Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 03–080–1]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and are proposing to add Canada to this category. We are also proposing to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions. We believe this action is warranted because it would continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on certain commodities from Canada and other regions that qualify as BSE minimal-risk regions.

DATES: We will consider all comments that we receive on or before January 5, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–080–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–080–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 03–080–1'' on the subject line.

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

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

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent and is not known to exist in the United States. The disease has been difficult to define experimentally with precision, although risk factors that are independent of the causative agent have been identified and can be mitigated. Much of the available data originated from epidemiological observations and not from controlled studies. Controlled studies are often difficult to conduct because of limitations in experimental models and the length of time necessary to conduct the studies, which may require years. Currently, the most accepted theory is that the agent is a modified form of a normal cell surface component known as prion protein, although other types of agents have been implicated, including virinos. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any demonstrated immune response or inflammatory reaction in host animals.

Despite the difficulty in defining BSE experimentally with precision, risk factors for BSE that can be mitigated have been identified. These factors are based on technical knowledge and disease epidemiology and do not require definition of the nature of the agent. We believe that risk mitigation measures that address the risk factors for BSE will be effective regardless of the precise nature of the BSE agent.

It appears that BSE is spread primarily through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Ruminants in the United States could be exposed to the disease if materials carrying the BSE agent—such as certain meat, animal products, or animal byproducts from ruminants—were imported into the United States and were fed to ruminants in this country. BSE could also be introduced into the United States if ruminants with BSE were imported into the United States.

Because of these risks, the regulations prohibit the importation of live ruminants and certain ruminant products and byproducts from two categories of regions: (1) Those regions in which BSE is known to exist, which are listed in § 94.18(a)(1) of the regulations; and (2) those regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. These regions of ''undue

risk'' are listed in § 94.18(a)(2) of the regulations.

The prohibitions on the importation of animals, meat, and other animal products into the United States from regions listed in § 94.18(a)(1) or (a)(2) are set forth in 9 CFR parts 93, 94, 95, and 96. Section 93.401 prohibits the importation of any ruminant that has been in these regions. Except for certain controlled transit movements, paragraph (b) of § 94.18 prohibits the importation of fresh (chilled or frozen) meat, meat products, and most other edible products of ruminants that have been in any of the regions. Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of the regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of the regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of the regions.

Essentially then, under the current regulations, there are three categories of regions with regard to BSE. Currently, a region is considered either: (1) A region free of BSE; (2) a region in which BSE is known to exist; or (3) a region that presents an undue risk of BSE. Imports from free regions are generally not subject to restrictions because of BSE. Imports from BSE-affected regions and those that present an undue risk are governed by the same set of restrictions.

We believe it is appropriate to recognize an additional category of regions with regard to BSE—the BSE minimal-risk region. This category would include (1) those regions in which a BSE-infected animal has been diagnosed, but in which measures have been taken that make it unlikely that BSE would be introduced from the region into the United States, and (2) those regions that cannot be considered BSE free even though BSE has not been detected, but that have taken sufficient measures to be considered minimal risk. For instance, a region listed in § 94.18(a)(2) as an ''undue risk'' region might have increased its levels of surveillance or import restrictions to the point that the risk of BSE introduction from that region becomes unlikely, but not yet have had mitigation measures in place long enough to be considered BSE-free.

In § 94.0, we would define *bovine spongiform encephalopathy (BSE) minimal-risk region* by listing the factors we would consider in determining the region's risk status. In a new § 94.18(a)(3), we would list the regions that the Administrator has approved for this designation. At this time, we are proposing to designate one country, Canada, as a BSE minimal-risk region according to the newly proposed factors. (These factors, and the reasons why we believe Canada meets them, are discussed in detail below.) In § 94.18(a)(4), we would explain that a region may request to be designated a BSE minimal-risk region by following the procedures set forth in our regulations in 9 CFR part 92, ''Importation of Animals and Animal Products: Procedures for Requesting Recognition of Regions.''

Canada as a BSE Minimal-Risk Region

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. Therefore, in order to prevent the introduction of BSE into the United States, we published an interim rule on May 29, 2003 (68 FR 31939–31940, Docket No. 03–058–1), effective retroactively to May 20, 2003, to add Canada to the list of regions where BSE exists. As a result of that action, the importation of ruminants that have been in Canada and the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Canada are prohibited or restricted.

Following the detection of the BSE-infected cow, Canada conducted an epidemiological investigation of the BSE occurrence, and took action to guard against any spread of the disease, including the quarantining and depopulation of herds and animals determined to possibly be at risk for BSE. Subsequently, Canada asked APHIS to consider reestablishing the importation of ruminants and ruminant products into the United States from that country, based on information made available to APHIS regarding Canada's veterinary infrastructure, disease history, practices for preventing widespread introduction, exposure, and/or establishment of BSE, and measures taken following detection of the disease.

In this document, we are proposing to list Canada as a BSE minimal-risk region based on an analysis we conducted of the conditions considered for such a designation and the information available to us regarding how Canada meets those conditions. The risk document, ''Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States,'' also identifies the measures we believe are necessary to mitigate any BSE risk that specific commodities imported from Canada might present to the United States (discussed in this proposed rule, below, under the heading ''Importation of Ruminant Commodities from a BSE Minimal-Risk Region'').

You may view the analysis in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this proposed rule). You may also request a copy by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the analysis when requesting copies. You may also view the analysis on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov*. At the APHIS Web site, click on the ''Hot Issues'' button. On the next screen, click on the listing for ''Bovine Spongiform Encephalopathy (BSE).'' On the next screen, click on the listing for ''Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States.''

In this proposed rule, we first discuss the factors we would consider in classifying a region as a BSE minimal-risk region. We would consider these factors in considering requests from any region to be classified as a BSE minimal-risk region. We then discuss why we believe Canada qualifies as a BSE minimal-risk region. Following that, we discuss mitigations that we would apply to specific commodities from Canada.

Proposed Factors for BSE Minimal-Risk Regions

APHIS has developed a list of factors we would use to evaluate the BSE risk from a region and classify a region as a BSE minimal-risk region. We would use these factors as a combined and integrated evaluation tool. We are proposing to base the classification on an evaluation of the sum total of these factors, focusing on overall effectiveness of control mechanisms in place (*e.g.*, surveillance, import controls, and a ban on the feeding of ruminant protein to ruminants). For regions in which BSE has been diagnosed, we would base our evaluation on the overall effectiveness of such control mechanisms in place at the time BSE was diagnosed in the region, and on actions taken after the diagnosis (*e.g.*, an epidemiological investigation of the occurrence). For regions in which BSE has not been diagnosed, we would base our evaluation on the adequacy of surveillance mechanisms to detect disease, efficacy of a feed ban, and effectiveness of programs in place to prohibit entry into and establishment of disease in the region. This approach differs from some of the numerical criteria specified by the Office

International des Epizooties (OIE) in its recommendations for a BSE minimal-risk country or zone. (The OIE recommendations are recognized by the World Trade Organization as international recommendations for animal disease control.)

For example, according to OIE recommendations, a ban on the feeding of ruminant protein to ruminants should have been in place for a minimum of 7 years for a region to meet the criteria for BSE minimal risk, even though there is a significant level of variability in current estimates of the BSE incubation period, which should govern the recommended length of time of an effective feed ban. According to this criterion, a region could fail to be classified as a BSE minimal-risk region because it had not had a feed ban in effect for the precise period of time specified, even if it has excelled in surveillance and control mechanisms. We believe it is more appropriate to evaluate the overall combined effect of the factors described below when assessing the BSE risk level of a region.

Definition of Bovine Spongiform Encephalopathy Minimal-Risk Region

We propose to define *bovine spongiform encephalopathy (BSE) minimal-risk region* in § 94.0 to mean a region that:

1. Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

a. Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;

b. Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and

c. A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

2. In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

Each element of this definition is explained below.

1. The region maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease.

This factor is important in determining those regions in which a BSE outbreak is unlikely to occur, or, if an outbreak does occur, in which it is likely to be limited. If a region maintains controls designed to minimize BSE introduction or exposure of animals, and, in those regions where BSE has been detected, if the region had such controls in place at the time of detection, it is more likely to present minimal risk than a region that does not have such controls in place. According to our definition of a BSE minimal-risk region, such measures would include importation restrictions, surveillance, and a feeding ban, as follows:

1a. Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE.

This factor addresses whether the region faces a high risk of initial or recurrent BSE outbreaks from multiple importations of animals or products that may spread BSE. In those regions in which BSE has been detected, it addresses whether the region's BSE outbreak was more likely the result of a point failure in its import controls or possible exposure prior to the implementation of such import controls. Because the incubation period for BSE is generally measured in years, the finding of a case of BSE reflects an exposure that occurred several years in the past.

A region that has prohibited the importation of high-risk animals and products from regions that are affected with or pose an undue risk of BSE will have minimized its possible exposure to the disease. Conversely, a region that continues to import high-risk commodities until a case of BSE is diagnosed has continued exposure and presents a more significant risk. Whether commodities are considered low-risk or high-risk can be based on the commodities' inherent lack of risk, the low risk level of the exporting region, and/or controls on the movement and use of the commodities after entry.

1b. Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE.

This factor addresses whether BSE outbreaks are or would be likely to be quickly and reliably identified in a region, helping support a minimal-risk designation, or whether lack of effective surveillance suggests the possibility that BSE-infected animals may be overlooked and the scale of a BSE problem may be greater than is officially recognized.

As noted above, the OIE recommendations are recognized by the World Trade Organization as international recommendations for animal disease control. The OIE Code provides guidelines for surveillance and monitoring systems for BSE, identifying the minimum number of annual investigations recommended based on the adult cattle population of a country.

1c. A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

The primary source of BSE infection appears to be feed contaminated with the infectious agent. Scientific evidence [1] shows that feed contamination results from the incorporation of ingredients that contain ruminant protein derived from infected animals. Standard rendering processes do not completely inactivate the BSE agent. Therefore, rendered protein such as meat-and-bone meal derived from infected animals may contain the infectious agent. Bans prohibiting incorporation of mammalian or ruminant protein into ruminant feed are imposed to mitigate risk.

This factor distinguishes between regions with effective feed bans and those without them. In a region in which BSE has been detected, if an animal with BSE was born after a feed ban was implemented, it is a sign that the feed ban may not be effectively enforced.

2. In a region in which BSE has been detected, the region conducted an

[1] Wilesmith, J.W., Wells, G.A.H., Cranwell, M.P., and Ryan, J.B.M.; 1988; Bovine spongiform encephalopathy; epidemiological studies; Veterinary Record; 123, pg 638–644.

Wilesmith, J.W., Ryan, J.B.M, and Atkinson, M.J.; 1991; Bovine spongiform encephalopathy; epidemiological studies of the origin; Veterinary Record; 128, pg 199–203.

