primarily addressed by the proposed rule, the changes that we proposed to these sections necessitated proposing a number of smaller, harmonizing changes throughout the regulations. Therefore, for the sake of completeness, we now discuss all of the changes that we proposed. We present these sequentially, except when the various provisions work in consort and a thematic discussion is therefore warranted.

[2] A fuller discussion of the scientific information in support of the proposed rule is found in the supporting scientific documentation that accompanied that rule. See footnote 1.

[3] 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, the consumption of which can result in BSE transmission. For these reasons, we continue to restrict the importation of these commodities.

[4] An extensive discussion of the transmissibility of scrapie is found in our prior proposed and final rules to revise our domestic scrapie regulations, and their supporting documents. To view these documents, go to *https://www.regulations.gov/docket/APHIS-2007-0127.*

[5] See footnote 1.

§ 93.400, Definitions

We proposed to revise definitions for *designated feedlot* and *flock.* We proposed to change the definition of *designated feedlot* to reference scrapie-related restrictions rather than BSE-related restrictions. We proposed to expand the definition of *flock* to include goats as well as sheep. We also proposed to remove the definition of *suspect for a transmissible spongiform encephalopathy* because that term would no longer appear in the regulations. We received no comments on these changes and they will not be discussed further in this document.

We also proposed to add definitions for terms that are currently not defined in the regulations. Specifically, we proposed to define *certified status, classical scrapie, flock of birth, flock of residence, killed and completely destroyed, non-classical scrapie, transmissible spongiform encephalopathies (TSEs),* and *TSE-affected sheep or goat.* We received no comments on these changes and they will not be discussed further in this document.

We proposed to define *country mark* to distinguish this mark from other forms of identification, such as eartags or backtags, that might be used on an animal. We also proposed 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 received no comments on the definition itself, but did receive comments on the proposed use of country marks for imported sheep and goats. The comments are discussed below.

We proposed to 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 received comments on these definitions and discuss them below.

§ 93.401, General Prohibitions; Exceptions

As noted above, § 93.401 of the regulations contains general prohibitions on the importation of ruminants. We proposed to amend this section by revising the second sentence, which prohibits the importation of non-bovine ruminants that have been in regions listed in § 94.24(a). (Section 94.24(a) currently contains a list of regions in which BSE is known to exist, but is being removed because this blanket prohibition was no longer needed since we were proposing to allow the importation of small ruminants from BSE-affected regions of the world.) We also proposed to amend the second sentence of § 93.401 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.

We received comments on these changes to § 93.401 and discuss them below.

§ 93.404, Import Permits for Ruminants

We proposed to specify additional information that an importer would have to submit with the application for an import permit for sheep and goats for immediate slaughter or restricted feeding for slaughter. 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 also is needed to clarify that these animals are in, and are not to be removed from, slaughter channels. We also proposed to require additional information for sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter. 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 received some questions about these requirements. We respond to them below.

We also proposed to add a new paragraph to this section to address mitigation measures to allow the importation of zoological ruminants. This change, and the scientific basis for it, are discussed at greater length below under the heading ''Zoological Ruminants.'' We received comments on this change and will discuss them below.

Last, we proposed to 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. We received several questions about this provision. We respond to them below.

§ 93.405, Health Certificate for Ruminants

We proposed to revise the requirements for health certificates for sheep and goats to remove BSE-specific requirements. The requirements that we proposed included some information that was previously required; however, that information is relevant to animal diseases other than BSE and could not be removed. We also proposed to remove certain additional requirements for health certificates for sheep. We received no comments on these changes and will not discuss them further in this document.

§ 93.406, Diagnostic Tests

We proposed a minor harmonizing change to this section due to our proposed removal of § 93.419, which we discuss immediately below. We received no comments on this change and will not discuss it further in this document.

§ 93.419, Sheep and Goats From Canada

We proposed to remove and reserve this section, and move provisions for the importation of sheep and goats from Canada to § 93.435. We received no comments on this change and will not discuss it further in this document.

§ 93.420, Ruminants From Canada for Immediate Slaughter Other Than Sheep and Goats

Paragraph (a) of this section referred to the provisions regarding sheep and goats for immediate slaughter in § 93.419. We proposed to update the reference because we proposed to move these provisions to § 93.435. We received no comments on this change and will not discuss it further in this document.

§ 93.424, Import Permits and Applications for Inspection of Ruminants (From Mexico)

The regulations in this section 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 proposed to revise the requirements in this section 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 United States/Mexico border. We proposed to remove this exemption for small ruminants not intended for immediate slaughter because we need the information from the import permit to conduct a traceback investigation in the event of a disease outbreak. We received no comments on these proposed changes and will not discuss them further in this document.

§ 93.428, Sheep and Goats and Wild Ruminants From Mexico

We proposed to revise this section to refer to the scrapie provisions in § 93.435, which would apply to sheep and goats from anywhere in the world, including Mexico. We received no comments on this change and will not discuss it further in this document.

§ 93.435, Sheep and Goats

We proposed to revise this section to contain provisions for importing sheep and goats from anywhere in the world. We proposed provisions for sheep and goats imported for immediate slaughter or restricted feeding for slaughter, and provisions for other intended purposes.

The provisions for sheep and goats imported for immediate slaughter and restricted feeding for slaughter that we proposed are similar to the requirements for sheep and goats imported for those purposes from Canada, which had been contained in § 93.419. In other words, we proposed to make the provisions, which had been Canada-specific, broadly applicable to ruminants from anywhere in the world.

We also proposed to update the requirements for importing sheep and goats for other purposes, which had been contained in § 93.435. Because we proposed to remove the general prohibition on importing small ruminants from BSE-affected regions in § 93.401, we proposed to make the requirements here 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 change was intended to work in tandem with the proposed revision to § 93.401 to allow for the importation of animals that are very low risk for scrapie due to their genotype or other factors, in the absence of a general BSE-specific prohibition. We received some comments on these changes and discuss them below.

We also proposed to 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 approach is similar to the method we use to recognize disease status for other diseases. It would also allow more timely changes to the list than if we had to do it through rulemaking, as we do now. We received several comments on the implementation of this approach and discuss them below.

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 proposed 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 that we proposed are similar to those that already exist in § 94.15.

We proposed that 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. We also proposed that § 95.15 would be removed. Finally, we proposed to remove references in parts 94 and 95 to §§ 94.27 and 95.15.

We received no comments on these changes and will not discuss them further in this document.

Sheep and Goat Products

The regulations in 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 proposed to amend parts 94, 95, and 96 of the regulations to remove the current BSE provisions regarding sheep and goats. In the following sections, we identify those sections and paragraphs from which regulatory text relating to BSE and sheep and goats would be removed.

As we mentioned previously in this document, § 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.

We proposed to remove §§ 94.24 and 94.25. We also proposed 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.

We received no comments on these changes and will not be discussing them further in this document.

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.

Section 95.1 contains definitions of terms used in the part. We proposed 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 would no longer appear in the regulations. We received no comments on these changes and will not be

discussing them further in this document.

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 proposed amending this section first by revising the section heading to remove the exception for certain tallow derivatives. We are also revising paragraph (b)(1) to remove the exception for tallow derivatives from that paragraph. We proposed 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. We received no comments on these changes and will not be discussing them further in this document.

In paragraph (c) of § 95.4, we proposed to remove the reference to paragraph (a)(4) from paragraph (c)(1)(iv), and to remove paragraphs (c)(2) and (3) entirely. These revisions would collectively remove BSE-related restrictions from these products when derived from sheep and goats.

We also proposed to amend paragraphs (c)(1)(ii) and (iv) to clarify that the material that is imported must not be ineligible for importation under the conditions of § 95.5 of the regulations. Section 95.5 contains our restrictions on the importation of processed animal protein to address possible BSE risk; as we mentioned previously in this document, consumption of processed animal protein is a viable pathway for the transmission of BSE.

This was a clarification rather than a new requirement; 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. We also proposed to redesignate paragraphs (c)(4) through (8) as paragraphs (c)(2) through (6), respectively. We received no comments on these changes and will not be discussing them further in this document.

In newly redesignated paragraph (c)(3), we proposed amending 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 continue to require inspections for facilities that process or handle processed animal proteins.

We received no comments on this change and will not be discussing it further in this document.

Paragraphs (d) and (e) in § 95.4 contain restrictions on serum, serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ovines and caprines due to BSE. We proposed 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.

We received no comments on these changes and will not be discussing them further in this document.

Paragraph (g) contains restrictions on offal derived from ovines and caprines. These restrictions are no longer warranted and paragraph (g) would be removed. We received no comments on this change and will not be discussing it further in this document.

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 proposed to remove § 95.40. We received no comments on this change and will not be discussing it further in this document.

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 proposed to 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 received no comments on this change and will not be discussing it further in this document.

Sheep and Goat Germplasm

The regulations in part 98 govern the importation into the United States of germplasm (embryos and semen), including germplasm from sheep and goats.

Subpart A sets forth requirements for ruminant and swine embryos from regions free of foot-and-mouth disease (FMD), and for embryos of horses and asses.[6] Subpart B sets forth requirements for ruminant and swine embryos from regions where FMD exists. Subpart C sets forth the requirements for the importation of animal semen from species regulated by APHIS.

The regulations in § 98.10a require that embryos from sheep in regions other than Australia, Canada, and New Zealand may be imported only under certain conditions that serve to protect against the introduction of TSEs into the United States. 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 proposed to add provisions for goat embryos and both sheep and goat oocytes to the regulations in § 98.10a. Specifically, we proposed to revise the section heading to read ''Sheep and goat embryos and oocytes.'' We also proposed to add a definition of *oocyte* consistent with international standards. We received no comments on these changes and will not be discussing them further in this document; however, we did receive other comments on the requirements for imported embryos and oocytes and discuss them below.

We proposed to allow the importation of in vivo-derived sheep and goat

[6] At the time the 2016 proposed rule was published, these regulations also governed the importation of ruminant and swine embryos from regions where rinderpest exists. Since then, rinderpest was removed from the regulations in a final rule published on April 11, 2018 (83 FR 15491–15495) because the disease has been eradicated worldwide. Therefore, we will not be referring to rinderpest in this document. To view the rule removing rinderpest from the regulations, go to *https://www.regulations.gov/document/APHIS-2017-0070-0001.*

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. We received some comments on these changes and will discuss them below.

We proposed that 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 proposed 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 received comments on these changes and will discuss them below.

We also proposed 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 proposed making this change because the scientific literature demonstrates that embryos are low risk for scrapie transmission. APHIS has determined that requiring all first-generation offspring to be maintained in an SFCP flock is unnecessary as well as overly burdensome on importers.

Instead, we proposed to 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 also proposed to 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) Service Center. To be listed in the National Scrapie Database, a flock owner must contact the local VS Field Operations (FiOps) office for the receiving State 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 FiOps 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 FiOps office, contact the State or Territory Point of Contact (POC). A list of POCs can be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/contact-us.*

We received no comments on these changes and will not be discussing them further in this document.

Finally, we proposed to 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. We received no comments on this change and will not be discussing it further in this document.