Wilesmith, J.W., Ryan, J.B.M, and Hueston W.D.; 1992; Bovine spongiform encephalopathy: Case control studies of calf feeding practices and meat-and-bone meal inclusion in proprietary concentrates; Res Vet Sci; 52, pg 325–331.

epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

This factor addresses whether a region adequately investigates a case of BSE to determine if any of the risk factors have changed. If there has been any significant change in risk factors, there might be the possibility of increased incidence of BSE. Such an investigation would include, at the minimum, a traceback from the BSE-infected animal to determine possible herds of origin of the animal, a traceforward of any animals that moved from the BSE-affected herd, a traceforward of feed or rendered material that was derived from the carcass of the infected animal, and an investigation to determine the most likely source of the animal's exposure to BSE.

3. In a region in which BSE has been detected, the region took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

This factor addresses whether a region implements all necessary risk mitigation measures to prevent further exposure to BSE. It distinguishes between those regions that thoroughly analyze their situation and address any problems from those that do not take mitigation measures and thus prolong possible exposure to BSE. Depending on the conclusions of the risk analysis conducted following the diagnosis of BSE, additional risk mitigation measures could include a broad eradication program, increased surveillance, or additional import restrictions.

Evaluating Canada as a BSE Minimal-Risk Region

We considered the above factors in combination in evaluating whether Canada qualifies as a BSE minimal-risk region, and discuss below the actions Canada took and continues to take regarding each of the factors.

Import Restrictions

Canada has maintained stringent import restrictions since 1990,[2] prohibiting the importation of live ruminants and most ruminant products from countries that had not been recognized as free of BSE by either the United States, Canada, or Mexico, which have an agreement to recognize country evaluations conducted by any of the three countries, using the same standards. Canada prohibited the importation of live cattle from the United Kingdom and the Republic of Ireland starting in 1990, and subsequently applied the same prohibitions to other countries as those additional countries identified native cases of BSE. In 1996, Canada made this policy even more restrictive and prohibited the importation of live ruminants from any country that had not been recognized as free of BSE. Some animals were imported into Canada from high-risk countries prior to the imposition of these import restrictions. A total of 182 cattle were imported into Canada from the United Kingdom between 1982 and 1990. Similar to actions taken in the United States, efforts were made in Canada to trace these animals. In late 1993, after Canada identified a case of BSE in one of the imported bovines, all cattle imported from the United Kingdom or the Republic of Ireland that remained alive at that time were killed.

Import restrictions have also been imposed on ruminant products, including import restrictions on meat-and-bone meal that have been in place since 1978. In general, Canada has prohibited the importation of most meat-and-bone meal from countries other than the United States, Australia, and New Zealand. Limited amounts of specialty products of porcine or poultry origin were allowed to be imported into Canada under permit for use in aquaculture feed products. No meat-and-bone meal for livestock feed-associated uses has been imported, except from the United States, Australia, and New Zealand.

Surveillance

Canada has conducted surveillance for BSE since 1992. The OIE Code, Appendix 3.8.4, provides guidelines for surveillance and monitoring systems for BSE, identifying the minimum number of annual investigations recommended based on the adult cattle population of a country. To meet this recommendation, Canada would have to test a minimum of 336 samples annually, based on a population of 5.5 million adult cattle. Canada exceeds this recommendation, and has tested more than this minimum number of samples for the past 7 years. Additionally, Canada exceeds OIE recommendations by conducting active targeted surveillance. (Active targeted surveillance involves sampling animals with risk factors for BSE, even if the animals have not shown clinical signs of disease.)

Feed Ban

Canada implemented a feed ban in 1997 that prohibits the feeding of most mammalian protein to ruminants. This ban exceeds what we consider the minimal necessary measure of banning the feeding of ruminant material to ruminants. Under the ban in Canada, mammalian protein may not be fed to ruminants, with certain exceptions. These exceptions include pure porcine or equine protein, blood, milk, and gelatin. The feed ban is essentially the same as the feed ban in place in the United States.

APHIS believes the length of the feed ban in Canada is sufficient to classify that country as a minimal-risk region for BSE. In comparison, classification as a minimal-risk country or zone by OIE criteria requires that a feed ban be in place for 8 years. This value may be set at a conservative level to account for the wide range that has been reported for the incubation period of BSE. Because of the variability in the incubation period for BSE, APHIS chose not to specify an amount of time that a feed ban needed to be in place in a minimal-risk region. Rather, we considered the sum total of the control mechanisms (*e.g.,* effectiveness of surveillance, import controls, and feed ban) in place at the time of the diagnosis of BSE and the actions taken subsequently (*e.g.,* epidemiological investigations and depopulation), thereby allowing the actions Canada took with regard to the other factors to compensate for a shorter feed ban. As an example, as discussed above, the level of surveillance in Canada, and the fact that it has been active and targeted, has exceeded OIE recommendations.

Canadian Government authorities inspect rendering facilities, feed manufacturers, and feed retailers to ensure compliance with the feed ban. Rendering facilities are regulated under an annual permit system, and compliance with the regulations is verified through at least one inspection each year. Feed manufacturers or mills, feed retailers, and farms have been inspected on a routine basis. These inspections have shown a high level of compliance. As noted above, Canada has maintained an effective ban on feeding mammalian protein to ruminants, with requirements similar to the feed ban in place in the United States, since 1997. The animal in which BSE was diagnosed in May 2003 was an 6-year-old native-born beef cow in the Province of Alberta that was born before the implementation of the feed ban.

[2] Canadian Food Inspection Agency (CFIA), December 2002; Risk Assessment on Bovine Spongiform Encephalopathy in Cattle in Canada.

Morley, R.S., Chen, S., Rheault, N.; 2003; Assessment of the risk factors related to bovine spongiform encephalopathy; Rev. Sci. Tech. OIE; 22(1); pg 157–178.

Epidemiological Investigation

Canada conducted an extensive epidemiological investigation after the one case of BSE in May 2003. This investigation included detailed tracebacks to identify possible herds of origin of the infected animal, traceforwards from the infected herd, and traceforwards of any possible feed or rendered material derived from the carcass of the infected animal. Fifteen premises were quarantined as part of the traceback and traceforward investigations, and cattle on the quarantined premises were slaughtered. Additionally, cattle that were determined to have moved from a quarantined herd to another herd were slaughtered.

The investigation included any possible exposure from the use of rendered material or feed that could have been derived from the carcass of the infected cow. Using a broad definition to include all possible exposures, the rendered material could have been distributed to approximately 1,800 sites, including sites with no ruminants. These included 600 facilities that receive bulk shipments of either rendered protein or feed, and 1,200 individual producers or consumers who purchased finished feed by the bag. A survey was conducted of those entities that were at some risk of having received such rendered material or feed. This survey suggested that 99 percent of the sites surveyed experienced either no exposure of cattle (96 percent of the sites) to the feed or only incidental exposure (3 percent of the sites). The remaining 1 percent represented limited exposures, such as cattle breaking into feed piles, sheep reaching through a fence to access feed, and a goat with possible access to a feed bag.

The investigation included a consideration of several possibilities for the source of the infected cow's exposure to BSE. Although it has not been confirmed, it is assumed, based on the age of the cow, that the infected cow was exposed through contaminated feed. The infected animal was born prior to the implementation of a feed ban within Canada and could have had exposure to contaminated feed at an early age.

The renderers and feed mills associated with the investigation had records of good compliance with the feed ban. The on-farm inquiries demonstrated a very small probability of exposure of ruminants to prohibited feed. Although the possibility exists that the original source of the BSE agent could have been imported, there was no evidence that this was due to an illegal import. The BSE agent could have been from animals imported from the United Kingdom prior to import restrictions established in 1990. The surveillance program was sufficient to confirm the continued existence of adequate measures to prevent further introduction or spread of BSE.

Additional Risk Mitigation Measures

Following the detection of BSE in Canada, a broad eradication program was followed during the epidemiological investigation, in which more than 2,700 head of cattle were culled. As part of the culling activity, more than 2,000 animals 24 months of age or older were tested (those animals less than 24 months of age were not tested), with no further evidence of BSE found in any of these animals.

Importation of Ruminant Commodities From a BSE Minimal-Risk Region

Because we believe regions, such as Canada, that qualify as BSE minimal-risk regions based on the factors described above, would pose a minimal risk of introducing BSE into the United States, we believe it is warranted to allow the importation from such regions of some animals and animal products and byproducts that are prohibited importation from regions in which BSE exists and regions that present an undue risk of BSE. However, because BSE is a difficult disease to define experimentally with precision, epidemiological evidence suggests that risk factors are specific to the commodity, and multiple risk sources may be associated with a given commodity, we believe it is necessary to also apply individual risk mitigation measures to specified commodities intended for importation from BSE minimal-risk regions.

For example, as noted above and discussed further below, contaminated feed appears to be the most likely pathway of BSE transmission. However, it has not been established with certainty that contaminated feed is the only pathway. Furthermore, we cannot assume complete compliance with a ban on the feeding of ruminant protein to ruminants, which is the most effective mitigation for contaminated feed. Therefore, we believe it is necessary to apply certain other mitigation measures, in addition to implementation of a feed ban, to reduce the risk of the introduction of BSE into the United States. Each of these proposed mitigation measures is discussed below.

We are proposing to add the conditions for importing specified ruminant commodities from a BSE minimal-risk region to the regulations in 9 CFR parts 93, 94, and 95. The measures appropriate for specific commodities intended for importation would be determined by the presence or absence of factors that make it more or less likely the commodity might be contaminated or infected with the BSE. These factors are discussed in the following paragraphs.

Feed Source and Exposure

Oral ingestion of feed contaminated with the abnormal BSE prion protein is the only documented route of field transmission of BSE.[3] Thus, animals that have not ingested contaminated feed are unlikely to harbor the agent, so feed exposure influences risk. Animals, and the products derived from those animals, are unlikely to have infectious levels of the agent and will present a lower risk if the animals were (a) born after the implementation of an effective feed ban or (b) not fed risk material (*e.g.,* wild animals or farmed animals that are not fed feeds containing meat-and-bone meal).

The risks associated with feed source and exposure can be mitigated by accepting for import only animals or products derived from animals that have not been fed commercial feed that is likely to be contaminated with infectious levels of the agent.

Animal Age

Levels of infectious agent in certain tissues vary with the age of an animal, so the age of the animal influences risk. Pathogenesis studies, where tissues obtained from orally infected calves were assayed for infectivity, have illustrated this.[4] Infectivity was not detected in most tissues until at least 32 months post-exposure. The exception to this is the distal ileum (a part of the intestines), where infectivity was

[3] Prince, M.J., *et al.*; 2003; Bovine Spongiform Encephalopathy; Rev. sce. tech. OIE; 22 (1), pg 37–60.

Wilesmith *et al.*; 1988; 1991; 1992.

[4] Wells, G.A.H., *et al.*; 1994; Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy; Veterinary Record; 135 (2), pg 40–41.

Wells, G.A.H., *et al.*; 1998; Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): An update; Veterinary Record; 142, pg 103–106.

European Union Scientific Steering Committee (EU SSC), 2002; Update of the opinion on TSE infectivity distribution in ruminant tissues (initially adopted by the Scientific Steering Committee at its meeting of 10–11 January 2002 and amended at its meeting of 7–8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection, Food, and Agriculture, and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General.

confirmed from the experimentally infected cattle as early as 6 months post-exposure. In this proposed rule, we take these findings into account when establishing measures to mitigate the risk of infectious levels of the BSE agent being present in animals and animal products imported from a BSE minimal-risk region. For example, with regard to bovines, because BSE infectivity has not been found in most bovine tissues until at least 32 months post-exposure, we believe that by requiring that bovines imported into the United States from BSE minimal-risk regions be less than 30 months of age, the risk of the BSE agent being present at infectious levels in most tissues in the animal is minimized. The 30-month age limit is accepted internationally in BSE standards set by various countries and is consistent with OIE recommendations. Similarly, the proposed regulations would require that imported meat from bovines be derived from animals less than 30 months of age when slaughtered. However, because of evidence that the BSE agent may be present at infectious levels in the distal ileum of infected bovines as early as 6 months post-exposure, we would require that the intestines of bovines imported into the United States be removed at slaughter, and that meat imported from bovines from BSE minimal-risk regions be derived from animals from which the intestines were removed at slaughter.

Although the risks associated with age can be mitigated by accepting for import only animals or commodities derived from animals of an age where even high risk tissues (discussed below) are unlikely to have infectious levels of the BSE agent, restrictions applicable to age alone may not always be possible or sufficient. For instance, in the case of wild cervids, because it is not always possible to determine the age of the cervids, we believe that alternative risk measures, discussed below, are necessary.

Research demonstrates that the incubation period for BSE is apparently linked to the infectious dose received—*i.e.,* the larger the infectious dose received, the shorter the incubation period (EU SSC 2002). While some cases of BSE have been found in animals less than 30 months of age, these are relatively few and have occurred primarily in countries with significant levels of circulating infectivity (*i.e.,* where infected ruminants are used for feed for other ruminants, which in turn become infected). The conditions, discussed above, for qualifying for a BSE minimal-risk region guard against such circulating infectivity.

Similar observations regarding the importance of the size of the infectious dose were made in sheep and goats (EU SSC 2002). In these animals, infectivity could not be demonstrated in most tissues until at least 16 months post-exposure to the agent.

In summary, infected cattle over 30 months of age or sheep and goats over 16 months of age may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected animals less than 30 months of age or sheep and goats less than 16 months of age are unlikely to have infectious levels of the prion protein (EU SSC 2002; Wells, *et al.*; 1994; Wells, *et al.*; 1998).

Animals that were born before the feed ban but were not fed risk material, such as wild ruminants or domestic livestock in the minimal-risk region that were fed solely materials that are extremely unlikely to contain the infectious agent, are unlikely to contain infectious levels of BSE.

Tissue Localization

Some bovine tissues have demonstrated infectivity, whereas others have not. Tissues that have demonstrated infectivity, and thus are likely to contain the infectious agent in infected cattle, are brain, tonsil, spinal cord, eyes, trigeminal ganglia, dorsal root ganglia, and distal ileum. (Please note that, as discussed above, the age of an animal is a key factor in whether the animal is likely or unlikely to be infected. Cattle less than 30 months of age unlikely to be infected with BSE, and, therefore, even the tissues listed above, except for the distal ileum, from such animals are unlikely to contain the infectious agent.) Affiliated tissues or structures such as skull or vertebral column are considered risk materials because of the difficulty in separating out small tissues such as dorsal root ganglia from the vertebral column. Possibilities for cross contamination from risk materials must be considered also. However, even cattle carrying the infectious agent are unlikely to carry that agent in tissues that have not demonstrated infectivity (*e.g.,* muscle, liver, skin, hide, milk, embryos) or products derived from these tissues [5] (also, Wells, *et al.*; 1994; Wells, *et al.*; 1998).

The risks associated with tissue localization can be mitigated by accepting only tissues that are unlikely to have infectious levels of the agent, due to the nature of the tissue or the age of the animal (in cattle under 30 months of age, only the distal ileum is such a risk material), or commodities derived from those tissues.

Source Species

Tissue distribution of the agent varies with species. Results from experimental infections of sheep have shown that the BSE prion is distributed more widely in sheep tissues than in cattle.[6] This distribution is similar to the distribution of scrapie (a transmissible spongiform encephalopathy present in the United States) infections in sheep. In these infections, the agent may be found in the lymphoreticular system and in peripheral nerves (Foster *et al.*; 1996; Foster *et al.*; 2001).

However, no natural infections with BSE have yet been confirmed in sheep, although testing is ongoing in Europe. Similarly, no natural infections have been confirmed in goats, although actual experiments have not been conducted in the species. In the absence of actual data, distribution of the agent in goat tissues has been assumed to be similar to distribution of the agent in sheep tissues, based on the fact that scrapie acts very similarly in sheep and goats.

Similarly, natural infection of cervids (deer and elk species) with BSE has not been documented, and no challenge studies on cervid susceptibility to BSE have been conducted. In the absence of actual data, it is assumed that distribution of any BSE agent in cervid tissues would be similar to the distribution of the chronic wasting disease agent in cervid tissues, which is a naturally occurring transmissible spongiform encephalopathy.

Prevalence of BSE

The possible prevalence of disease in the region of origin will influence the risk. Prevalence of the disease will be lower in a country with adequate prevention and control measures; thus, animals from such a region will be at lower risk of being exposed to infection. The risks associated with prevalence can be mitigated by accepting commodities only from a country with low prevalence that can be classified as minimal or low risk.

[5] Wrathall, A.E., *et al.*; 2002; Studies of embryo transfer from cattle clinically affected by bovine spongiform encephalopathy (BSE); Veterinary Record; 150; pg 365–378.

[6] Foster, J.D., *et al.*; 1996; Detection of BSE infectivity in brain and spleen of experimentally infected sheep; Veterinary Record; 139; pg 912–915.

Foster, J.D., *et al.*; 2001; Distribution of the prion protein in sheep terminally affected with BSE following experimental oral transmission; J. Gen Virol.; 82; pg 2319–2326.

Importation of Live Ruminants

We believe the categories of ruminants discussed below from BSE minimal-risk regions are unlikely to be a source of infectivity of the BSE agent if the conditions specified below are met, and we propose to allow for such importation under those conditions in a new § 93.436. In each case where we are proposing to allow importation, the animals would have to arrive through a designated port of entry as listed in current § 93.403(b) (designated ports of entry for ruminants from Canada), or through some other port that has been designated as a port of entry by the Administrator under § 93.403(f). If, in the future, we add other countries to the list of BSE minimal-risk regions in § 94.18(a)(3), we would adjust the list of designated ports accordingly.

In those cases where a ruminant is imported into the United States, and subsequently does not meet one of the conditions set forth in § 93.436 (*e.g.,* animals that die before reaching the slaughtering establishment; animals that are moved from a feedlot in this country to slaughter after they are 30 months of age), the regulations would provide that the animal must be disposed of in a manner approved by the Administrator.

Bovines Less Than 30 Months of Age for Immediate Slaughter

Section 93.436, paragraph (a), would allow the importation of bovines for immediate slaughter under the following conditions:

- The bovines are less than 30 months of age and are moved directly as a group from the port of entry to a recognized slaughtering establishment (the definition of recognized slaughtering establishment is set forth in § 93.400) for immediate slaughter as a group. (Under the definition of *immediate slaughter* in § 93.400, the bovines must be slaughtered within 2 weeks of the date of entry. In § 93.400, we would add a definition of *as a group* to mean collectively, in such a manner that the identity of the animals as a unique group is maintained.)
- The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The bovines are accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that certifies the above conditions have been met.
- The bovines are moved as a group from the port of entry to the slaughtering establishment in conveyances sealed at the port of entry with seals of the United States Government, which are broken only at the slaughtering establishment by a USDA representative, and the shipment is accompanied by an APHIS Veterinary Services (VS) Form 17–33, Animals Imported for Immediate Slaughter.
- At the slaughtering establishment, the bovines are slaughtered as a group and each animal's intestines are removed.
- The intestines removed from the bovines are disposed of in a manner approved by the Administrator.

We believe the conditions described above, combined with the fact the exporting region is one of minimal risk for BSE, make it very unlikely that meat derived from bovines meeting those conditions would contain the BSE agent. The requirement that the bovines imported from a BSE minimal-risk region be less than 30 months of age would make it unlikely they would have infectious levels of the prion protein. The requirements that the bovines be moved to slaughter in a sealed conveyance and be slaughtered as a group are designed to ensure that the animals are not diverted while being moved to slaughter and that the intestines are removed at slaughter from all bovines imported from the minimal-risk region. If any bovines not from the minimal-risk region are commingled with the group of bovines from the minimal-risk region at the slaughtering establishment, then those added animals would be treated as if they were from the minimal-risk region and their intestines would have to be removed and disposed of in accordance with our proposed provisions. The requirement that the bovines be slaughtered at a recognized slaughtering establishment (as defined in § 93.400) would ensure the animals are slaughtered at a facility approved by APHIS where slaughtering operations are regularly carried on under Federal or State inspection. The requirement that the intestines be removed from the animal at slaughter and be disposed of in a manner approved by the Administrator would minimize the possibility that such materials will be fed to ruminants. We believe it is necessary to provide the Administrator discretion in the specific means of disposal used, to allow for the use of different but equally effective methods of disposal.

Bovines Less Than 30 Months of Age Moved to a Designated Feedlot and Then to Slaughter

We would apply the slaughtering conditions described above to bovines imported for slaughter in the United States after first being contained at a designated feedlot in this country. However, instead of being moved directly from the port of entry to a recognized slaughtering establishment, such animals would first be moved directly, as a group, to a designated feedlot for feeding, and then directly to a recognized slaughtering establishment. In § 93.400, we would define *designated feedlot* to mean a feedlot indicated on the declaration required under § 93.407 as the destination of the ruminants imported into the United States. Under current § 93.407, the importer of ruminants (or the importer's agent) must present a declaration at the port of entry that provides information about the ruminants, their origin, and their destination. For identification purposes, prior to being imported into the United States, each bovine would have to have been tattooed inside one ear with letters identifying the exporting country. Bovines from Canada would have to be tattooed with the letters ''CAN.''

Therefore, § 93.436(b) would allow the importation of bovines for feeding under the following conditions:

- The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime and are less than 30 months of age when imported into the United States.
- The inside of one ear on each animal is permanently and legibly tattooed with letters identifying the exporting country.
- The bovines are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The bovines are moved directly from the port of entry as a group to the designated feedlot and the shipment is accompanied by an APHIS Form VS 1–27, Permit for Movement of Restricted Animals.
- The bovines are moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter, where each animal's intestines are removed. The shipment is accompanied by APHIS Form VS 1–27.
- The intestines removed from the bovines are disposed of in a manner approved by the Administrator.
- The bovines are less than 30 months of age when slaughtered.