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 micromanipulated embryos except as provided under § 98.10. We stated that we intended 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.

We received no comments on this explanation of the interaction between the two sections and will not be discussing it further in this document.

The regulations in § 98.13 provide requirements for import permits for ruminant and swine embryos from regions where FMD exists. We proposed 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 proposed this change to ensure that the permit requirements for sheep and goat embryos and oocytes from regions where FMD exists are consistent with the requirements for sheep and goat embryos and oocytes from regions that are free of the disease. We received no comments on this change and will not be discussing it further in this document.

The regulations in § 98.15 set forth the requirements for ruminant and swine embryos from regions where foot-and-mouth disease exists. 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 proposed 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. We received no comments on this provision and will not be discussing it further in this document.

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 proposed to remove 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. We received no comments on this provision and will not be discussing it further in this document.

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 proposed 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. We received no comments on this provision and will not be discussing it further in this document.

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 proteins 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).

More 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 proposed to amend § 98.35 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 to redesignate the subsequent paragraphs. We also proposed 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 proposed to add a new paragraph to allow APHIS to establish testing requirements for semen and/or semen donors. We received no comments on these changes and will not be discussing them further in this document.

We also proposed 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 proposed to add new paragraphs 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. We received no comments on these provisions and will not be discussing them further in this document.

We now discuss the comments that we did receive, by topic.

Importation of Live Ruminants

We proposed to amend § 93.404 to specify additional information that an importer would have to submit with the application for an import permit for sheep and goats. For sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter, we proposed to require that, 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 also proposed to 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 NVSL or another laboratory approved by the Administrator.

One commenter stated that sheep entering the United States from other countries should be held to the same set of rules and regulations as flocks at the Export Certified level in the U.S. SFCP (described in the regulations in 9 CFR part 54) in the United States. The commenter also stated that sheep should not be allowed to enter the country based solely on codon test results.

We agree with the commenter that the same level of risk mitigation should be required for imported sheep and goats as required by the Export Category of the U.S. SFCP. However, we disagree that genotype should not be used to mitigate risk associated with imported sheep. As we explained in the supporting scientific documentation that accompanied the proposed rule, resistance to classical scrapie is consistently associated with the presence of alanine (A) at codon 136, arginine (R) at codon 154, and R at codon 171. Sheep homozygous for this combination appear almost completely resistant to classical scrapie under natural conditions. Female sheep with RR at codon 171, or male sheep either with RR at codon 171 or with AA at codon 136 and QR at codon 171, are no more likely to transmit classical scrapie than sheep meeting the requirements of the Export Category of the U.S. SFCP.

We proposed to remove BSE-related restrictions from goats as well as sheep. Four commenters stated that there is neither sufficient published literature nor large enough surveillance sampling to draw the conclusion that there is no BSE risk in goats. The commenters stated that surveillance for goats needs to be expanded in the national scrapie eradication program and APHIS should recommend that trading partners expand their TSE surveillance for goats so good decisions may be made regarding safe trade. The commenters further stated that APHIS should publish another proposed rule regarding goats specifically when APHIS is able to demonstrate and cite evidence documenting BSE restrictions on goats should be removed.

As we explained in the supporting scientific documentation accompanying the proposed rule, naturally occurring BSE has only been documented in two goats, as a result of retrospective surveillance studies. Both goats were born prior to the initiation of extended ruminant feed bans, and ongoing surveillance has not shown evidence of BSE circulating within domestic sheep and goat populations. Experience internationally in countries with BSE has demonstrated that feed bans are effective control measures and the incidence of BSE worldwide continues to decline because of these measures. Furthermore, we will require that any goat imported into the United States either comes from a region recognized by APHIS as free of classical scrapie or has reached and maintained certified status in a SFCP determined by APHIS to provide equivalent risk reduction as the USDA APHIS Export Category of the SFCP. The requirements for APHIS to determine classical scrapie-free status and for equivalent status for scrapie flock certification programs in an exporting region are set out in the APHIS guidance document accompanying the proposed rule,[7] and includes the flock meeting the requirements equivalent to the Export Certified status of the U.S. SFCP while participating in a program under the supervision of the national veterinary authority of the region of origin. This equivalency must be determined by APHIS evaluation. We also require that the feeding of meat and bone meal, greaves, or similar materials of ruminant origin to sheep and goats is banned and has been effectively enforced in the region for at least 7 years.

As discussed previously in this document, we proposed a requirement for additional information that an importer would have to submit with the application for an import permit for sheep and goats. One commenter stated the proposed rule seemed to require an import permit, but currently, all other livestock exports from Canada to the United States are completed with only an export certificate or a less complex requirement, if the animals are entering the United States via a land port. The commenter asked for Canada and the United States to enter into a bilateral agreement to remove the requirement for an import permit for live sheep and goats and replace it with an export certification.

In § 93.417, paragraph (a) specifies that for ruminants imported from Canada, the importer must apply for and obtain an import permit as provided in § 93.404. An exception to the permit requirement is provided for certain ruminants, including wethers and sheep or goats imported for immediate slaughter, if those ruminants are offered for entry at a land border port, and provided certain other conditions are met. We did not propose to amend this section. A permit ensures collection of the additional information needed to determine the initial eligibility of animals for importation.

One commenter stated that it appears in cases of export of small ruminants for any purpose other than slaughter or feeding for slaughter, the export certificate required in § 93.405(b) will require an extensive amount of information including transport route, port of entry, and, most notably, all premises on which the animal has resided throughout its life. The commenter asked us to explain the need for this documentation.

The documentation is needed to ensure animals have been kept in holdings complying with § 93.405(b) and (c), equivalent to the Export Category of the U.S. Scrapie Flock Certification Program. This certification requirement is incorporated to address the potential risks of other premises where the donor animals resided which were not of equivalent status.

We proposed to define *country mark* as ''a permanent mark approved by the Administrator for identifying a sheep or goat to its country of origin.'' We proposed this definition to distinguish this mark from other forms of identification, such as eartags or backtags, that might be used on an

[7] See *https://www.regulations.gov/document/APHIS-2009-0095-0005.*

animal. We also proposed to require the use of country marks for sheep and goats imported for purposes other than immediate slaughter or restricted feeding for slaughter because these other purposes are not terminal, and 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.

One commenter stated that the proposed changes do not address the requirement for animal branding. The commenter claimed that current requirements for cattle branding are not enforced consistently at different border ports, creating trade barriers and expressed concern that branding requirements for sheep and goats exported for feeding prior to slaughter may present similar trade barriers. The same commenter and four other commenters also noted the proposed rule required a permanent country mark for all imported live sheep and goats. The commenters stated branding is not common practice in the sheep and goat industries and has been raised as a significant issue for the humane treatment of these animals. The commenters asked APHIS to provide an alternative option to branding, where possible.

APHIS notes that we proposed in § 93.435(a)(3) to require imported sheep and goats to be permanently identified with a country mark using a means and in a location on the animal approved by the Administrator, but we did not specify any particular method of identification. We may approve methods other than hot iron branding to permanently identify animals; however, no consistently effective alternative methods exist currently. The revisions that we proposed were simply to allow for their development, should it occur.

This requirement is similar to the requirements for bovines from Canada, which must be permanently identified with a brand, ear tattoo, or other means deemed acceptable by the Administrator. This permanent identification allows APHIS to trace an animal back to the country of origin in the event the animal shows symptoms of a TSE. Because many forms of eartags are not tamper-evident and may be lost or removed and reused, we generally do not consider eartags a permanent form of identification. We are not aware of these requirements resulting in barriers to trade.

We proposed to require that health certificates for imported sheep and goats include the official individual sheep or goat identification applied to the animals. One commenter asked what would be required as official identification, particularly for goats. The commenter noted that in Canada, all sheep are currently required to be tagged with an official Canadian government radio frequency identification (RFID) device when they leave the farm of origin, but goats are not required to be tagged. However, for the voluntary scrapie flock certification program, animals must only carry two unique forms of identification while on farm, but neither of those identification methods is required to be the Canadian official RFID. The commenter asked if APHIS would recognize this as acceptable identification.

APHIS will require official Canadian RFID eartags for goats and sheep imported from Canada and this will be specified in guidance published on APHIS' website. Sheep and goats imported for purposes other than immediate slaughter will also require a permanent mark unless maintained as a segregated group in a designated feedlot.

One commenter noted that under proposed § 93.435(b), officials of the country of origin would be required to seal conveyances at the point of departure for animals going directly to slaughter or feeding for slaughter. The commenter asked why this is different from the requirements for cattle, where seals are placed at the port of entry by U.S. inspection staff.

The commenter is correct in identifying a discrepancy between the treatment of cattle going directly to slaughter or restricted feeding for slaughter and our proposed requirements for sheep and goats going directly to slaughter or restricted feeding for slaughter. This was an oversight in the proposed rule and there is no technical basis for such a discrepancy. The requirement that conveyances carrying sheep and goats for immediate slaughter be sealed at the point of departure is a BSE-related restriction and is no longer warranted. We have amended § 93.435(b) to remove this restriction.

One commenter stated that while the proposed § 93.435(e) addresses provisions for transit through the United States, it does not seem to address the possibility of a rest stop should the duration of travel be excessive.

Under the 28-Hour Law (49 U.S.C. 80502), rest stops are required for animals being transported in the United States. Section 93.401(b) of the regulations sets out the conditions under which rest stops for ruminants may occur. We did not propose any changes to those provisions.

In proposed § 93.435(f), we set out the process by which we would recognize regions as free of classical scrapie. One commenter asked what criteria would be used to determine whether a region is free of classical scrapie and if those criteria were consistent with World Organization for Animal Health (OIE) guidelines. The commenter noted three European Union (EU) Member States have met EU criteria to be considered negligible risk for classical scrapie, and asked whether, given the EU criteria were the same as the OIE, EU Member States could be recognized (or receive an expedited review) as free of classical scrapie by the United States.

The criteria for classical scrapie-free country status were described in the guidance document published with the proposed rule. The criteria are consistent with OIE guidelines and include the existence of a system of effective official veterinary control and oversight within the region for at least 7 years, a program of targeted surveillance and monitoring for classical scrapie in place for at least 10 years, and a ban on feeding to sheep and goats of meat and bone meal, greaves, or similar materials of ruminant origin that has been effectively enforced in the region for at least 7 years, among other requirements. EU Member States will be reviewed in accordance with § 92.2 of the regulations using the criteria in the guidance document in the order in which complete submissions are received.

One commenter asked why, for imports based on the scrapie status of the flock of origin, the certification program of the country must be approved by APHIS. The commenter asked APHIS to consider, as recommended by OIE, including in its import health certificate requirements criteria that are equivalent to the OIE's criteria for ''scrapie free establishments'' and accept imports based on the certification that these criteria have been met.

We cannot accept imports solely on certification that OIE requirements have been met. The United States needs to ensure that proper oversights by the competent authority exist in the region of origin and that the program has been effectively implemented. Further, because the OIE guidelines do not specify a minimum number of animals that must be tested before a flock is certified, we believe that testing levels specified by OIE may not be sufficient to detect scrapie in a flock before it is certified as free.