Unlike the requirement for bovines moved directly to immediate slaughter, we would not require that the animals

be moved from the port of entry to the designated feedlot in sealed conveyances. The only region we are proposing at this time to classify as BSE minimal-risk is the country of Canada. Under the current APHIS regulations and policy, bovines imported from Canada for movement directly to immediate slaughter do not have to be accompanied by the health certificate required under § 93.405 that attests to the animal's health history with regard to various diseases and pests. However, the bovines must be moved to slaughter in a sealed conveyance. (**Please note:** The regulations in part 93 use the term ''cattle'' rather than ''bovines.'' However, in § 93.400, *cattle* is defined as animals of the bovine species.) Because of the requirement for direct movement to slaughter in a sealed conveyance, there is little danger the bovines will be diverted on their way to the slaughtering establishment. Those requirements would remain unchanged by this proposed rule, although animals for immediate slaughter would have to be accompanied with the certification with regard to BSE specified in this proposal.

Under the current regulations, however, bovines imported from Canada for other than immediate slaughter do have to be accompanied by a certificate attesting to their health history with regard to various diseases, in order to ensure they do not spread such diseases to other livestock in this country. Because of their acceptable health history, it has not been necessary to require that the animals be moved in a sealed conveyance. This requirement for a health certificate would remain in place for bovines imported from Canada for feeding before slaughter (and be joined with the certification with regard to BSE specified in this proposal). Because of this health certification, and because, with regard to BSE, the bovines would have to be tattooed with the letters CAN, possible diversion is not an issue and we do not consider it necessary to begin to require that feeder bovines be moved from the U.S. port of entry to the designated feedlot in a sealed conveyance.

Additionally, we are not requiring that the bovines be moved from the designated feedlot to slaughter as a group. A shipment of bovines that arrives at a feedlot may contain animals of varying ages. Some will be ready for shipment to slaughter before others. However, we would require that all animals moved from the designated feedlot be moved directly to slaughter, where they would be identifiable as a shipment from a minimal-risk region by the required ear tattoo.

Sheep or Goats Less Than 12 Months of Age for Immediate Slaughter

Section 93.436, paragraph (c), would allow the importation of sheep or goats under the following conditions:

- The sheep or goats are less than 12 months of age at the time of importation.
- The sheep or goats are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The sheep or goats are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The sheep or goats are moved directly from the port of entry as a group to a recognized slaughtering establishment in conveyances sealed at the port of entry with seals of the United States Government, which are broken only at the slaughtering establishment by a USDA representative, and must be slaughtered as a group. The shipment is accompanied by an APHIS Form VS 17–33.

Although there is no naturally occurring BSE infection of sheep and goats, the species can be infected with the BSE agent experimentally. However, in view of the relatively young age of the sheep and goats that would be allowed importation (we would allow importation of sheep and goats only of 12 months of age or less, the industry standard for commercial shipments of such animals), the likelihood that these sheep or goats could provide a source of infection is extremely low.

Sheep or Goats Less Than 12 Months of Age Moved to a Designated Feedlot and Then To Slaughter

We would apply the slaughtering conditions described above to sheep or goats imported for slaughter in the United States after first being contained at a designated feedlot in this country. However, instead of being moved directly from the port of entry to a recognized slaughtering establishment, such animals would be moved to a designated feedlot, and then directly to a recognized slaughtering establishment. For identification purposes, prior to being imported into the United States, each sheep and goat would have to have been tattooed inside one ear with letters identifying the exporting country. Sheep and goats from Canada would have to be tattooed with the letters ''CAN.''

Therefore, § 93.436(d) would allow the importation of sheep and goats under the following conditions:

- The sheep and goats are not known to have been fed ruminant protein, other than milk protein, during their lifetime and are less than 12 months of age at the time of importation into the United States.
- The inside of one ear on each animal is permanently and legibly tattooed with letters identifying the exporting country.
- The sheep or goats are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The sheep or goats are moved directly from the port of entry as a group to a designated feedlot and the shipment is accompanied by an APHIS Form VS 1–27.
- The sheep or goats are moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter. The shipment is accompanied by APHIS Form VS 1–27.
- The sheep and goats are less than 12 months of age when slaughtered.

Cervids for Immediate Slaughter

Section 93.436, paragraph (e), would allow the importation of cervids under the following conditions:

- The cervids were members of a herd in which surveillance for transmissible spongiform encephalopathies (TSE's) was conducted by appropriate authorities according to national standards or standards of the region itself if the region is a jurisdiction that has effective oversight of normal animal movements into, out of, or within the region and that, in association with national authorities if necessary, has the responsibility for controlling animal disease locally.
- The herd is not known to have been infected with or exposed to a TSE.
- The cervids were born after the implementation of a ban on feeding of ruminant protein to ruminants.
- The cervids were not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The cervids are accompanied by authorized official certification, as described above, that the above conditions have been met.
- The cervids are moved from the port of entry as a group directly to a recognized slaughtering establishment in conveyances sealed at the port of entry with seals of the United States Government, which are broken only at the slaughtering establishment by a USDA representative. The cervids must be slaughtered as a group. The shipment is accompanied by an APHIS Form VS 17–33.

As ruminants, cervids are subject to import restrictions because of BSE. We believe that the above conditions are necessary for the importation of cervids intended for immediate slaughter, because, although there have been no

confirmed cases of BSE in cervids, it is possible that they are susceptible to BSE. To date, there have been no challenge studies for BSE in cervids (*i.e.*, studies in which cervids are intentionally exposed to the BSE agent) to indicate the level of susceptibility of cervids to BSE. Given the stringent controls described above, however, and the fact that there have been no confirmed cases of BSE in cervids, we believe the likelihood BSE would be introduced into the United States through cervid importations is extremely low, and we do not believe that mitigation measures other than those listed above are necessary.

One of the requirements listed above is that the cervids have been members of a herd in which surveillance for TSE's was conducted by appropriate authorities according to national or regional standards. At present, the TSE program for cervids in Canada, the one region we are proposing to classify as BSE-minimal risk at this time, is one that monitors for chronic wasting disease (CWD). However, all sampling done to monitor for CWD would identify animals that might be affected with other TSE's such as BSE.

Ruminant Products From Minimal-Risk Regions

We are proposing to add a new § 94.19 to list those ruminant products that would be allowed importation from a BSE minimal-risk region and to set forth the conditions for such importation.

In evaluating the risk that ruminant products imported into the United States might present, the same factors affecting the BSE risk of the live animals from which the products are derived are applicable. Additionally, other factors must be considered due to the processing the products undergo. Slaughter methods and the removal of risk material from source animals in the exporting region affect the level of risk associated with meat and meat products from those animals, as do intended use and the demonstrated likelihood of the animal product in question to contain the BSE agent.

Similar to the slaughter requirements for ruminants imported live into the United States for immediate slaughter, it would be necessary to require that most ruminant products intended for importation into the United States from a BSE minimal-risk region come from animals from which intestines were removed during processing. In some cases, however, because of other mitigating factors, such as if no natural infection has been observed in the type of animal, we do not believe it would be necessary to require that the intestines have been removed from the animal from which the product is derived.

We believe that the importation of the categories of meat and other edible products from ruminants from BSE minimal-risk regions discussed below would be unlikely to contain the BSE agent provided the following conditions are met, as certified to on an original certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so.

As one of the conditions for bringing the commodity into the United States, we are proposing that the meat and edible products, if arriving at a land border port, arrive only at one of the ports we would list in new § 94.19(k). At this time, the only region that would be listed in § 94.18(a)(3) as a BSE minimal-risk region would be the country of Canada. Because the type of shipments that would require inspection under this proposed rule have not been subject to inspection in recent years when arriving at land border ports from Canada, we believe it is advisable to limit their arrival by land from Canada to those U.S. ports staffed with personnel fully trained in the inspection of such shipments.

We would list the following as designated land border ports in § 94.19(k): Eastport, ID; Houlton, ME; Detroit (Ambassador Bridge), Port Huron, and Sault St. Marie, MI; International Falls, MN; Sweetgrass, MT; Alexandria Bay, Buffalo (Lewiston Bridge and Peace Bridge), and Champlain, NY; Pembina and Portal, ND; Derby Line and Highgate Springs, VT; and Blaine (Pacific Highway and Cargo Ops), Lynden, Oroville, and Sumas (Cargo), WA. If, in the future, we add other countries to the list of BSE minimal-risk regions in § 94.18(a)(3), we would adjust the list of designated ports accordingly.

Fresh (Chilled or Frozen) Meat From Bovines Less Than 30 Months of Age

Section 94.19, paragraph (a), would allow the importation of meat under the following conditions:

- The meat is fresh (chilled or frozen) meat from bovines less than 30 months old at the time of slaughter that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The bovines from which the meat is derived were slaughtered in a slaughtering establishment that slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.
- The intestines of the bovines were removed at slaughter.
- The product qualifies as meat according to the definition of meat set forth in USDA's Food Safety and Inspection Service's (FSIS) regulations at 9 CFR 301.2.
- The shipment is accompanied by authorized official certification, as described above, that the above conditions have been met.

We would require that the commodity meet the definition of ''meat'' according to the FSIS regulations to ensure that, if imported as ground meat, it has not been combined with meat that might contain high-risk tissues from high-risk animals. Under the FSIS definition in 9 CFR 301.2, to be considered ''meat,'' product that undergoes mechanical separation and meat recovery from the bones of livestock must be processed in such a way that the processing does not crush, grind, or pulverize bones, so that bones emerge comparable to those resulting from hand-deboning and the meat itself meets the criteria of no more than 0.15 percent or 150 mg/100 gm of product for calcium (as a measure of bone solids content) within a tolerance of 0.03 percent or 30 mg. We are proposing to use this standard for the eligibility of meat from bovines (and, as indicated later, for meat from sheep and goats) to ensure that the product contains no mechanically separated meat that might contain high risk-tissues. (**Please note:** Except where the FSIS definition of *meat* is specifically referenced in proposed § 94.19(a)(3) with regard to meat from bovines, and in proposed § 94.19(e)(2) with regard to meat from sheep or goats or other ovines or caprines, the standard dictionary definition of meat is intended throughout this proposed rule.)

To avoid commingling or contamination of meat from bovines under 30 months of age with materials from older bovines, we would require that the slaughtering facility in the region of origin either slaughter only bovines less than 30 months of age or comply with an approved segregation process. Such segregation during

slaughtering could be accomplished, for instance, by slaughtering bovines over 30 months of age only at the end of the day on lines and with equipment dedicated exclusively to slaughtering such older animals.

Fresh (Chilled or Frozen) Whole or Half Carcasses of Bovines Less Than 30 Months of Age

Section 94.19, paragraph (b), would allow the importation of bovine carcasses under the following conditions:

- The products are fresh (chilled or frozen) whole or half carcasses derived from bovines that were less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The bovines from which the carcasses are derived were slaughtered in a slaughtering establishment that slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling with products not eligible for importation into the United States.
- The intestines of the bovines were removed at slaughter.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

Fresh (Chilled or Frozen) Bovine Liver

Section 94.19, paragraph (c), would allow the importation of fresh (chilled or frozen) bovine liver, provided the product is combined with no other product, is derived from bovines for which no air-injected stunning process was used at slaughter, and is accompanied by authorized official certification that the above conditions have been met. In and of itself, the liver is unlikely to contain infectious levels of the BSE agent, so we are not proposing to require that liver be derived from animals less than 30 months of age or not known to have been fed ruminant protein, other than milk protein, during their lifetime. However, we would prohibit the importation of liver derived from bovines for which an air-injected stunning process was used. The liver, because of its anatomical location and size of its blood vessels, is the organ that could potentially receive emboli or tissue fragments distributed in the animal due to the use of an air-injected stunning process. Because there would be no age limit on the bovines from which the liver is derived, we believe it is necessary to ensure that the liver be free of such potentially high-risk material.

Fresh (Chilled or Frozen) Bovine Tongues

Section 94.19, paragraph (d), would allow the importation of fresh (chilled or frozen) bovine tongues that meet the following conditions:

- The tongues are derived from bovines that were born after the implementation of an effective feed ban.
- The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The tonsils of the bovines were removed at slaughter.
- The tongues are accompanied by authorized official certification that the above conditions have been met.

The tongue itself is unlikely to contain the BSE agent in animals of any age. However, because the tongue and the tonsils are connected, and the tonsils consist of tissue with demonstrated infectivity, we believe it is necessary to require that the tonsils have been removed from bovines greater than 30 months of age from which tongues for importation are derived. To eliminate the need to determine the exact age of the animals from which tongues are derived, we would require that the tonsils have been removed at slaughter from all bovines from which tongues intended for importation from a BSE minimal-risk region are derived.

Fresh (Chilled or Frozen) Meat of Sheep or Goats or Other Ovines or Caprines

Section 94.19, paragraph (e), would allow the importation of meat under the following conditions:

- The product is fresh (chilled or frozen) meat from sheep or goats or other ovines or caprines less than 12 months of age at the time of slaughter that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The animals from which the meat is derived were slaughtered in a slaughtering establishment that slaughters only sheep and/or goats or other ovines or caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.
- The product qualifies as meat according to the definition of meat set forth in USDA's Food Safety and Inspection Service's (FSIS) regulations at 9 CFR 301.2.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

Fresh (Chilled or Frozen) Carcasses of Ovines or Caprines

Section 94.19, paragraph (f), would allow the importation of fresh (chilled or frozen) carcasses of ovines and caprines under the following conditions:

- The carcasses are derived from ovines or caprines that were less than 12 months old when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.
- The ovines or caprines from which the carcasses were derived were slaughtered in a slaughtering establishment that slaughters only ovines and/or caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the carcasses with products not eligible for importation into the United States.
- The carcasses are accompanied by authorized official certification that the above conditions have been met.

Hunter-Harvested Wild Ruminant Products

Section 94.19, paragraph (g), would allow the importation of hunter-harvested wild ruminant products under the following conditions:

- The product is meat or a dressed (eviscerated and the head is removed) carcass of a wild sheep, goat, cervid, or other ruminant;
- The meat or dressed carcass is intended for personal use, and the hunter provides proof to the U.S. Customs and Border Protection official that the animal was a legally harvested wild (not ranched) animal. Such proof will include the hunting license, tag, or equivalent;
- The game and wildlife service of the jurisdiction where the ruminant was harvested has informed the Administrator that the jurisdiction either: (1) Conducts no type of game feeding program, or (2) has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region.

Meat and meat products from wild animals not maintained on ranches or farms are unlikely to have ingested contaminated commercial feed and are unlikely to have infectious levels of the BSE agent. Also, the nature of hunter-harvested ruminant products to be used

for personal use makes it highly unlikely that the product will enter the commercial food chain for animals. (In § 94.0, we would add a definition of *personal use* to mean only for personal consumption or display and not distributed further or sold.) If the game and wildlife service of the jurisdiction where the ruminant was harvested has not informed the Administrator either that the jurisdiction conducts no game feeding program or has complied with, and continues to comply with, the feed ban, we would direct U.S. inspectors at the designated ports of arrival not to allow such hunter-harvested ruminant products from the jurisdiction to be imported into the United States.

Fresh (Chilled or Frozen) Meat of Cervids Either Farm-Raised or Harvested on a Game Farm or Similar Facility

Section 94.19, paragraph (h), would allow the importation of meat and meat products under the following conditions:

- The product is fresh (chilled or frozen) meat derived from cervids that were born after an effective feed ban was implemented, that were not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy.
- If the product is ground meat or sausage, it was derived either from all cervine meat or from cervine meat mixed with nonruminant meat.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

No natural infection of BSE has been documented in cervids, and we believe there is a very low risk that any tissue in cervids is likely to contain the BSE agent. Therefore, we believe it is unnecessary to prohibit the importation of ground meat or sausage that is exclusively cervid meat or cervid meat and nonruminant meat. However, because it has not been proven that cervids are not susceptible to BSE, we believe it is necessary to require that the cervid meat and meat products be derived from cervids that were members of a herd not known to have been infected with or exposed to a transmissible spongiform encephalopathy.

Fresh (Chilled or Frozen) Meat From Wild-Harvested Caribou, Musk Ox, or Other Cervids

Section 94.19, paragraph (i), would allow the importation of meat under the following conditions:

- The meat is from wild caribou, musk ox, or other cervids harvested within a jurisdiction specified by the Administrator for which the game and wildlife service has informed the Administrator that the jurisdiction either: (1) Conducts no type of game feeding program, or (2) has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region.
- The cervids from which the meat is derived were either slaughtered in a slaughtering establishment that slaughters only cervids eligible for entry into the United States or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.
- The shipment is accompanied by authorized official certification that the above conditions have been met.

This meat differs from the meat described above under the heading ''Hunter-harvested wild ruminant products'' in that, although it is hunter-harvested, it is done so on a larger scale for commercial sale.

Gelatin

Section 94.19, paragraph (j), would allow the importation of gelatin from bones of bovines that were less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, provided the shipment is accompanied by authorized official certification that these conditions have been met.

Importation of Certain Tallow and Offal

Section 95.4 of the regulations currently restricts the importation of animal protein, tankage, fat, glands, tallow other than tallow derivatives, and serum from regions where BSE is known to exist or that present an undue risk of BSE. Of these products, we believe that certain tallow and offal could be imported from BSE minimal-risk regions under certain conditions with little likelihood of containing infectious levels of the BSE agent, and are proposing to amend § 95.4 to allow the importation of such materials. We do not have evidence at this time that the other products prohibited under § 95.4 could be imported with little likelihood of containing infectious levels of the BSE agent.

As one of the conditions for importation, the tallow and offal, if arriving at a U.S. land border port, would have to arrive at one of the ports we would list in new § 94.19(k).

Tallow

In the case of tallow, we would require that it contain less than 0.15 percent protein and be obtained from bovines less than 30 months of age when slaughtered. This product would be considered low risk because it is primarily lipid material with a minimal cellular component. When it is derived from low-risk bovines and the level of protein is low, the material would be unlikely to contain prion protein.

Section 95.4, paragraph (f), would allow the importation of tallow under the following conditions:

- The tallow is composed of less than 0.15 percent protein.
- The tallow was derived from animals that were less than 30 months of age when slaughtered, that were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants, and that were not known to have been ruminant protein, other than milk protein, during their lifetime.
- The tallow is not derived from an animal that died otherwise than by slaughter.
- The intestines were removed from each animal at slaughter.
- The shipment of tallow to the United States is accompanied by authorized official certification that the above conditions have been met.

Cervine Offal

In the case of offal, we would require that it be derived from cervids born after the implementation of an effective feed ban that were not known to have been fed ruminant protein, other than milk protein. Because the offal would be derived from low-risk animals, we would consider the product to be unlikely to contain the BSE agent. We would limit the importation of offal to cervine offal, because bovine offal could contain the distal ileum, which is a tissue with confirmed infectivity in BSE-infected bovines.

Section 95.4, paragraph (g), would allow the importation of offal from cervids under the following conditions:

- The offal was derived from cervids that were born after the feed ban, that were not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy.
- The shipment of offal to the United States is accompanied by authorized

official certification that the above conditions have been met.

Additionally, because offal can encompass a variety of materials, for clarification we would add a definition of offal to § 95.1 to mean the parts of a butchered animal that are removed in dressing, consisting largely of the viscera and the trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, and kidney.

APHIS Inspection of Processing and Handling Facilities; Certification of Compliance

Although § 95.4 restricts the importation of animal protein, tankage, fat, glands, tallow other than tallow derivatives, and serum from regions where BSE is known to exist or that present an undue risk of BSE (as listed in current § 94.18(a)), paragraph (c) of § 95.4 exempts certain materials from the restrictions, under certain conditions, provided the material is derived from a nonruminant species, or from a ruminant species if the ruminants have never been in a region listed in § 94.18(a). One of the conditions for such importation is that all steps of processing and storing the material be carried out in a facility that has not been used for the processing or storage of any materials derived from ruminants that have been in any region listed in § 94.18(a). A further requirement is that, if the facility processes or handles any material derived from mammals, the facility must have entered into a cooperative service agreement with APHIS to pay for the costs of an APHIS veterinarian to make annual inspections of the facility.

Because we believe the regions we are proposing to include in § 94.18(a)(3) of this proposal present a minimal risk for BSE, we believe that, in lieu of annual APHIS inspections of the facility, such inspections could be carried out by the government agency responsible for animal health in the region, although APHIS would reserve the right to inspect as deemed necessary. Therefore, we are proposing to amend § 95.4(c)(4) to exclude facilities in BSE minimal-risk regions from the requirement for a cooperative service agreement and to require that annual inspections of the facility be carried out by a representative of the government agency responsible for animal health in the region. We would, however, still apply to BSE minimal-risk regions the provisions of § 95.4(c)(5), which require the facility to allow periodic inspections by APHIS.

Additionally, we are proposing to amend § 95.4(c)(6), which currently specifies that each shipment imported into the United States in accordance with § 95.4(c) be accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the conditions of that section have been met. Because of the reduced risk of such exports from regions we would consider minimal risk, we are proposing to provide in § 95.4(c)(6) that, for shipments of animal feed, the necessary certification may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

Definitions

In addition to adding definitions of *as a group, designated feedlot, bovine spongiform encephalopathy (BSE) minimal-risk region, offal,* and *personal use* to the regulations, as discussed above, we are proposing to define in § 93.400 the term *USDA representative* to mean a veterinarian or other individual employed by the United States Department of Agriculture who is authorized to perform the services required by part 93.

Executive Order 12866 and Regulatory Flexibility Act

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

Under the Animal Health Protection Act of 2002 (7 U.S.C. 8301 *et seq.*) the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock.

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. To prevent the introduction of this disease into the United States, APHIS issued an interim rule to classify Canada as a region where BSE exists, thereby prohibiting the importation of ruminants and most ruminant products from Canada, effective May 20, 2003.