One commenter asked whether APHIS could approve the EU scrapie status flock certification program as a whole, instead of requesting applications from each Member State. The commenter stated that the EU flock certification

program respects harmonized rules, laid down in Annex VIII to Regulation (EC) No 999/2001,[8] which follow OIE criteria for establishments free from scrapie, and require the Member State to maintain lists of holdings with negligible risk of classical scrapie based on those criteria. The commenter also stated that EU holdings listed as having a negligible risk of classical scrapie would be considered equivalent to 'Export Certified Flocks' in the United States and also meet the recommendations at Article 14.8.5 of the OIE Code. The commenter stated that, once APHIS considers and confirms this to be the case, documentation detailing all the holdings of residence or provenance since birth of sheep and goats intended for export to the United States should not be necessary or required.

We will review the EU scrapie status flock certification program when the first EU Member State applies. If the implementation by that Member State of the EU scrapie flock certification program requirements are determined to be equivalent to the United States' program requirements, subsequent Member State certification program reviews may be limited to an evaluation of the Member State's implementation of the EU scrapie status flock certification program and may take into consideration the prior APHIS determination of the EU scrapie flock certification program. We will not prejudge the results of any EU Member State's program evaluation in this final rule.

In the proposed rule, we proposed 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.

One commenter asked if the program in Canada, which is administered by Scrapie Canada but is overseen by the Canadian Food Inspection Agency (CFIA), and for which all inspections are performed by federally accredited veterinarians, would meet the requirements. The commenter noted that in the U.S. SFCP, Export Certified flocks receive a high level of monitoring, including annual inspections and inspection of all cull animals. The commenter stated that in Canada, cull animals are not inspected although records of sales are reviewed. On-farm adult mortalities are tested for scrapie by accredited laboratories. The commenter asked if this level of surveillance would be acceptable.

Countries should request evaluation of their certification program to have it officially recognized by APHIS as equivalent. We will not prejudge the results of any country's program evaluation in this final rule.

We proposed to allow sheep and goats for breeding to be imported in two ways. One way is for the animal to originate in a region recognized by APHIS as free of classical scrapie. The other is for the animal to reach and maintain certified status in a scrapie flock certification program determined to provide the same risk reduction as the Export Category of the U.S. SFCP. One commenter stated that Canada's voluntary scrapie free flock certification program has been designed based on OIE guidelines, with some exceptions based on equivalent risk outcomes. Canada's program differs in allowing flocks or herds to achieve certified status after 5 years of monitoring, whereas the OIE guidelines and the U.S. program require 7 years of monitoring. The commenter stated that the rule only considers a country's flock certification program guidelines and does not consider the impact of a country's national scrapie prevalence, or the presence of a national scrapie eradication program. The commenter stated that the very low national prevalence for scrapie and the CFIA's ongoing and robust national scrapie eradication program, in combination with strict flock certification program requirements, provide the confidence needed to certify flocks or herds as negligible risk after 5 years on the program.

Countries should request evaluation of their certification program to have it officially recognized by APHIS as equivalent. In recognizing equivalence, we will consider the possibilities that countries could apply additional or different mitigations to provide equivalent risk status as the U.S. program. We will not prejudge the results of any country's program evaluation in this final rule.

We proposed to allow for permits to be issued by the Administrator for sheep of certain classical scrapie-resistant genotypes, as determined by testing at the NVSL or another laboratory approved by the Administrator. One commenter expressed confusion about what will be expected for sheep tested for genetic markers of scrapie resistance. The commenter noted that the proposed rule states such sheep must meet all requirements for import other than the requirement that they originate in a flock or region free of classical scrapie. The commenter asked if this means sheep confirmed to carry the specified genes for scrapie resistance will not be required to be from a flock that is certified under the CFIA's Voluntary Scrapie Flock Certification Program (VSFCP). The commenter asked if this would apply uniformly to both males and females. The commenter also asked if importation of these genetically low-risk sheep would be at the discretion of the Administrator, *i.e.* on a case-by-case basis.

The provisions for the importation of genetically resistant sheep are in § 93.404(a)(6). Sheep permitted entry under these provisions are not required to come from a flock certified under a scrapie free certification program. However, as we explained in the proposed rule, only females that are genotype AARR, or males that are genotype AARR or AAQR, may be imported under this provision on a case-by-case basis at the discretion of the Administrator.

One commenter noted that in § 93.404(a)(6), we proposed to require that genetic testing be completed at the National Veterinary Services Laboratories or another laboratory approved by the Administrator. The commenter asked whether we would require these tests to be completed at a laboratory in the United States. The commenter also asked if a laboratory recognized by the CFIA for the VSFCP in Canada would be recognized, and if we would make a list of acceptable laboratories available.

APHIS will consider approval of foreign laboratories with the required expertise and where there are appropriate quality assurance procedures in place. In general, APHIS will consider approving laboratories that are approved by the competent veterinary authority of the national government of the exporting region, provided that region has a scientifically sound approval and oversight process in place for laboratories. Review of the degree of laboratory oversight in the country will occur in our overall evaluation of the country's scrapie program. If we approve foreign laboratories, this will be detailed in the import protocols designed for the importation of sheep/goats for specific countries/regions and the negotiated export health certificates. APHIS will need the approved laboratory results before import permit issuance, and the information will accompany export health certificates.

One commenter stated that the EU recognizes sheep with genotype ARR/

[8] The EU regulations can be viewed online at *https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001R0999&from=EN.*

ARR as genetically resistant. The commenter asked APHIS to take this into consideration for all sheep, not just those for research and diagnostics, when a permit is requested.

As we explained in the proposed rule, only females with genotype AARR or males with genotype AARR or AAQR may be imported under this provision. The reason for this restriction is that the OIE does not recognize the ARR/ARR genotype as genetically resistant to scrapie. Permits will still be required for animals with known genotypes which may be allowed if they meet other import requirements. The genotyping requirements are not specific to sheep for research/diagnostics.

We proposed to amend § 93.405(b)(2)(i) to require that the health certificate accompanying imported sheep and goats state that the sheep or goats originated from a region recognized as free of classical scrapie by APHIS, or that the animals had reached and maintained certified status in a scrapie flock certification program approved by APHIS. One commenter suggested that we amend this requirement to read ''or the animals have reached and maintained certified status in a scrapie flock certification program approved by APHIS or equivalent status.'' The same commenter also suggested amending § 93.435(d) in a similar fashion. The commenter stated these changes would accommodate holdings in the EU designated as negligible risk for classical scrapie.

Our intent is to recognize equivalent status in an equivalent program regardless of the name given to the status or to the program. For clarity, we will revise both paragraphs, paragraph (b)(2)(i) of § 93.405 and paragraph (d) of § 93.435, to read ''certified status or equivalent status in a scrapie flock certification program approved by APHIS.''

We proposed that sheep and goats entering ''terminal feedlots'' be required to be permanently identified. One commenter stated that while there is no scrapie transmission risk associated with lambs being fed for slaughter, on occasion ewe lambs do move out of feedlots and enter breeding flocks. The commenter stated that this poses an enforcement problem and an unnecessary risk since records and inspection are the only practical tools for assuring all animals in a terminal feedlot are either processed or terminated and are properly disposed of. The commenter stated that APHIS should require all imported sexually intact sheep and goats be permanently identified in a tamper-proof manner regardless of their age or intended use.

Since all imported animals require official identification, we presume the commenter is referring to the country marks exemption for animals kept segregated in feedlots as provided in § 93.435(a)(3). While there are circumstances where the Administrator may determine that a country mark is required for animals imported to terminal feedlots, we disagree that there is significant risk associated with animals properly handled within these terminal feedlots under APHIS oversight and restrictions that would necessitate all such animals having country marks as well as official identification.

One commenter recommended that APHIS place additional requirements on designated feedlots receiving imported animals from regions not free of classical scrapie for restricted feeding and eventual slaughter to include that there be no fence-line contact with other sheep or goats. The commenter stated that this could be accomplished by requiring at least a 30-foot fence separation or a solid-wall perimeter designed to prevent fluid transfer between animals in the designated feedlot and sheep or goats outside the feedlot. The commenter also stated that APHIS should also inspect and approve the designated feedlot's biosecurity provisions and practices to minimize the risk of TSE transmission between animals in and outside the designated feedlot.

We agree with the commenter. A designated feedlot may be a specified area within a larger facility that contains animals intended for subsequent movement from the facility. Additionally, scrapie may be spread through contact with bodily fluids such as nasal mucus, urine, saliva, and feces and therefore fence-line contact between imported animals in designated feedlots and other sheep or goats that could subsequently move from the facility could pose a risk of scrapie transmission. We have amended § 93.435 to include a new paragraph (c)(11)(viii) requiring the operator of the feedlot to prevent fence-line contact by a method acceptable to the Administrator. We will work with individual operators to determine the best means of preventing such contact in their feedlots.

One commenter asked that, in addition to recognizing the negligible risk that genotype AARR females pose in transmitting scrapie, APHIS also allow the import of genotype AAQR females under the same conditions. The commenter cited the limited risk genotype AAQR females pose, given the additional requirement that these animals must come from a flock known to be free of classical scrapie.

APHIS disagrees. In general, a glutamine (Q) at codon 171 of the PrP allele is associated with susceptibility to scrapie. AAQR scrapie-positive animals occur with some frequency.[9] AARR sheep imported under this provision of the proposed rule do not have to originate in scrapie-free flocks, only in flocks having no known risk for scrapie.

One commenter noted that for ruminant species that are not bovines, cervids, sheep, goats or camelids, the rule indicates a case-by-case approach will be used to mitigate TSE risk for zoological or wild ruminants considered for import. The commenter stated this approach works well in these unique situations but may be too burdensome for certain farmed alternative livestock (*e.g.,* water buffalo and yaks) posing an extremely low risk based on both reported susceptibility to TSEs and known feeding practices.

Farmed alternative bovid livestock (domestic water buffalo, *Bubalus bubalis* or domestic yak, *Bos grunniens*) that are not sheep or goats are recognized as very low risk for BSE, but unknown risk for other TSEs. An unknown risk should not be presumed to be a negligible risk, particularly when the diseases in question are degenerative and fatal. Accordingly, these species may be evaluated under a similar process as zoological ruminants on a case-by-case basis, or through protocols with detailed mitigations for import of these domestic bovid species.

Zoological Ruminants

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

[9] The genetics of scrapie resistance were discussed extensively in a rulemaking that amended the domestic scrapie regulations in 2019. To view the proposed and final rules, supporting materials, and comments we received, go to *https://www.regulations.gov* and enter APHIS–2007–0127 in the Search field.

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).

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 (*https://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. The precise measures APHIS considers necessary could vary on a case-by-case basis.

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.

Therefore, we proposed to add a new paragraph (a)(5) to the import permit provisions in § 93.404 to address such situations. The new paragraph provides 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 also proposed to require that importers seeking a permit pursuant to the paragraph must send their request by postal mail to the Administrator, c/o Strategy and Policy, 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 website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-permits.*

Several commenters raised concerns about the conditions for importation of zoological ruminants.

Four commenters stated that for true (traditional) zoo animals, the originally imported animals should stay in zoo confinement—that is, essentially quarantined—for life and only their progeny could move, provided there was the observed and/or tested absence of TSEs in the imported animals and the progeny.

APHIS generally agrees with the commenters, and it is our intent that the animals would remain under quarantine within a zoo for life. If an animal had to be transferred between zoos, the receiving zoo would need APHIS approval as a quarantine facility and would need to operate under a compliance agreement with APHIS. As we explained in the proposed rule, importation of zoological ruminants will be considered on a case-by-case basis. This includes a compliance agreement between APHIS and the zoo regarding how the animal will be maintained, including with cohorts and offspring, APHIS approval of any post-importation movement of the animal, proper notification upon death of the animal, post-mortem examination, and proper carcass disposal.

The same commenters stated, with regard to importing any zoological or wild animals into the United States other than to traditional zoos, that APHIS should consider this only after a whole country or region risk assessment has been done with a finding of negligible risk for TSEs and a proposal for public notice and comment be published.

We do not consider that a TSE risk assessment of the country or region of origin is warranted. As we explained above, the pathology and spread of TSEs associated with zoological ruminants vary from the pathologies of BSE in cattle and scrapie in domesticated sheep and goats, and there is not yet any evidence for TSEs in free-living zoological ruminants. The evaluations will be case-specific, and will focus on the TSE risk associated with each specific importation. We will evaluate herd and individual health histories for the animals, necropsy records maintained by the zoos and in large databases maintained by zoo organizations (such as the International Species Information System) and the ability of the zoo to quarantine the animals. We would have to reach a determination that it is possible to mitigate any TSE risk through post-export quarantine and movement regulation.

We proposed to define *goat* as ''any animal of the genus *Capra*'' and *sheep* as ''any animal of the genus *Ovis*.'' One commenter stated that classifying all species in the genus *Ovis* as sheep and all species in the genus *Capra* as goats for the purposes of importation and with regards to TSE requirements is overly cautious and puts unwarranted restrictions on wild members of the genera. The commenter stated that bighorn sheep (*O. canadensis*) from wild populations present a limited risk for the introduction of TSEs. The mitigation measures provided as examples would be impossible to apply to a free-ranging population. The commenter recommended factors such as the history of exposure to domestic sheep as well as other criteria be considered in the evaluation of requests for importation of bighorn sheep by wildlife management agencies.

The rule provides the flexibility necessary to assess each importation in light of the science known at the time, the risk factors associated with the area from which the animals are to be imported, and the risk factors associated with the animals themselves, including for imports of wild and free-ranging species, such as bighorn sheep.

One commenter stated that non-bovine ruminants, other than domestic sheep and goats, should be subject to import restrictions and concurred with APHIS that at least some animals in this category present enough of a potential risk of spreading TSEs that their importation should be prohibited, unless certain risk mitigation measures are in place. The commenter stated it is inappropriate to propose regulatory changes for zoological and wild ruminants in this rulemaking and that APHIS should withdraw the sections dealing with these animals and propose them in a separate rulemaking, if warranted.

APHIS disagrees that making changes to the regulations governing the importation of zoological and wild ruminants is inappropriate in this rulemaking. As we explained in the proposed rule, APHIS will consider the potential TSE risk for each proposed importation on a case-by-case basis and may deny entry if the risk presented is too great.

Sheep and Goat Germplasm

One commenter stated that sheep with genotype AARR are considered genetically resistant and the EU accepts semen of such sheep. Under EU regulations, if the donor is not genetically resistant, then the donor must belong to a holding listed as presenting at least a controlled risk of classical scrapie. The commenter asked that APHIS take this into consideration when a permit is requested.

We agree that semen from genotype AARR rams is genetically resistant to scrapie and should be accepted with minimal additional requirements; we have amended § 98.35(e) accordingly.

Five commenters stated that the risk of scrapie transmission via semen or embryos is very low and the genetic profile of rams for scrapie resistance may be even more important than country status. The commenters therefore asked APHIS to grant permit exemptions for semen collected from rams testing AARR and AAQR. The commenters stated that this change would result in the sheep semen import requirements being generally equivalent to the embryo importation requirements.

APHIS agrees with the commenters concerning the low risk of scrapie transmission from AARR and AAQR semen donors and we have amended § 98.35(e) accordingly.

One commenter stated that there should be no restrictions pertaining to scrapie for ovine in vivo-derived

embryos to be consistent with Article 4.7.14 of the OIE Code.

APHIS disagrees. As we explained in the supporting scientific documentation accompanying the proposed rule, although the scientific literature has supported classifying embryos collected in accordance with International Embryo Transfer Society guidelines as low risk with respect to scrapie transmission, the limited number of animals studied, and the lack of diversity of scrapie strains evaluated, make it appropriate to apply additional mitigations in order to reduce the likelihood embryos selected for export will be infected. These concerns also extend to the use of in vivo-derived sheep embryos, which the OIE classifies as unrestricted. Therefore, APHIS will also apply the OIE criteria for in vivo-derived goat embryos to in vivo-derived sheep embryos unless the embryo is of genotype AA at codon 136 and either RR or QR at codon 171. APHIS may also require additional testing for sheep and goat-derived oocytes and embryos (and their donor animals) originating from countries or regions not considered scrapie-free by APHIS.

One commenter noted that the proposed rule mentioned possible additional certification or testing requirements as established by APHIS for semen and embryos. The commenter stated that if this is to allow for flexibility as science progresses, they supported the provisions, but they would also appreciate further details and clarification if APHIS intends to add further certification and testing requirements immediately.

The commenter's interpretation is correct. The provisions in § 98.10a(c) are intended to address any new developments in scrapie testing, our understanding of embryo risk, or unforeseen situations. We have no plans to implement additional certification or testing requirements for semen and embryos at this time.

One commenter stated that in the EU, ARR/ARR homozygote or ARR heterozygote embryos are considered genetically resistant and may be traded regardless of the scrapie status of the donor flock. The commenter noted that the provisions in § 98.10a(b)(1)(ii) appear to allow this possibility. The commenter asked for clarification about what would be required under § 98.10a(c), which provides that any additional certifications or testing requirements will be specified on the import permit.

The commenter's understanding of § 98.10a(b)(1)(ii) is correct. We note that the requirements for additional certification and testing in § 98.10a(c) are the same as those in § 98.35; that is, these requirements are the same for both semen and embryos. APHIS notes most conditions are waived for genetically resistant embryos, but the statement that the donors were not affected by, or exposed to, a TSE is required for all embryos, even those that are genetically resistant.

One commenter stated that if embryos are not genetically resistant, then the EU requires that the donors belong to a holding designated as at least ''controlled risk'' for classical scrapie. The commenter noted § 98.10a(a) requires that the holding has a certified status equating to 'negligible risk' under EU TSE legislation. However, § 98.10a(b)(1)(iii) provides another option provided the country requirements and donor requirements can be met. The commenter asked for clarification that this arrangement would be considered acceptable by APHIS.

The commenter is correct; the provisions in § 98.10a(b)(1)(iii) allow for the importation of genetically susceptible embryos with additional certifications.

Issues Outside the Scope of the Rule

Two commenters were opposed to the importation of live animals because of concerns about humane treatment of the animals.

The humane treatment of regulated animals is outside the scope of this rulemaking.

One commenter stated that APHIS should also harmonize its other import regulations, especially those for FMD, with OIE standards to remove impediments to trade.

Amending our other import regulations, including those governing imports from regions where FMD exists, is outside the scope of this rulemaking.

One commenter asked for requirements for importation of cervids in regard to the presence or absence of TSEs to be included in the rules. The commenter noted that chronic wasting disease has been detected in moose and reindeer in Norway, a country that has conducted a low level of surveillance for a number of years. The commenter further stated that it is clear that the full-range of susceptible species has not yet been identified for this disease, in spite of more than 20 years of research.

Amending our import regulations regarding cervids is outside the scope of this rulemaking. We removed BSE-related restrictions from cervids in a final rule published in the **Federal Register** on December 4, 2013 (78 FR 72980–73008, Docket No. APHIS–2008–0010).[10]

Five commenters noted that we did not propose to prohibit the feeding of sheep and goat milk or milk products to ruminants in the United States. The commenters stated that this is a mistake because of the risk of scrapie transmission through these products. The commenters also stated that the importation of sheep and goat milk or milk products into the United States from scrapie-infected countries for sheep and/or goat feeding should be prohibited as recommended by the OIE and supported by the scientific literature. The same five commenters stated that the importation and feeding of blood and blood products from sheep and goats to sheep and goats from countries not free of scrapie and not at least negligible risk for BSE is a risk and should not be allowed. This is because blood and blood products are not covered under the U.S. Food and Drug Administration's (FDA) ruminant feed rule and therefore not covered under the processed animal protein restrictions as discussed in the proposed rule.

Provisions governing the importation of most milk and milk products are contained in §§ 94.2 and 94.16 of the regulations. We note that animal feed is within the purview of the FDA and that prohibiting the use of any products in animal feed is outside the scope of APHIS' regulatory authority.

Miscellaneous

In part 92, we are revising the Office of Management and Budget statement at the end of § 92.2 to add reference to the paperwork burden requirements associated with this final rule, which were filed under 0579–0453.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a not a 'major rule', as defined by 5 U.S.C. 804(2).

We have prepared an economic analysis for this rule. The economic

[10] To view the rule, the supporting documents, and the comments we received, go to *https://www.regulations.gov* and enter APHIS–2008–0010 in the Search field.

analysis provides a cost-benefit analysis, as required by Executive Order 12866, which directs 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). The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act.

This analysis examines impacts on U.S. entities of a rule that will remove BSE restrictions on the importation of live sheep and goats and most of their products. We are amending the import regulations for certain wild, zoological, or other non-bovine ruminant species by adding safeguards related to transmissible spongiform encephalopathies. The rule aligns our scrapie regulations in general with OIE guidelines and establish a notice-based approach for recognizing regions as free of scrapie. This action 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.

This rule's impact will stem from its effect on U.S. imports of the affected commodities. Consumer welfare gains from the increase in imports are expected to exceed producer welfare losses. While the rule will 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 non-bovine ruminant species received by zoos, but APHIS does not have information that would allow us to evaluate such impacts. Estimated net benefits of the rule are quantified in terms of increased imports of sheep meat and goat meat.

Over the past 5 years, 2016–2020, annual live sheep and goat imports averaged about 12,167 head, valued at a little over $800,000, and all of which came from Canada (see table 2). We do not anticipate a significant increase because of this rule in the number of sheep and goats imported.

U.S. imports of sheep and goat meat come almost entirely from Australia and New Zealand (see table 5), 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 increase in import quantities attributable to this rule is expected to be small in comparison to existing imports. We model three levels of additional sheep and goat meat imports: 1,582 metric tons (MT), 3,165 MT, and 4,747 MT. These quantities are equal to approximately 5, 10, and 15 percent of the sum of (i) average EU–27 sheep and goat meat exports to non EU–27 markets, 2016–2019 (*i.e.,* 26,251 MT, see table 8), and (ii) average sheep and goat meat exports to EU–27 countries by other eligible countries, 2016–2019, excluding Australia and New Zealand (see table 9) of 5,396 MT. In sum, this is the EU–27's external volume of trade of the above-mentioned commodities. The largest assumed quantity (*i.e.,* 4,747 MT) is equivalent to less than 2 percent of average annual U.S. sheep and goat meat consumption (*i.e.,* 193,839 MT) during this same time period (see table 4).