This proposed rule would amend the regulations by establishing a category of regions that present a minimal risk of introducing BSE into the United States. The rule would set forth factors considered for placing a region in this category, and risk mitigations that would be required for the importation of certain ruminants and ruminant products from such regions. Although the proposed rule would list Canada as the only BSE minimal-risk region at this time, APHIS would evaluate requests and supporting information submitted by other regions for inclusion in this category.

In accordance with Executive Order 12866 and the Regulatory Flexibility Act, we assessed the potential economic costs and benefits of this rule and potential effects on small entities. Although not addressed in the analysis, Canadian producers/suppliers of ruminants and ruminant products would benefit from the resumption of exports to the United States.

Below is a summary of our economic analysis. A copy of the full economic analysis is available for review in our reading room (see the **ADDRESSES** section at the beginning of this document). You may also view the economic analysis on the Internet by accessing the APHIS Web site at *http://www.aphis.usda.gov.* At the APHIS Web site, click on the ''Hot Issues'' button. On the next screen, click on the listing for ''Bovine Spongiform Encephalopathy (BSE).'' On the next screen, click on the listing for ''Economic Analysis, Proposed Rule, Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities (APHIS Docket No. 03–080–1).'' We do not have enough data for a comprehensive analysis of the potential economic effect of this proposed rule on small entities. Therefore, in accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis for this proposed rule. We are inviting comments about this proposed rule as it relates to small entities. In particular, we are interested in determining the number and kind of small entities that would incur benefits or costs from the implementation of this proposed rule and the economic effect of those benefits or costs.

Because Canada is the only region we are proposing to include in the BSE minimal-risk category at this time, ruminant and ruminant product imports from Canada that would be reestablished under the proposed rule are the focus of our analysis. However, this minimal-risk category is not limited to Canada and could include other regions in the future. The analysis also considers effects of the rule for U.S. ruminant and ruminant product exports should other countries not consider our minimal-risk requirements sufficient to safeguard against BSE introduction into the United States and/or do not accept our listing of Canada as a region of minimal risk.

The commodities that would be allowed to enter under the proposed rule are:

- Cattle less than 30 months of age, sheep and goats less than 12 months of age, and cervids of any age, imported in all cases for immediate slaughter;
- Cattle less than 30 months of age and sheep and goats less than 12 months of age imported for feeding at a designated feedlot (for slaughter at less than 30 months and 12 months of age, respectively);
- Meat from cattle, sheep, and goats that have been slaughtered within these age restrictions;
- Meat of cervids either farm-raised or harvested on a game farm or similar facility;
- Meat from wild-harvested caribou, musk ox, or other cervids that has been commercially processed;
- Certain hunter-harvested wild ruminant products for personal use; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, tallow, and cervid offal.

With respect to Canada, slaughter cattle, feeder cattle, and beef would be the main commodities affected by resumption of ruminant and ruminant product imports. The additional supplies would cause prices to fall. Welfare gains for consumers and losses for producers/suppliers are measured, and net benefits and losses estimated. Since May of this year, U.S. producers/suppliers of ruminants and ruminant products have benefited from high price levels at least partly attributable to the ban on imports from Canada. Estimated price declines for producers/suppliers and consumers/buyers of slaughter cattle, feeder cattle, and beef largely reflect a return to the more normal market conditions that prevailed before Canada's BSE discovery.

Expected effects due to reestablished slaughter cattle and feeder cattle imports from Canada are shown in table 1. (The model and parameters used are explained in the body of the economic analysis.) The estimated effects are near-term, and would occur during the first year or so following the resumption of imports. In the longer term, production and marketing adjustments in response to changed market conditions would create new price-quantity equilibriums.

TABLE 1.—ECONOMIC EFFECTS OF REESTABLISHED SLAUGHTER CATTLE AND FEEDER CATTLE IMPORTS FROM CANADA

	Slaughter cattle	Feeder cattle
Assumed reestablished slaughter and feeder cattle imports from Canada (head)	840,800	504,500
Change in numbers slaughtered and fed (head)	366,350	221,318
Change in numbers supplied by U.S. entities (head)	(474,450)	(283,182)
Change in the prices of slaughter and feeder cattle (dollars per 100 pounds)	($1.30)	($0.72)
Change in consumer surplus	$455,317,000	$188,220,000
Change in producer surplus	($448,744,000)	($182,053,000)
Annual net benefit	$6,573,000	$6,167,000

Reestablished slaughter cattle imports from Canada of 840,000 head would result in a price decline of $1.30 per 100 pounds. This price decline would be accompanied by an increase of about 366,350 head in the number of cattle slaughtered, and a decrease of 474,450 head in the number of slaughter cattle supplied by U.S. entities. These changes translate into an increase in consumer surplus of $455.3 million for buyers of slaughter cattle, and a decrease in producer surplus of $448.7 million for sellers of slaughter cattle, for an annual net benefit of $6.6 million.

Whether a portion of this benefit would be realized by beef consumers would depend upon wholesale and retail margins and elasticities of demand. The price decline would reduce incomes of domestic suppliers who would be competing with slaughter cattle imports from Canada. The estimated price change is small, falling within expected variations of recent USDA price projections. A price decrease of $1.30 per 100 pounds would represent a decline of 1.7 percent and would not significantly affect buyers or sellers of slaughter cattle.

Reestablished feeder cattle imports from Canada totaling 504,500 head would result in a price decline of 72 cents per 100 pounds. This fall in price would be accompanied by an increase of 221,318 head in the number of cattle fed, and a decrease of 283,182 head in the number of cattle supplied to feedlots by U.S. entities. Consumer surplus would rise by $188.2 million for buyers of feeder cattle, and producer surplus would fall by $182 million for sellers of feeder cattle, for an annual net benefit of about $6.2 million.

A price decline resulting from reestablished feeder cattle imports from Canada would benefit the receiving feedlots. The decline would also reduce incomes for domestic suppliers, such as stocker operations, in competition with importers of feeder cattle from Canada. The estimated effects are small. A price decrease of 72 cents per 100 pounds would represent a decline of 0.9 percent and would not result in significant gains or losses for the affected entities.

Beef is modeled as a single aggregate commodity, but two analyses are performed. Boneless beef and certain other ruminant products are allowed to enter the United States from Canada under permit. We do not know whether quantities of boneless beef that enter under permit will reach levels that prevailed prior to the ban. This uncertainty is acknowledged by using two different import levels. The first analysis assumes that boneless beef imports from Canada under permit will reach 2002 levels; the effect of the proposed rule with respect to beef would be in reestablishing beef with bone and whole/half carcass imports. The second analysis assumes that no boneless beef is imported under permit, and all reestablished beef imports from Canada would be attributable to the proposed rule. The two analyses are hypothetical extremes that provide a lower bound and an upper bound of possible effects. Effects for two price levels of beef, $3.00 and $3.50 per pound, are estimated, as shown in table 2.

TABLE 2.—ECONOMIC EFFECTS OF REESTABLISHED BEEF IMPORTS FROM CANADA, FOR HYPOTHETICAL LOWER AND UPPER BOUNDS OF POSSIBLE EFFECTS OF THE PROPOSED RULE

	Only reestablished beef with bone and whole/half carcass imports from Canada assumed attributable to the proposed rule		All reestablished beef imports from Canada assumed attributable to the proposed rule	
	$3.00 per pound beef	$3.50 per pound beef	$3.00 per pound beef	$3.50 per pound beef
Assumed beef imports from Canada (tons)	84,000	84,000	382,000	382,000
Change in U.S. consumption (tons)	40,324	40,324	183,378	183,378
Change in U.S. production (tons)	(43,676)	(43,676)	(198,622)	(198,622)
Change in the price of beef (per pound)	(1.1 cents)	(1.3 cents)	(5.2 cents)	(6.1 cents)
Change in consumer surplus	$313,260,000	$365,455,000	$1,416,390,000	$1,652,383,000
Change in producer surplus	($289,425,000)	($337,648,000)	($1,325,068,000)	($1,545,845,000)
Annual net benefit	$23,835,000	$27,807,000	$91,322,000	$106,538,000

For beef prices of $3.00 and $3.50 per pound, respectively, annual net benefits of established beef imports would be $23.8 million and $27.8 million (only beef with bone and whole/half carcass imports assumed to be reestablished due to the proposed rule), and $91.3 million and $106.5 million (all beef imports assumed to be reestablished due to the proposed rule). As with reestablished imports of slaughter and feeder cattle, expected price declines due to reestablished beef imports from Canada would not be of a magnitude to significantly affect the economic welfare of producers or consumers. In the first case, price declines of 1.1 cents and 1.3 cents per pound are estimated for assumed beef prices of $3.00 and $3.50 per pound, respectively. In the second case, price declines of 5.2 cents and 6.1 cents per pound are estimated. Even in the latter analysis (all reestablished beef imports from Canada attributable to the proposed rule), the price declines represent less than a 2 percent fall in price.

Other, more minor commodities that would be allowed entry under the proposed rule and for which we have trade data are sheep, goats, and farmed cervids; meat from these ruminants; and bovine tongues and livers. In all cases, reestablished imports from Canada would not significantly affect the U.S. supply of these commodities or the welfare of U.S. entities.

The United States prohibits ruminant imports from BSE-affected regions. Under the proposed rule, the United States would recognize Canada as a minimal-risk region for BSE, under which ruminant imports could resume. U.S. ruminant and ruminant product exports would be placed in jeopardy if importing countries do not agree that the factors the United States would consider justify the categorization of a region as one of minimal risk, and do not agree that the proposed age restrictions and other measures provide an adequate safeguard against the risk of BSE introduction from such a region.

We therefore analyze the economic effects that would occur if the United States would lose major export markets due to this proposed rule and its inclusion of Canada as a minimal-risk region.

Because U.S. ruminant and ruminant product exports to Canada and Mexico would not be jeopardized by this proposed rule, exports to these two countries are excluded from the analysis. Since nearly all U.S. cattle exports are to Canada and Mexico, we can also limit the analysis to possible effects for beef exports.

Canada and Mexico together imported about 36 percent of U.S. beef exports in 2002. Removing these exports from consideration leaves about 64 percent of U.S. beef exports that could be affected by the proposed rule. About 56 percent of U.S. beef exports (over 87 percent, excluding shipments to Canada and Mexico) were sold to Japan and Korea. Given the predominance of these two countries among importers of U.S. beef, the analysis is performed for two levels of export reduction: 32 percent of 2002 exports, or 263,360 tons (loss of one-half of export markets other than Canada and Mexico), and 64 percent, or 546,720 tons (loss of all export markets other than Canada and Mexico). For each of these assumed levels of export reduction, impacts are estimated using the same beef prices, $3.00 and $3.50 per pound. The results of the analysis are shown in table 3.