The medium level of assumed additional imports, 3,165 MT, would cause a decrease in wholesale prices of less than 1.5 percent and a fall in domestic production of 878 MT, whereas U.S. consumption would increase by 2,287 MT. U.S. producer welfare would decline by about $8.7 million and U.S. consumer welfare would increase by about $23.7 million, yielding an annual net welfare benefit of about $15.1 million (see table 10). 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 U.S. imports from existing sources, the price and welfare effects would be smaller than indicated; we note that over one-half of the U.S. market for sheep and goat meat is imported.[11]

The majority of establishments that may be affected by the rule are small entities, and economic impacts are likely to be small as well. If an additional 3,165 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 $67, or the equivalent of about 1 percent of average annual sales by small entities.

Introduction

This economic analysis examines impacts on U.S. entities for a rule that will change BSE and scrapie import and transit restrictions for sheep, goats, and non-bovine wild ruminants, their embryos, semen, and products. The rule will amend most of the BSE restrictions on the importation of live sheep and goats and their products; align our scrapie regulations in general with OIE guidelines and establish a notice-based approach for recognizing regions as free of scrapie; and 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 document provides a benefit-cost 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 potential net economic benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This document also examines the potential economic effects of the rule on small entities, as required by the Regulatory Flexibility Act, and possible cost savings.

When the BSE regulations were codified in 1991, they applied to all ruminants. Over the past two decades, however, extensive research on BSE has been conducted. Based on the information now available, it is not warranted to continue to prohibit or restrict the importation of sheep and goats and their products with regard to BSE, other than processed animal protein.

The revisions for scrapie will set restrictions for live animal importation that are generally consistent with those recommended by the OIE. For embryos of sheep and goats, APHIS will require the donor to be eligible for importation, genetically resistant, or tested and found negative for scrapie, and the sire to not be a suspect, scrapie-positive, or high-risk animal. The revisions will also allow importation of most sheep- and goat-derived material in imported feed or feed ingredients from countries that are scrapie-free.

This rule's expected impact stems from its potential effect on U.S. imports of the affected commodities. We begin the analysis with an overview of production and trade in sheep and goats and their meat by the United States and other countries. While the rule will allow imports of sheep and goats and their products without regard to a country's BSE status, we restrict the analysis to countries of negligible or

[11] USDA, National Agricultural Statistics Service (NASS), Sheep and Goats; Commodity Trade, United Nations Trade Data Base (HTS–0104): *https://comtrade.un.org.*

controlled BSE risk. Regions of unknown risk for BSE are likely as well to be of unknown risk for scrapie. Scenarios are modeled to evaluate the significance of potential changes in sheep and goat meat imports.

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. Potential net benefits of the rule are quantified in terms of increased availability of sheep and goat meat to U.S. consumers at competitive prices.

Overview of the Action and Affected Entities

U.S. Production and Trade of Sheep, Goats, and Their Products

The United States is not a major producer of sheep, and the sector has been in long-term decline for decades. The Nation's sheep inventory fell by 7 percent between 2010 and 2019 (from 5.62 million to 5.23 million head).

Over half of the U.S. produced sheep are raised primarily in western, southwestern and midwestern States, such as: California, Idaho, Montana, Wyoming, Texas, and South Dakota; and in the east, mainly in Vermont.

The U.S. meat goat industry is small, with the national inventory averaging, between 2016 and 2020, at 2.1 million head. The number of goats raised for meat production increased between 2016 and 2020 on average by about 13 percent. On average between 2016 and 2020 the U.S. goat inventory was around 2.1 million animals.

Goats are raised in many States, with major holdings in 10 States: Alabama, California, Georgia, Kentucky, Missouri, North Carolina, Oklahoma, South Dakota, Tennessee, and Texas, which account for 70 percent of the total.

TABLE 1—U.S. INVENTORY (IN 1,000 HEAD) OF LIVE GOATS BY CLASS

U.S. goat inventory by class	January 1, 2017	January 1, 2018	January 1, 2019	January 1, 2020	January 1, 2021	5-yr average
All Goat and kids	1,706	1,675	1,646	2,655	2,582	2,053
Market	409	400	409	478	465	432
Breeding	1,305	1,275	1,270	2,177	2,117	1,629

Source: USDA, NASS, Sheep and Goats (February 2021).

Between 2016 and 2020, Canada was the only foreign supplier of sheep and goats into the United States. Over these 5 years, the annual average U.S. imports of sheep and goats was 12,167 animals, valued on average at $801,383 (tables 2 and 3). In 2016, there was a notable increase in the number of imported sheep and goats. However, after that year, their numbers decreased substantially.

TABLE 2—U.S. NUMBER (HEAD) OF IMPORTED LIVE SHEEP (HS 010410) AND GOATS (HS 010420) BY COUNTRY

Country	2016	2017	2018	2019	2020	5-yr average
Canada	21,223	8,829	7,338	13,341	10,102	12,167
World	21,223	8,829	7,338	13,341	10,102	12,167

Source: Commodity Trade, United Nations Trade Data Base (HTS–0104) (*https://comtrade.un.org*)/.

TABLE 3—U.S. VALUE (US $) OF IMPORTS OF LIVE SHEEP (HS 010410) AND GOATS (010420) BY COUNTRY

Country	2016	2017	2018	2019	2020	5-yr average
Canada	1,641,000	497,437	402,884	817,565	648,029	801,383

Source: Commodity Trade, United Nations Trade Data Base (HTS–0104) (*https://comtrade.un.org/*).

In order for sheep and goats to be eligible to be imported into the United States, they have to be from scrapie-free flocks. Under the rule, sheep and goats from flocks having certified status (meeting requirements equivalent to the Export Certified status of the U.S. Scrapie Flock Certification Program) would be eligible for U.S. importation. Only two countries are recognized by the United States as being wholly free of scrapie: Australia and New Zealand.

With this rule, we do not anticipate a significant increase in the number of sheep and goats imported. The fact that Australia and New Zealand have ceased exporting sheep and goats to the United States in recent years supports this expectation. A major reason is the cost of transporting live animals.

Over the 5-year period, 2016–2020, the year average value of sheep and goats imported by the United States was around $801,000, as shown in table 3, was small in comparison to the value of $548 million per year in imported lamb, mutton, and goat meat. The quantity of U.S. imported lamb, mutton and goat meat supplies was over one-half of the U.S. consumption for these meats. Over the 2016–2020 period, lamb, mutton, and goat meat consumption grew from around 179,000 MT to over 195,000 MT, a 9 percent increase (table 4).

The amount of U.S. exports of lamb and mutton during this period when compared to U.S. imports of the same product accounts for only 5 percent. In terms of value, the difference is even greater since U.S. imports of lamb and goat meat consist of higher quality lamb cuts such as legs and loins, whereas it exports primarily lower quality cuts. Over one-half of U.S. lamb, mutton, and goat meat exports, 2016–2020, were to Mexico (40 percent), the Netherlands (10 percent), and Canada (7 percent).

TABLE 4—U.S. LAMB, MUTTON, AND GOAT PRODUCTION, IMPORTS, EXPORTS, AND CONSUMPTION

[2016–2020]

Year	U.S. production (MT)	U.S. imports (MT)	U.S. imports ($1,000)	U.S. exports (MT)	U.S. exports ($1,000)	U.S. consumption (MT)
2016	78,729	103,893	$785,801	3,381	$17,222	179,241
2017	74,491	122,078	978,335	3,849	20,377	192,720
2018	79,926	124,874	1,032,717	3,867	19,732	200,933
2019	77,316	127,150	1,149,380	4,104	19,448	200,362
2020	72,596	132,966	1,010,793	9,625	16,644	195,937
Average	76,595	122,192	991,405	4,965	19,448	193,839

Source: UN Commercial Trade Data (*https://comtrade.un.org*), USDA/ERS/Red Meat Production, and Consumption Statistics by meat categories, 2019; *https://www.ers.usda.gov/data-products/* Lamb, Mutton and Goat Meat Domestic Historical and Recent data, 2020.

Roughly 99 percent of U.S. imports of sheep and goat meat have been supplied by Australia (*i.e.,* 77 percent) and New Zealand (*i.e.,* 22 percent) during 2016 and 2020 (table 5).

TABLE 5—U.S. IMPORTS OF LAMB, MUTTON, AND GOAT MEAT BY COUNTRY OF ORIGIN IN MT

2014–2018

Country	2016	2017	2018	2019	2020	Average (2016–2020)
Australia	80,949	92,514	97,448	101,031	107,516	95,892
New Zealand	22,222	28,034	26,011	24,465	23,380	24,822
Rest of the World	723	1,530	1,415	1,654	2,070	1,478
TOTAL	103,894	122,078	124,874	127,150	132,966	122,192

Source: USDA/Foreign Agricultural Service (FAS), United Nations Commercial Trade Data (*https://comtrade.UN.ORG/*). *https://www.ers.usda.gov/data-products/* Lamb, Mutton, and Goat Meat Domestic Historical and Recent data, 2020.

The increasing U.S. demand for meats of goat as well as lamb is reflected in the increasing import levels. The volume of imported meats of goat, lamb, and mutton between 2016 and 2020 increased by 28 percent from 103,894 to 132,966 metric tons.

Production and Trade by Countries of Negligible-Risk or Controlled-Risk for BSE

This section presents information on sheep and goat inventories; lamb, mutton, and goat meat production; and trade of these animals and products by countries listed by OIE as having negligible- or controlled-risk for BSE. Tables 6 and 7 show the countries classified, as of September 2021, as having negligible BSE risk or controlled BSE risk. The lists include Australia, New Zealand, and Canada, the principal sources of U.S. imports of these commodities. Also included are EU–27 members and other countries that are potential sources of additional imports. (Source: *https://www.oie.int/en/disease/bovine-spongiform-encephalopathy/#uiid-2*).

TABLE 6—MEMBER COUNTRIES RECOGNIZED AS HAVING A NEGLIGIBLE BSE RISK *

Argentina	Hungary	Panama
Australia	Iceland	Paraguay
Austria	India	Peru
Belgium	Ireland	Poland
Bolivia	Israel	Portugal [7]
Brazil	Italy	Romania
Bulgaria	Japan	Serbia [8]
Canada	Korea (Rep. of)	Singapore
Chile	Latvia	Slovakia
Colombia	Liechtenstein	Slovenia
Costa Rica	Lithuania	Spain [9]
Croatia	Luxembourg	Sweden
Cyprus	Malta	Switzerland
Czech Republic	Mexico	The Netherlands
Denmark	Namibia	United States of America
Estonia	New Zealand	Uruguay
Finland [10]	Nicaragua	
Germany	Norway	

* In accordance with Chapter 11.4 of the *Terrestrial Code* OIE (September 2021) *https://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/.*

[7] Includes Azores and Madeira.

[8] Includes Excluding Kosovo administered under the United Nations.
[9] Includes Balearic Islands and Canary Islands.
[10] Includes Asland Island.

TABLE 7—OIE-MEMBER COUNTRIES RECOGNIZED AS HAVING A CONTROLLED BSE RISK**

Chinese Taipei. Ecuador.	France. Greece.	Ireland.

** In accordance with Chapter 11.4 of the Terrestrial Code of OIE (September 2021).

China (with the exclusion of Hong Kong and Macau) as of November 2013 is recognized as a country having one zone with negligible BSE risk. United Kingdom as of September 2016 is recognized as a country with two negligible BSE risk zones: England and Wales, and Scotland, according to Chapter 11.4 of the *Terrestrial Code*. For this analysis, we categorize potential sources into two groups: Countries that belong to the EU and all others. Trade information for the two groups of countries is presented in tables 8 and 9.

The EU–27 had on average between 2016 and 2020 annual inventories of 90 million sheep and 13 million goats.[12] Five countries (France, Greece, Italy, Romania, and Spain) accounted for 85 percent of the goat inventory and 80 percent of the sheep inventory.[13] Combined sheep and goat meat production in the EU–27 averaged about 926,000 MT during the same period.

As can be seen in table 8, between 2016 and 2019, live sheep and goats imported by EU–27 countries averaged around 716 animals. Almost all of these imports were sourced within the EU–27. Four countries (Italy, France, Greece, and Spain) accounted for over 70 percent of imports. Exports of live sheep and goats totaled over 2.67 million head. Three EU–27 countries (Romania, Spain, and France) accounted for 75 percent of the EU–27's sheep and goat exports.

TABLE 8—EXTERNAL TRADE FLOWS OF LIVE SHEEP AND GOATS (HS: 0104) AND THEIR MEAT (HS: 0204) BETWEEN THE EU–27 GROUP COUNTRIES WITH NEGLIGIBLE-BSE RISK OR CONTROLLED-BSE RISK AND THE NON EU–27 GROUP COUNTRIES

Year	Sheep and goats (numbers)		Meat of sheep and goat (metric tons)	
	Export	Import	Export	Import
2016	2,650,680	133	16,462	161,418
2017	2,496,323	714	29,873	140,283
2018	2,432,082	953	25,408	141,472
2019	3,117,174	1,065	33,261	112,070
Average	2,674,065	716	26,251	138,811

Data Source: *https://comtrade.un.org/*.

Table 8 shows that EU–27 countries as a group were net importers of sheep meat and goat meat with annual imports averaging between 2016 and 2020 around 139,000 MT, compared to their annual exports of 26.3 thousand metric tons. The yearly average number of EU–27 exports of live sheep and goats between 2016 and 2020 was approximately 2.7 million. EU–27 countries are net exporters of these animals, even though exporting live animals costs more than exporting their animal products (*i.e.,* due to higher transportation costs which include the cost of veterinarians accompanying animals in long distances to ensure their good health.)

New Zealand is the largest exporter of sheep and goats to the EU–27 countries followed by Australia and the South American countries of Chile and Argentina. Other non EU–27 countries that supply this group are Canada, Norway, Iceland, Switzerland, and Singapore (table 9).

New Zealand and Australia with about 90 percent of sheep and goat meat exports in their group are the dominant exporters. Excluding these two countries, because they are already the principal U.S. suppliers, the remaining countries in this group exported on average between 2016 and 2020 annually about 5,396 MT of goat and sheep meat and 58 live animals.

Excluding Australia and New Zealand (*i.e.,* 96 percent of this group's exports to EU–27), seven other countries (*i.e.,* Argentina, Canada, Chile, Iceland, Norway, Singapore, and Uruguay) supplied the EU–27 group with less than 4 percent (or 5,640 MT) of sheep and goat meat on average between 2014 and 2018.

Several of the non-EU group countries are not free of FMD. For live sheep and goats and their products to be eligible to be imported by the United States, they have to come from regions that are free of this disease. The rule would revise import restrictions related to BSE and scrapie only; other animal health restrictions would still apply, so imports from those non-EU group countries with FMD would still be prohibited and are not considered in this analysis.

Altogether, the North and South American countries of Canada, Argentina, Uruguay, Chile; the Asian country of Singapore; and the European countries of Norway, Switzerland, and Iceland exported to the EU–27 an annual average of 5,396 MT of sheep and goat meat between 2016 and 2020. We combine this quantity of sheep and goat meat with the average amount

[12] European Commission Agriculture and Rural Development, EU agriculture- statistical & economic information. Sheep meat & goat meat. *https://ec.europa.eu/agriculture/statistics/agricultural/20162011/pdf/d17-0-417_en.pdf*

[13] Although Romania is the fourth largest producer of sheep & goats in the EU & about 88 percent of its exports goes to EU countries, it is not classified as negligible- or controlled-risk for BSE by the OIE.

shipped by EU–27 countries to non EU–27 markets, 26,251 MT (table 8) and from table 9 the amount of sheep meat countries that are allowed to ship to EU–27 (*i.e.,* 5,396 MT), to arrive at a base value for examining possible impacts of the rule for U.S. entities (26,251 + 5,396 = 31,647 MT). Particularly in the case of Argentina, Canada, Chile, and Uruguay, lower transportation costs could provide an incentive for exporters to divert a share of their sheep and goat meat EU–27 shipments to the United States.

TABLE 9—EXPORTS OF LIVE SHEEP AND GOATS (NUMBER) AND THEIR MEAT (METRIC TONS) BY NON-EU COUNTRIES WITH NEGLIGIBLE- OR CONTROLLED-BSE RISK

[2016–2019 annual averages to EU–27 group]

Non-EU countries	Meat of goats and sheep (HS:0204) in metric tons	Number of live sheep and goats (HS: 0104)
Argentina	1,060	0
Australia	14,205	6
Brazil	0	0
Canada	4	0
Chile	1,834	0
Colombia	0	0
Costa Rica	0	0
Japan	0	0
Iceland	1,571	0
India	0	0
Israel	0	0
Mexico	0	0
Namibia	0	0
New Zealand	116,661	12
Nicaragua	0	0
Norway	222	3
Panama	0	0
Paraguay	0	0
Peru	0	0
Rep. of Korea	0	0
Singapore	6	0
Switzerland	3	40
Taiwan	0	0
Uruguay	702	0
USA	0	0
TOTAL	136,262	58
Australia & New Zealand	130,866	18
All (except Australia & New Zealand)	5,396	40

Source: United Nations (*https://www.trademap.org/*) Department of Economic and Social Affairs, Statistics Division, Trade Statistics (HS2007 commodity codes) October 2020. HS:0204 & HS:0104.

Expected Benefits and Costs of the Rule

To evaluate potential effects of the rule, we estimated impacts for U.S. production, consumption, and prices of sheep and goat meat imports from EU and non-EU sources, as described. We use a net trade [14] welfare model, and data from the USDA Foreign Agricultural Service's Global Agricultural Trade System (GATS), Food and Agriculture Organization of the United Nations' FAO Stat, and the United Nations Commercial Trade Statistics (*https://comtrade.un.org*). The demand and supply elasticities used are –0.77 (Sande and Houston 2007) and 0.80 respectively (Sullivan, Wainio, and Roningen 1989). These are still the most recent estimated elasticities for sheep and goat meat that are available in the literature.

We modeled three levels of additional sheep meat imports by the United States: 1,582 MT, 3,165 MT, and 4,747 MT. These quantities are equal to approximately 5, 10, and 15 percent of the sum of (i) average EU–27 sheep and goat meat exports to non EU–27 markets, 2016–2019 (*i.e.,* 26,251 MT, see table 8), and (ii) average sheep and goat meat exports to EU–27 countries by other eligible countries, 2016–2019, excluding Australia and New Zealand (see table 9) of 5,396 MT. In sum, this is the EU–27's external volume of trade of the above-mentioned commodities. The largest assumed quantity (*i.e.,* 4,747 MT) is equivalent to less than 2 percent of average annual U.S. sheep and goat meat consumption (*i.e.,* 193,839 MT) during this same time period (see table 4).

Table 10 presents the changes that would result from the assumed increased imports. For the medium-level increase, 3,939 MT, the wholesale price would decline by approximately 1.53 percent and domestic production would fall by 878 MT. U.S. consumption would increase by 2,287 MT. Producer welfare would decline by about $8.67 million and consumer welfare would increase by about $23.7 million, yielding an annual net welfare gain of about $15.1 million.

[14] In this case ''net trade'' welfare model refers to the way we model the importing country (*i.e.,* USA) as a net trader (*i.e.,* either a net exporter when exports are greater than imports or net importer)—whatever is the specific case of the commodity in question (*i.e.,* goats and sheep and their meat in this case).

TABLE 10—ESTIMATED IMPACTS OF SHEEP MEAT IMPORTS AS A RESULT OF THE FINAL RULE, FOR THREE ASSUMED LEVELS OF IMPORTATION

Assumed additional sheep and goat meat imports per year, metric tons	1,582	3,165	4,747
Change in U.S. consumption, metric tons	1,143	2,287	3,430
Change in U.S. production,* metric tons	−439	−878	−1,317
Percentage change in U.S. price	−0.77	−1.53	−2.30
Change in consumer welfare (U.S. dollars)	$11,824,458	$23,725,979	$35,689,520
Change in producer welfare (U.S. dollars)	($4,344,373)	($8,664,768)	($12,955,727)
Annual net welfare gain (U.S. dollars)	$7,480,086	$15,061,211	$22,733,799

Note: The baseline data used are 5-year annual averages for production, consumption, price, exports and imports, as reported in the last row of table 3. The demand and supply elasticities used are −0.70 and 0.80, respectively. * U.S. production data is for sheep meat only, goat meat data is unavailable.

For each of the three assumed levels of sheep and goat meat imports, consumer welfare gains would outweigh producer welfare losses. The majority of establishments that may be affected by the final rule are small entities, and economic impacts are likely to be small as well. If an additional 3,165 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 $67.15, or the equivalent of about 1.3 percent of average annual sales by small entities (table 11).

As another aspect of the rule, U.S. sheep and goat producers may benefit from resulting genetic improvements through increased imports of sheep and goat germplasm (breeding animals, embryos, and semen). These imports may yield advantageous genetic characteristics such as heavier bone and greater muscle expression, higher productivity and product quality, disease resistance, reproductive efficiency and greater feed efficiency. However, additional germplasm imports also are not expected to be significant.

TABLE 11—ECONOMIC IMPACT FOR U.S. SMALL ENTITIES OF ADDITIONAL ANNUAL SHEEP AND GOAT MEAT IMPORTS OF 3,165 METRIC TONS

Total decline in producer welfare [1]	$8.66 million.
Decrease in welfare incurred by small entities [2]	$6.07 million.
Average decrease per animal, small entities [3]	$2.17.
Average decrease per small entity [4]	$67.15.
Average decrease as a percentage of average sales by small entities [5]	1.3%.