TABLE 3.—ECONOMIC EFFECTS OF THE LOSS OF U.S. BEEF EXPORT MARKETS, ASSUMING EXPORT REDUCTIONS OF 32 PERCENT AND 64 PERCENT

[Quantities equivalent to one-half and all U.S. beef exports when exports to Canada and Mexico are excluded]

	Loss of export markets equivalent to 32 percent of 2002 beef exports		Loss of export markets equivalent to 64 percent of 2002 beef exports	
	$3.00 per pound beef	$3.50 per pound beef	$3.00 per pound beef	$3.50 per pound beef
Assumed reduction in beef exports (tons)	263,360	263,360	546,720	546,720
Change in U.S. consumption (tons)	116,483	116,483	232,967	232,967
Change in U.S. production (tons)	(146,877)	(146,877)	(293,753)	(293,753)
Change in the price of beef (cents per pound)	(3.6 cents)	(4.2 cents)	(7.2 cents)	(8.4 cents)
Change in consumer surplus	$910,983,000	$1,062,767,000	$1,831,174,000	$2,136,278,000
Change in producer surplus	($965,636,000)	($1,126,526,000)	($1,919,660,000)	($2,239,507,000)
Annual net benefit	($54,653,000)	($63,759,000)	($88,486,000)	($103,229,000)

Loss of one-half of U.S. beef export markets other than Canada and Mexico and redirection of the beef to the U.S. market would result in annual net welfare losses of about $54.7 million and $63.8 million, for beef prices of $3.00 and $3.50 per pound, respectively. The associated declines in price would be 3.6 cents and 4.2 cents per pound. The effects if all U.S. beef export markets other than Canada and Mexico were to close would be annual net welfare losses of about $88.5 million and $103.2 million for the two beef price levels, with decreases in price of 7.2 cents and 8.4 cents per pound. As explained, these effects would occur only if the proposed rule is adopted as final and the countries to which the United States exports beef decided to refuse its entry as a result.

The main industries that would be affected by the proposed rule, such as livestock producers, slaughtering establishments, and meat processors, are composed predominantly of small entities. As indicated above, since May of this year, U.S. producers/suppliers of ruminants and ruminant products have benefited from high price levels at least partly attributable to the ban on imports from Canada. By the same token, buyers of slaughter cattle, feeder cattle, and beef would benefit from price declines (slaughter cattle, 1.7 percent; feeder cattle, 0.9 percent; and beef, less than 2 percent) resulting from the reestablishment of these imports.

Effects from the possible loss of U.S. export markets and subsequent industry contractions, if this proposed rule is adopted as final and other countries were to refuse entry of our beef as a result, would harm small as well as large entities. This outcome could occur, even though BSE has never been discovered in the United States, if, as described above, countries importing U.S. beef do not agree that the factors the United States would consider justify the categorization of a region as one of minimal risk, and do not agree that the proposed age restrictions and other measures provide an adequate safeguard against the risk of BSE introduction from such a region.

Alternatives to the proposed rule would be to (1) leave the regulations unchanged—that is, continue to prohibit entry of ruminants and most ruminant products from regions of minimal BSE risk (other than products allowed entry under permit), or (2) allow the commodities to enter from such regions without the age restrictions or other measures set forth in the proposed rule. Because Canada is the only country we are proposing to list as a BSE minimal-risk region at this time, the alternatives are discussed in terms of Canada.

By maintaining current import restrictions, estimated benefits of reestablishing slaughter cattle, feeder cattle, and beef imports from Canada would not be realized. Continuation of the status quo would also eliminate any possibility of adverse effects for U.S. exports.

Concerning the second alternative, the proposed age requirements and other measures are based on the known epidemiology of BSE. Without these mitigations, we believe importation of ruminants and ruminant products (other than those allowed entry by permit) would expose the United States to greater risk of BSE introduction.

A BSE discovery in the United States would have economic consequences similar to those that have occurred in Canada and elsewhere. Losses would take the form of lowered demand, closed export markets, animal depopulations, and increased government expenditures for disease management and compensation for depopulated livestock. Tens of thousands of jobs with total earnings in the hundreds of millions of dollars could be threatened by the loss of export markets due to a discovery of BSE.

Because BSE has been linked to variant Creutzfield-Jakob disease, one of the most significant impacts of a BSE occurrence in the United States would be the potential loss of consumer confidence in the safety of the U.S. beef supply. An incidence of BSE could result in a downward shift in demand for beef, leading to lowered prices and production.

APHIS acknowledges a theoretical increased risk of BSE introduction into the United States because of this rule. However, we conclude in the risk analysis used as a basis for this rule that, with the proposed mitigation measures, this risk is extremely small. If an introduction occurred, few, if any, additional animals would be infected. It is highly unlikely that such an introduction would pose a major animal health or public health threat in the United States; regulations and practices in the United States are robust and would militate against human exposure or disease spread.

The proposed rule is considered preferable to either continuing to prohibit the entry of ruminants and certain ruminant products from a BSE minimal-risk region or allowing their entry unconditionally. We believe the factors considered in listing a region as one of minimal risk and the mitigations required for the entry of ruminants and ruminant products would make the likelihood of the introduction of even one animal or product containing infectious levels of the BSE agent extremely small. We also believe that listing Canada as a BSE minimal-risk region, together with the risk-mitigation measures that would be required, is a balanced, science-based response to Canada's request that ruminants and certain ruminant product imports by the United States from Canada be allowed to resume.

Executive Order 12988

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

National Environmental Policy Act

We have prepared an environmental assessment regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts from Canada under the conditions specified in this proposed rule. APHIS' review and analysis of the potential environmental impacts associated with these proposed importations are documented in an environmental assessment titled ''Proposed Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Environmental Assessment (October 2003).'' We are making this environmental assessment available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the heading **DATES** at the beginning of this notice.

Copies of the environmental assessment are available for public inspection in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this proposed rule). In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.** The environmental assessment may also be viewed on the Internet at *http://www.aphis.usda.gov/ppd/es/vsdocs.html.*

The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the

Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 03–080–1. Please send a copy of your comments to: (1) Docket No. 03–080–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would recognize a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products, and would add Canada to this category. The proposed rule would also allow the importation of certain live ruminants and ruminant products from such BSE minimal-risk regions under certain conditions.

Accomplishing this would require the use of several information collection activities, including the completion of certification statements for the importation of both ruminants and ruminant-derived products by the national veterinary authority of the region of origin, permits for the movement of restricted animals, forms associated with the importation of animals for immediate slaughter, the placing of seals on certain conveyances, and the tattooing of letters on certain livestock.

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

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

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

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

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

Estimate of burden: Public reporting burden for this collection of information is estimated to average 2 hours per response.

Respondents: Canadian veterinary authorities, herd owners, and exporters of ruminants and ruminant-derived products; slaughter plant and feedlot personnel in the United States, accredited veterinarians, and State veterinary authorities.

Estimated annual number of respondents: 6,000.

Estimated annual number of responses per respondent: 20.

Estimated annual number of responses: 120,000.

Estimated total annual burden on respondents: 240,000 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

9 CFR Part 93

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

9 CFR Part 94

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

9 CFR Part 95

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

Accordingly, we propose to amend 9 CFR parts 93, 94, and 95 as follows:

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

1. The authority citation for part 93 would continue to read as follows:

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

2. Section 93.400 would be amended by adding definitions of *as a group, designated feedlot,* and *USDA representative,* in alphabetical order, to read as follows:

§ 93.400 Definitions.

* * * * *

As a group. Collectively, in such a manner that the identity of the animals as a unique group is maintained.

* * * * *

Designated feedlot. A feedlot indicated on the declaration required under § 93.407 as the destination of the ruminants imported into the United States.

* * * * *

USDA representative. A veterinarian or other individual employed by the United States Department of Agriculture who is authorized to perform the services required by this part.

* * * * *

3. A new § 93.436 would be added to subpart D to read as follows:

§ 93.436 Ruminants from regions of minimal risk for BSE.

The importation of ruminants from regions listed in § 94.18(a)(3) of this subchapter is prohibited, unless the conditions of this section and any other applicable conditions of this part are met. Once the ruminants are imported, if they do not meet the conditions of this section, they must be disposed of as the Administrator may direct.

(a) *Bovines for immediate slaughter.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The bovines must be less than 30 months of age when imported into the United States;

(2) The bovines must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The bovines must be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that states that the conditions of paragraphs (a)(1) and (a)(2) of this section have been met;

(4) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly as a group from the port of entry to a recognized slaughtering establishment in conveyances that must be 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 a USDA representative;

(5) The shipment must be accompanied from the port of entry to the recognized slaughtering establishment by APHIS Form VS 17–33;

(6) At the recognized slaughtering establishment, the animals must be slaughtered as a group and each animal's intestines must be removed; and

(7) The intestines removed from the animals must be disposed of in a manner approved by the Administrator.

(b) *Bovines for feeding.* Bovines from a region listed in § 94.18(a)(3) of this subchapter may be imported under the following conditions:

(1) The bovines must be less than 30 months of age when imported into the United States;

(2) The bovines must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The inside of one ear on each animal must be permanently and legibly tattooed with letters identifying the exporting country. Animals exported from Canada must be tattooed with the letters ''CAN'';

(4) The bovines must be accompanied by a certificate issued in accordance with § 93.405(a) that states, in addition to the statements required by § 94.405(a), that the conditions of paragraphs (b)(1) through (b)(3) of this section have been met;

(5) The bovines must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly from the port of entry as a group to the designated feedlot;

(6) The shipment must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 1–27;

(7) The bovines must be moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter;

(8) The shipment must be accompanied from the designated feedlot to the recognized slaughtering establishment by APHIS Form VS 1–27;

(9) The bovines must be less than 30 months of age when slaughtered;

(10) At the recognized slaughtering establishment, each animal's intestines must be removed; and

(11) The intestines removed from the animals must be disposed of in a manner approved by the Administrator.

(c) *Sheep or goats for immediate slaughter.* Sheep and goats from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The sheep or goats must be less than 12 months of age when imported into the United States;

(2) The sheep or goats must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The sheep or goats must be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that states that the conditions of paragraphs (c)(1) and (c)(2) of this section have been met;

(4) The sheep or goats must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly as a group from the port of entry to a recognized slaughtering establishment for slaughter as a group in conveyances that must be 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 a USDA representative; and

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

(d) *Sheep or goats for feeding.* Sheep and goats from a region listed in § 94.18(a)(3) of this subchapter may be imported under the following conditions:

(1) The sheep or goats must be less than 12 months of age when imported into the United States;

(2) The sheep or goats must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The inside of one ear on each animal must be permanently and legibly tattooed with letters identifying the exporting country. Animals from Canada must be tattooed with the letters ''CAN'';

(4) The sheep or goats must be accompanied by a certificate issued in accordance with § 93.405(a) that states, in addition to the statements required by § 94.405(a), that the conditions of paragraphs (d)(1) through (d)(3) of this section have been met;

(5) The sheep or goats may be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly as a group from the port of entry to a designated feedlot;

(6) The shipment must be accompanied from the port of entry to the designated feedlot by APHIS Form VS 1–27;

(7) The sheep or goats must be moved directly from the designated feedlot to a recognized slaughtering establishment for slaughter;

(8) The shipment must be accompanied from the designated feedlot to the recognized slaughtering establishment by APHIS Form VS 1–27; and

(9) The sheep and goats must be less than 12 months of age when slaughtered.