[1] From table 10.
[2] Change in producer welfare multiplied by 70 percent, the percentage of total sales by sheep and lamb producers with annual revenues of not more than $750,000, that is, small entities. We assume that the change in producer welfare would be proportional to sales share.
[3] Decrease in producer welfare for small entities divided by 2.8 million, the number of sheep and lamb sold by small entities.
[4] Average decrease per animal multiplied by 31, the average of the number of sheep and lambs and goats sold per small entity.
[5] Average decrease per small entity divided by $5,000, the average annual revenue per small entity.

Costs of Preventing Fence-Line Contact

There are currently no APHIS-approved feedlots in the United States for imported sheep and goats. This rule will require that the operator of an approved feedlot prevent fence-line contact between other sheep or goats being fed for purposes other than direct movement to slaughter or that are outside the feedlot and sheep and goats imported for restricted feeding and eventual slaughter from regions not free of classical scrapie by a method acceptable to the APHIS Administrator. The Agency will work with individual operators to determine the best means of preventing such contact in their feedlots. As a commenter on the proposed rule noted, one way of preventing fence-line contact would be to use double fencing to create a separation between paddocks.

One recommended type of fencing for sheep and goats is a perimeter of woven wire and high-tensile electrified fence. As shown in table 12, one estimate places the initial cost for this type of fencing at about $1.00 per foot, for a quarter-mile (1,320 feet) straight perimeter permanent fence (Iowa State University, 2012). Average annual maintenance costs would be about 5 percent of construction costs and the estimated useful life would be 25 years.

TABLE 12—CONSTRUCTION COSTS FOR HIGH-TENSILE ELECTRIFIED WIRE FENCE

[Based on a 1,320 ft. fence]

Item	Amount	Cost per unit (dollars)	Total cost (dollars, rounded)
Wood posts (8-inch diameter)	6	30.20	181
Wood posts (4-inch diameter	4	9.70	39
Steel posts (6.5 ft.)	52	5.40	281
Insulators	285	0.38	108
Springs	5	7.60	38
Strainers	5	3.80	19
High tensile wire	6,600 ft.	0.03	178
Energizer	25	1.19	30
Cut-out switch	1	8.10	8
Ground/lightening rods	4	17.30	69

TABLE 12—CONSTRUCTION COSTS FOR HIGH-TENSILE ELECTRIFIED WIRE FENCE—Continued

[Based on a 1,320 ft. fence]

Item	Amount	Cost per unit (dollars)	Total cost (dollars, rounded)
Labor and equipment	18 hours	17.50	315
Total			1,266
Cost per foot			0.96

Source: Iowa State University, 2012. Estimated Costs for Livestock Fencing. Extension and Outreach, Ag Decision Maker, File B1–75. Gates are not included in the estimate. Values converted from 2011 to 2016 dollars using gross domestic product (GDP) deflator.

Another estimate of fencing costs provided by a representative of the National Lamb Feeders Association (NLFA) is $4.00 per linear foot, with the size of an average square pen 150 feet on each side. The NLFA representative anticipates that there could be as many as 20 feedlots that will apply for import approval. He also noted that existing feedlots with multiple pens already have no need for double fencing on one side between them because of the ''bunk line'' feeding, where pens are separated by space to allow the bunk to be easily filled. Most feedlots have back-to-back pens in a row and would only need to double-fence a pen along sides not separated by a bunk line from another pen.

The cost of double fencing for a feedlot operator will depend on the number, size, and configuration of existing pens, and the distance between the existing pen and the added fencing. Industry sources suggest two likely courses of action by feedlots that decide to apply for import approval: Use an existing pen for which double fencing would need to be constructed on three side (the fourth side would have a bunk line with another pen); or construct a new pen near an existing pen, and add the double fencing on three sides. In the first instance, the length of additional fencing, assuming a pen with a side of 150 feet and a 20-foot distance between the two fences, would be 450 feet (the three sides), plus 120 feet (two lengths of 20 feet at each of the two rear corners and a 20-foot length at each corner on the bunk-line side), for a total of 570 feet. In the second instance, there would be the new pen, 600 feet, plus the 570 feet for the second fence, as described, for a total of 1,170 feet.

Based on unit costs of between $1.00 and $4.00 per linear foot, and assuming that the length of fencing that would be required ranges between 570 and 1,170 feet, averaging 870 feet, we estimate that the cost per feedlot may average between $870 and $3,480. Assuming that 20 feedlots apply for import approval, the total cost for the industry may range between $17,400 and $69,600.

Alternatives to the Rule

An alternative to this rule would be to remove BSE-related restrictions on the importation of small ruminants, but not establish a notice-based approach for recognizing regions as free of scrapie. Under this alternative, APHIS would evaluate regions in accordance with part 92 for scrapie and other TSE status, and then initiate rulemaking in order to authorize importation of This alternative was rejected because it would mean forgoing recognized trade advantages of timelier notice-based actions in comparison to rule promulgation. Based on APHIS experience in an analogous subject area, the authorization of fruit and vegetable imports, rulemaking takes, in general, 18 months to 2 years, whereas notice-based authorizations generally average 6–12 months. This longer time frame also delays the time it takes for consumers to experience the welfare benefits associated with increased imports.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations, and small governmental jurisdictions. This final regulatory flexibility analysis describes expected impacts of this rule on small entities, as required by section 604 of the Act.

Need for and Objectives of the Rule

The objective of the rule is to change BSE and scrapie import and transit restrictions for live sheep, goats, and wild ruminants, their embryos, semen, and products and byproducts, in recognition of actual risks posed by these diseases. The rule would remove BSE restrictions on the importation of live sheep and goats and most products of sheep and goats. It would amend the import regulations for certain wild, zoological, or other non-bovine ruminant species by adding restrictions related to transmissible spongiform encephalopathies. It would also establish a notice-based approach for recognizing regions as free of scrapie.

The legal basis for this rule is the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), by which the Secretary of Agriculture may restrict the importation of any animal or article if the Secretary determines that the prohibition is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.

Significant Issues Raised by Public Comment in Response to the Initial Regulatory Flexibility Analysis

There were no significant issues raised by public comment in response to the initial regulatory flexibility analysis.

Comments Filed by the Office of Advocacy of the U.S. Small Business Administration in Response to the Proposed Rule

There were no comments filed by the Office of Advocacy of the U.S. Small Business Administration in response to the Initial Regulatory Flexibility Analysis.

Potentially Affected Small Entities

The Small Business Administration (SBA) has established guidelines for determining which firms are considered small under the Regulatory Flexibility Act. This rule could affect 88,338 establishments categorized within the following industries and corresponding North American Industry Classification System codes: Animal (except poultry) slaughtering (NAICS 311611), meat processing (NAICS 311612), meat and meat product merchant wholesalers (NAICS 424470), sheep farming (NAICS 112410), and goat farming (NAICS 112420).

Under SBA standards, animal slaughtering and meat processing establishments with no more than 1,000 employees and meat and meat product wholesalers with no more than 150 employees are considered small. According to the 2012 Economic Census, there were 1,603 animal slaughtering establishments, of which

95 percent were considered small. Establishments with fewer than 20 employees accounted for over 81 percent of establishments, but their share of total sales was only 2.8 percent. In 2012, of the 1,381 U.S. companies that processed and sold meat, about 97 percent were small entities. Of the 2,295 establishments that were wholesaling meat and meat products that year, 96 percent were small. Thus, animal slaughterers, meat processors, and wholesalers that could be affected by the rule are predominantly small by SBA standards.

Sheep farming (NAICS 112410) and goat farming (NAICS 112420) establishments are classified as small if their annual receipts are not more than $750,000. According to the 2012 Census of Agriculture (most recent data on farm sizes), there were 88,338 farms that sold about 3.8 million lamb and sheep in the United States. Of these, 88,206 farms (99.9 percent) had combined sales of about 2.8 million head (about 70 percent of all lamb and sheep sold) and are considered small, with average sales of about 31 head and average annual receipts of about $5,000 in 2012. The remaining 0.1 percent of the farms sold a total of about 1 million lamb and sheep, and the farms had an average annual income from the sale of sheep and lamb of about $1.48 million.

In 2012, there were 63,844 farms that sold about 1.3 million goats for meat. The number of goats sold per farm in 2012 was about 20 head, compared to average lamb and sheep sales (all farms) of 43 head. We use the per farm statistics for lamb and sheep production in the following estimation of impacts for small entities, since the 2012 Census of Agriculture does not provide detailed size standards for goat farming. As shown in table 11, we can expect the impact for U.S. small-entity producers to be small. When we assume that an additional 3,165 MT of sheep and goat meat would be imported by the United States because of this rule, the annual decrease in producer welfare per small entity is estimated to be about $67.15 or the equivalent of about 1.3 percent of average annual sales by small entities.

Projected Reporting, Recordkeeping, and Other Compliance Requirements

Reporting and recordkeeping requirements associated with the final rule are discussed in the rule under the heading ''Paperwork Reduction Act.'' Under that heading, APHIS estimates that it will take 0.531 hours per response to comply with the paperwork and recordkeeping requirements of this rule.

Steps Taken by APHIS To Minimize Significant Economic Impacts on Small Entities

We had no initial information that would suggest significant impacts on small entities, and did not receive additional information concerning affected entities during the public comment period on the proposed rule that would alter this assessment. In the absence of apparent significant economic impacts, we have not identified steps that would minimize such impacts.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 13175

This 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.

APHIS is aware of growing interest among Tribal nations in rules that could result in price fluctuations, particularly after recent supply chain disruptions. APHIS invited general Tribal consultation during the proposed rulemaking process with no Tribal response. Recent evaluation for Tribal implications, however, indicate the potential for increased market variations in sheep, goat, and other ruminants warranting Tribal engagement.

APHIS collaborated with the USDA Office of Tribal Relations (OTR) to provide for a meaningful government-to-government consultation on these implications. This opportunity for consultation occurred on November 1, 2021, with 13 Tribal nations in attendance. The Tribes present did not express questions or concerns about the rule or its supporting documents. APHIS is committed to full compliance with Executive Order 13175 throughout the implementation of this rule.

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 the proposed rule and this final rule were previously approved under Office of Management and Budget (OMB) control numbers 0579–0040 and 0579–0101. The remaining reporting and recordkeeping requirements that were solely associated with the proposed rule to this final rule were submitted to OMB as a new information collection assigned OMB comment-filed number 0579–0453. The proposed rule allowed for public comment on the reporting and recordkeeping requirements. However, APHIS did not receive comments concerning the calculations for the information collection activities, their instruments (such as the import permits or health certificates), or reported burden.

Since publication of the proposed rule, the information collection procedures and forms are unchanged, except for the removal of one activity and adjustments in the estimates for seven activities. Information collected in accordance with the regulations of this final rule 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. APHIS removed the activity related to reporting of animals, poultry, or eggs offered for importation (VS Form 17–30) because this information is reported in another information collection. APHIS reduced the burden estimates for three activities because the number of respondents was overestimated and increased the burden estimates for four activities to account for rounding errors. Lastly, APHIS decreased the estimated number of respondents by 67 which in turn resulted in 906 fewer responses and 439 fewer burden hours. However, the public reporting burden estimated hours per response remains at 0.531 hours with 9 responses per respondent.

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. However, less than 1 percent of the information required to be collected under this final rule can be processed electronically, either by downloading a fillable PDF file, emailing a document, or for respondents with accounts, using APHIS' electronic information systems such as ePermits, Veterinary Services Process Streamlining, or Automated Commercial Environment to process and submit information. The remainder of the collection activities cannot be processed electronically because there are instruments (such as permanent country marks, seals, or the VS 1–27, Permit for Movement of Restricted Animals) that must typically accompany the animals during transit. For assistance with E-Government Act compliance related to this final rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483, or the Veterinary Services contact listed above under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

9 CFR Part 92

Animal diseases, Imports, Livestock, Quarantine.

9 CFR Part 93

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

9 CFR Part 94

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

9 CFR Part 95

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

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

9 CFR Part 98

Animal diseases, Imports.

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

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

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

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

■ 2. Section 92.2 is amended by revising the OMB statement at the end of the section to read as follows:

§ 92.2 Application for recognition of the animal health status of a region or a compartment.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0453)

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

■ 3. 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.

■ 4. 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 designated by the Administrator as one eligible to receive sheep and goats from regions 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 premise, 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 preventing disease spread until the animal is no longer living; and the remains have been disposed of in a manner preventing disease spread.

* * * * *

Non-classical scrapie. Any form of scrapie 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, typically producing 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.

* * * * *

■ 5. Section 93.401 is amended by revising paragraph (a) and adding a heading for paragraph (b) to read as follows:

§ 93.401 General prohibitions; exceptions.

(a) *General provisions.* 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; [3] 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.

[3] Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

(b) *Ruminants in transit.* * * *

* * * * *

■ 6. Section 93.404 is amended as follows:

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

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

■ c. In newly redesignated paragraph (a)(7)(v), by removing ''paragraph (a)(4)(iv)'' and adding ''paragraph (a)(7)(iv)'' in its place;

■ d. In newly redesignated paragraph (a)(7)(vi), by removing ''paragraph (a)(4)(iv)(A)'' and ''paragraph (a)(4)(iv)(B)'' and adding ''paragraph (a)(7)(iv)(A)'' and ''paragraph (a)(7)(iv)(B)'', respectively, in their place; and

■ e. By revising the OMB statement at the end of the section.

The additions and revision 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 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 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 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 (a)(5) must send their request to the Administrator, c/o Strategy and Policy, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, or via the APHIS website at *https://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 determined to be AA at codon 136 and either RR, HR, KR, or QR at codon 171 and for female sheep determined to be 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 in this part for import other than the requirement that they originate in a flock or region 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.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0224, and 0579–0453)

■ 7. Section 93.405 is amended as follows:

■ a. By adding a heading for paragraph (a) and removing paragraph (a)(4);

■ b. By revising paragraph (b);

■ c. By removing paragraph (c);

■ d. By redesignating paragraph (d) as paragraph (c);

■ e. By revising newly redesignated paragraph (c); and

■ f. By revising the OMB statement at the end of the section.

The addition and revisions read as follows:

§ 93.405 Health certificate for ruminants.

(a) *Issuance and required information.*

* * *

* * * * *

(b) *Sheep and goats*—(1) *Information required.* 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) *Additional statements.* 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 that:

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

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

(v) 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) 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) *Test results.* 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) *Sheep or goats imported for immediate slaughter.* 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 where the sheep or goats originated is recognized as free of classical scrapie by APHIS; or

(ii) The region where the sheep or goats originated 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 to the national veterinary authority of the region;

(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 where the sheep or goats originated is recognized as free of classical scrapie by APHIS; or

(ii) The region where the sheep or goats originated 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 to the national veterinary authority of the region;

(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) 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) 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) *Refusal of entry.* 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.

(Approved by the Office of Management and Budget under control numbers 0579–0040, 0579–0165, 0579–0234, 0579–0393, and 0579–0453)

§ 93.406 [Amended]

■ 8. Section 93.406(b) is amended 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]

■ 9. Section 93.419 is removed and reserved.

■ 10. Section 93.420 is amended in paragraph (a) introductory text 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. * * *
* * * * *

■ 11. 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).
* * * * *

■ 12. Section 93.428 is amended by revising paragraph (a) and the OMB statement at the end of the section to read as follows:

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

(a) Sheep, goats, and native wild ruminants 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.
* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0453)

■ 13. 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 official identification devices or methods and which will allow the animals 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 devices 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 devices or methods may be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/imports/live-animal-imports.*

(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 approved by the Administrator for this use. A list of the acceptable country marks may be found on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/imports/live-animal-imports.*

(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 including 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 for immediate slaughter may only be imported into the United States from countries or regions determined to be free of classical scrapie by APHIS, or that have scrapie awareness, surveillance, and control programs evaluated and determined by APHIS to be effective.

(2) Sheep and goats imported for immediate slaughter must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and be inspected at the port of entry and otherwise handled in accordance with § 93.408.

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

(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 determined to be free of classical scrapie by APHIS, or that have scrapie awareness, surveillance, and control programs 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 purposes of this paragraph (c)(11)(i) and will be linked as 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 they have the required country mark, or will maintain all imported animals in separate pens from U.S. origin animals, and 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 feedlot, 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) Will prevent fence-line contact with sheep or goats outside the designated feedlot;

(ix) 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;

(x) 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

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

(xii) 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) *Other importations.* 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 or equivalent status in a scrapie flock certification program or equivalent program approved by APHIS, 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 website at *https://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, Strategy and Policy, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 38, Riverdale, Maryland 20737.

(2) APHIS will add a region to the list in paragraph (f)(1) only after conducting an evaluation of the region in accordance with § 92.2 of this subchapter and finding classical scrapie is not likely to be present in its sheep or goat populations. In the case of a formerly listed region 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 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, 0579–0101, and 0579–0453)

§ 93.505 [Amended]

■ 14. Section 93.505(a) is amended by removing the citation ''§ 94.24(b)(6)'' and adding the citation ''§ 94.31(b)(6)'' in its place.

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

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

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 16. Section 94.15 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) 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 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, Strategy and Policy, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *https://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, Strategy and Policy, 4700 River Road Unit 38, Riverdale, MD 20737–1231, or electronically at *https://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 U.S. Customs and Border Protection (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, 0579–0145, and 0579–0453)

§ 94.18 [Amended]

■ 17. Section 94.18 is amended in paragraph (a) by adding the word ''and'' before the citation ''94.23'' and removing '', and 94.27''.

§ 94.24 [Removed and Reserved]

■ 18. Section 94.24 is removed and reserved.

§ 94.25 [Removed and Reserved]

■ 19. Section 94.25 is removed and reserved.

■ 20. 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.

(Approved by the Office of Management and Budget under control number 0579–0453)

§ 94.27 [Removed and Reserved]

■ 21. 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

■ 22. 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]

■ 23. Section 95.1 is amended by removing the definitions of Positive for a transmissible spongiform encephalopathy and Suspect for a transmissible spongiform encephalopathy.

■ 24. Section 95.4 is amended as follows:

■ a. By revising the section heading and paragraphs (a), (b) introductory text, (b)(1), and (c)(1)(ii) and (iv);

■ b. By removing paragraphs (c)(2) and (3) and redesignating paragraphs (c)(4) through (8) as (c)(2) through (6), respectively;

■ c. In newly redesignated paragraph (c)(3), by revising the first sentence;

■ d. In newly redesignated paragraph (c)(5), by removing the reference ''(c)(5)'' and adding the reference ''(3)'' in its place;

■ e. By removing paragraphs (d) and (e);

■ f. By redesignating paragraph (f) and the Note to paragraph (f) as paragraph (d) and Note 1 to paragraph (d), respectively; and

■ g. By removing paragraph (g).

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) The restricted materials are as follows:

(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 or camelids, and the material is not ineligible for importation under the conditions of § 95.5;

* * * * *

(iv) Ovines or 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]

■ 25. Section 95.15 is removed and reserved.

§ 95.40 [Removed and Reserved]

■ 26. Section 95.40 is removed and reserved.

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

■ 27. 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]

■ 28. Section 96.2 is amended as follows:

■ a. By removing paragraph (b)(1) and redesignating paragraph (b)(2) as paragraph (b)(1);

■ b. By adding a new reserved paragraph (b)(2); and

■ c. In paragraph (c)(3), by removing the words ''paragraphs (b)(2)(i) through (b)(3)(iv)'' and adding the words ''paragraph (b)(1)'' in their place.

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

■ 29. 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.

■ 30. 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, typically producing characteristic microscopic changes, including, but not limited to, noninflammatory neuronal loss, giving a spongiform appearance to tissues in the brains and nervous systems of affected animals.

* * * * *

§ 98.3 [Amended]

■ 31. 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:

■ i. Removing the ''part 92'' and adding the citation ''part 93'' in its place; and

■ ii. 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 ''§ 93.404(a)(2) or (3)'' and adding ''§ 93.404(a)(3) or (4)'' in its place.

■ 32. Section 98.4 is amended by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 98.4 Import permit.

* * * * *

(d) 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]

■ 33. Section 98.5 is amended as follows:

■ a. By removing and reserving paragraph (b); and

■ b. In the OMB statement at the end of the section, by removing ''number 0579–0040'' and adding ''numbers 0579–0040 and 0579–0453'' in its place.

■ 34. 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 from a flock or herd having 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 not of the genotype AAQR or AARR, and for all goat embryos, must contain the following additional certifications:

(A) In the country or zone:

(*1*) TSEs of sheep and goats are compulsorily notifiable to the national veterinary authority of the region;

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

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

(*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 where 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.

(2) [Reserved]

(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 where the recipients reside is listed in the National Scrapie Database; except 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 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 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 where 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) For in vitro-derived and manipulated sheep or goat embryos and oocytes, 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 as provided in § 98.10.

(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, 0579–0101, and 0579–0453).

■ 35. 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]

■ 36. 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; and

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

■ 37. 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.

* * * * *

■ 38. Section 98.35 is amended as follows:

■ a. By revising paragraph (e) introductory text;

■ b. By removing paragraph (e)(1)(ii) and redesignating paragraphs (e)(1)(iii) and (iv) as paragraphs (e)(1)(ii) and (iii), respectively;

■ c. By revising newly redesignated (e)(1)(iii);

■ d. By adding new paragraph (e)(1)(iv);

■ e. By removing ''; and'' at the end of paragraph (e)(2)(iv) and adding a period in its place;

■ f. By revising paragraph (e)(3);

■ g. By adding paragraphs (e)(4) and (5); and

■ h. By revising the OMB statement at the end of the section.

The revisions and additions read as follows:

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

* * * * *

(e) The certificates accompanying sheep semen collected from rams that are not of the genotypes AARR or AAQR, and for all goat semen shall, in addition to the statements required by paragraph (d) of this section, state that:

(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 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 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.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0453)

Done in Washington, DC, this 30th day of November 2021.

Jennifer Moffitt,

Undersecretary, Marketing and Regulatory Programs.

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