(e) *Cervids for immediate slaughter.* Cervids from a region listed in § 94.18(a)(3) of this subchapter may be imported for immediate slaughter under the following conditions:

(1) The cervids must have been members of a herd in which surveillance for transmissible spongiform encephalopathies was conducted by appropriate authorities according to national standards or standards of the region itself if the region is a jurisdiction that has effective oversight of normal animal movements into, out of, or within the region and that, in association with national authorities if necessary, has the

responsibility for controlling animal disease locally;

(2) The cervids must have been members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy;

(3) The cervids must have been born after a ban on the feeding of ruminant protein to ruminants was implemented;

(4) The cervids must not have been known to have been fed ruminant protein, other than milk protein, during their lifetime;

(5) The cervids must be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so, that states the conditions of paragraphs (e)(1) through (e)(4) of this section have been met;

(6) The cervids must be imported only through a port of entry listed in § 93.403(b) or as provided for in § 93.403(f) and must be moved directly from the port of entry as a group to a recognized slaughtering establishment for slaughter as a group in conveyances that must be 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 a USDA representative; and

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

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

4. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

5. Section 94.0 would be amended by adding new definitions of *bovine spongiform encephalopathy (BSE) minimal-risk region,* and *personal use,* in alphabetical order, to read as follows:

§ 94.0 Definitions.

* * * * *

Bovine spongiform encephalopathy (BSE) minimal-risk region. A region that:

(1) Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

(i) Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;

(ii) Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and

(iii) A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

(2) In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

(3) In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

* * * * *

Personal use. Only for personal consumption or display and not distributed further or sold.

* * * * *

§ 94.1 [Amended]

6. In § 94.1, paragraph (b)(4) and the introductory text to paragraph (d) would be amended by removing the reference to ''§ 94.21'' each time it appears and replacing it with a reference to ''§ 94.22''.

7. Section 94.18 would be amended as follows:

a. Paragraph (a)(3) would be redesignated as paragraph (a)(4) and revised to read as set forth below.

b. A new paragraph (a)(3) would be added, and paragraph (b) and the introductory text of paragraph (c) would be revised, to read as set forth below.

§ 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

(a) * * *

(3) The following are minimal-risk regions with regard to bovine spongiform encephalopathy: Canada.

(4) A region may request at any time that the Administrator consider its removal from a list in paragraphs (a)(1) or (a)(2) or this section, or its addition to or removal from the list in paragraph (a)(3) of this section, by following the procedures in part 92 of this subchapter.

(b) Except as provided in paragraph (d) of this section or in § 94.19, the importation of fresh (chilled or frozen) meat, meat products, and edible products other than meat (except for gelatin as provided in paragraph (c) of this section, milk, and milk products), from ruminants that have been in any of the regions listed in paragraph (a) of this section is prohibited.

(c) *Gelatin.* The importation of gelatin derived from ruminants that have been in any region listed in paragraph (a) of this section is prohibited unless the following conditions, or the conditions of § 94.19(j), have been met:

* * * * *

8. Sections 94.19 through 94.24 would be redesignated as §§ 94.20 through 94.25, respectively.

9. A new § 94.19 would be added to read as follows:

§ 94.19 Restrictions on importation from BSE minimal-risk regions of meat and edible products from ruminants.

Except as provided in § 94.18 and this section, the importation of fresh (chilled or frozen) meat, meat products, and edible products other than meat (excluding gelatin, milk, and milk products), from ruminants that have been in any of the regions listed in § 94.18(a)(3) is prohibited. The commodities listed in paragraphs (a) through (j) of this section may be imported from a region listed in § 94.18(a)(3) if the conditions listed are met and if, except for the commodities described in paragraph (g), the commodities are accompanied by an original certificate of such compliance issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so.

(a) *Fresh (chilled or frozen) meat from bovines less than 30 months of age.* The

meat is derived from bovines that were less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and meets the following conditions:

(1) The bovines from which the meat is derived were slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.

(2) The intestines of the bovines were removed at slaughter; and

(3) The product qualifies as *meat* under the definition of *meat* in USDA's Food Safety and Inspection Service's regulations at 9 CFR 301.2.

(b) *Fresh (chilled or frozen) whole or half carcasses of bovines less than 30 months of age.* The carcasses are derived from bovines that meet the following conditions:

(1) The bovines were less than 30 months of age when slaughtered;

(2) The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime;

(3) The intestines of the bovines were removed at slaughter; and

(4) The bovines were slaughtered at a facility that either slaughters only bovines less than 30 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling with products not eligible for importation into the United States.

(c) *Fresh (chilled or frozen) bovine liver.* The commodity is liver containing no other product and is derived from bovines for which an air-injected stunning process was not used at slaughter.

(d) *Fresh (chilled or frozen) bovine tongues.* The tongues are derived from bovines that were born after the region implemented an effective ban on the feeding of ruminant protein to ruminants, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and from which the tonsils of each animal were removed at slaughter.

(e) *Fresh (chilled or frozen) meat of sheep or goats or other ovines or caprines.* The meat is from sheep or goats or other ovines or caprines that were less than 12 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and meets the following conditions:

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

(2) The product qualifies as meat under the definition of *meat* in USDA's Food Safety and Inspection Service's regulations at 9 CFR 301.2.

(f) *Fresh (chilled or frozen) carcasses of ovines and caprines.* The carcasses are derived from ovines or caprines that were less than 12 months of age when slaughtered, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were slaughtered at a facility that either slaughters only ovines and/or caprines less than 12 months of age or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the carcasses with products not eligible for importation into the United States.

(g) *Fresh (chilled or frozen) meat or dressed carcasses of hunter-harvested wild sheep, goats, cervids, or other ruminants.* The meat or dressed carcass (eviscerated and the head is removed) is derived from a wild sheep, goat, cervid, or other ruminant and meets the following conditions:

(1) The meat or dressed carcass is intended for personal use and is derived from an animal that has been legally harvested in the wild, as verified by proof such as a hunting license, tag, or the equivalent that the hunter must show to the United States Customs and Border Protection official; and

(2) The animals from which the meat is derived were harvested within a jurisdiction specified by the Administrator for which the game and wildlife service of the jurisdiction has informed the Administrator either that the jurisdiction conducts no type of game feeding program, or has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region.

(h) *Fresh (chilled or frozen) meat of cervids either farm-raised or harvested on a game farm or similar facility.* The meat is derived from cervids that were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of a herd not known to be infected with or exposed to a transmissible spongiform encephalopathy, and, if ground meat or sausage, is either all cervine meat or cervine meat mixed with nonruminant meat.

(i) *Fresh (chilled or frozen) meat from wild-harvested caribou, musk ox, or other cervids.* The meat is derived from wild caribou, musk ox, or other cervids and meets the following conditions:

(1) The animals from which the meat is derived were harvested within a jurisdiction specified by the Administrator for which the game and wildlife service of the jurisdiction has informed the Administrator either that the jurisdiction conducts no type of game feeding program, or has complied with, and continues to comply with, the ban on the feeding of ruminant protein to ruminants in the BSE minimal-risk region; and

(2) The meat is derived from cervids that were slaughtered at a facility that either slaughters only cervids eligible for entry into the United States or complies with a segregation process approved by the national veterinary authority of the region of origin and the Administrator as adequate to prevent contamination or commingling of the meat with products not eligible for importation into the United States.

(j) *Gelatin.* The gelatin is derived from the bones of bovines less than 30 months of age when slaughtered and that are not known to have been fed ruminant protein, other than milk protein, during their lifetime.

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

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

10. The authority citation for part 95 would continue 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.

11. Section 95.1 would be amended by adding a new definition of *offal,* in alphabetical order, to read as follows:

§ 95.1 Definitions.

* * * * *

Offal. The parts of a butchered animal that are removed in dressing, consisting largely of the viscera and the trimmings, which may include, but are not limited to, brains, thymus, pancreas, liver, heart, kidney.

* * * * *

12. Section 95.4 would be amended as follows:

a. In paragraph (a), the words ''paragraphs (c) through (f)'' would be removed and the words ''paragraphs (c) through (h)'' would be added in their place.

b. In paragraph (b), the words ''paragraphs (d) and (f)'' would be removed and the words ''paragraphs (d) and (h)'' would be added in their place.

c. In paragraph (c)(4), the first sentence would be revised and a new sentence would be added after the final sentence to read as set forth below.

d. Paragraph (c)(6) would be revised to read as set forth below.

e. Paragraph (f) would be redesignated as paragraph (h).

f. New paragraphs (f) and (g) would be added to read as set forth below:

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

* * * * *

(c) * * *

(4) Except for facilities in regions listed in § 94.18(a)(3) of this subchapter, if the facility processes or handles any material derived from mammals, the facility has entered into a cooperative service agreement executed by the operator of the facility and APHIS. * * * In facilities in regions listed in § 94.18(a)(3) of this subchapter, the inspections that would otherwise be conducted by APHIS must be conducted at least annually by a representative of the government agency responsible for animal health in the region.

* * * * *

(6) Each shipment to the United States is accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the conditions of paragraph (c)(1) through (c)(3) of this section have been met, except that, for shipments of animal feed from a region listed in § 18(a)(3) of this subchapter, the certificate may be signed by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin.

* * * * *

(f) Tallow otherwise prohibited importation under paragraph (a)(1) of this section may be imported into the United States if it meets the following conditions:

(1) The tallow is composed of less than 0.15 percent protein;

(2) The tallow is derived from bovines that have not been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter:

(3) The bovines were less than 30 months of age when slaughtered and were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants;

(4) The bovines are not known to have been fed ruminant protein, other than milk protein, during their lifetime;

(5) The intestines were removed from each bovine at slaughter.

(6) The tallow is not derived from an animal that died otherwise than by slaughter;

(7) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraphs (f)(1) through (f)(6) of this section have been met; and

(8) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(k) of this subchapter.

(g) Offal derived from cervids that is otherwise prohibited importation under paragraph (a)(1) of this section may be imported if the following conditions are met:

(1) The offal is derived from cervids that were born after the region of origin implemented an effective ban on the feeding of ruminant protein to ruminants, that are not known to have been fed ruminant protein, other than milk protein, during their lifetime, and that were members of herd not known to be infected with or exposed to a transmissible spongiform encephalopathy;

(2) Each shipment to the United States is accompanied by an original certificate signed by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated by or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate must state that the requirements of paragraph (g)(1) of this section have been met; and

(3) The shipment, if arriving at a U.S. land border port, arrives at a port listed in § 94.19(k) of this subchapter.

* * * * *

Done in Washington, DC, this 29th of October 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 03–27611 Filed 10–31–03; 2:30 pm]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–120–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Airbus Model A320 series airplanes, that currently requires an inspection to detect moisture and migrated bushings of the guide fittings of the safety locking pins of the passenger doors, removal of any moisture, application of grease, and reinstallation of any migrated bushing. That AD also requires installation of a greasing nipple on the guide fitting of the locking pin and on three telescopic rods on the passenger doors. This action would add a requirement for modification of the upper guide fitting of the locking pin, and would expand the applicability in the existing AD. The